European Agency for Safety and Health at Work

EUROPEAN RISK OBSERVATORY REPORT

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Exploratory Survey of Occupational Exposure Limits for Carcinogens, Mutagens and Reprotoxic substances at EU Member States Level

European Agency for Safety and Health at Work

Exploratory Survey of OELs for CMR substances

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Lists of acronyms

ACSH	Advisory Committee on Safety and Health at Work
CAS	Chemical Abstracts Service
CMR(s)	Carcinogenic, Mutagenic, Reprotoxic (substances)
DG EMPL	Directorate General for Employment, Social Affairs and Equal Opportunities of the European Commission
EC	European Commission
EINECS	European Inventory of Existing Commercial Chemical Substances Information System
EU	European Union
FOP(s)	National Focal Point(s)
MAC	Maximum Acceptable/ Admissible Concentration Maximaal Aanvaarde Concentratie (Dutch)
MAI	Maximum Admissible Intensity
MAK	Maximale Arbeitsplatz Konzentration (German)
MS(s)	Member State(s)
NOAEL	No Adverse Health Effects Level
OEL(s)	Occupational Exposure Limit(s)
OSH	Occupational Safety and Health
SCOEL	Scientific Committee on Occupational Exposure Limits
TLV	Threshold Limit Value
TDK	Technically reachable concentration (Slovenia)
VCM	Vinyl Chloride Monomer
UK	United Kingdom

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Summary

Occupational Exposure Limits (OELs) are one of the major control instruments for workers' exposure to chemicals: they belong to the most important tools for exposure assessment and management. Given this importance, the European Commission has requested the Agency's assistance in collecting and analysing data on existing OELs for Carcinogenic, Mutagenic and Reprotoxic substances (CMRs) from the 27 Member States and from selected countries outside the EU, including methodology, criteria (scientific, technical and socio-economical) and sources. For that purpose, the Agency, in close cooperation with the Commission, has developed a 'Questionnaire on occupational limit values for carcinogens, mutagens and substances toxic for reproduction', which was sent to the 27 EU National Focal Points (FOPs)[1], Australia, Canada, Japan and US.

This report covers the questions as addressed in the questionnaire and provides analysis and overview of the systems in place in a number of EU Member States. The report does not provide information from Bulgaria, France, Hungary, Ireland, Malta, and Romania. Germany didn't provide OELs because of recent policy changes: the system in place was revoked in 2005 and limit values and the system of setting them are currently under revision[2]. It is worth noting that some Member States had based some of their limit values on the German (TRK) values.

The analysis is therefore limited to the situation on OELs for CMRs for the 21 remaining Member States: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, that have provided information.

This report includes an overview table and database of all national and EU limit values identified for CMR substances as outlined in the questionnaire to the FOPs. The main objective of the study and of the report was an analysis of the database and of the FOPs' answers to the Questionnaire following a structure in 8 points:

1. Types, legal level[3] and number of OELs for carcinogenic and mutagenic substances;
2. Selection and prioritisation of carcinogenic and mutagenic substances for OEL setting;
3. Derivation of OELs for carcinogenic and mutagenic substances;
4. Time for OEL setting of carcinogenic and mutagenic substances;
5. Revision of OELs for carcinogenic and mutagenic substances;
6. Monitoring and record-keeping of workers' exposure to carcinogenic and mutagenic substances;
7. Information and documentation regarding OELs of carcinogenic and mutagenic substances;

[1] The Agency's main safety and health information network is made up of a Focal Point in each EU Member State, as well as in Candidate Countries and EFTA countries. Focal Points are nominated by each government as the Agency's official representative in that country, and they are normally the national authority for safety and health at work. For more information see http://osha.europa.eu/about/partners/focal_points.

[2] Germany has revoked the TRK system in 2005 and was revising all its technically-based limit values in the AGS (the advisory body for dangerous substances). Some explanation is given in the comments to the new dangerous substances ordinance Gefahrstoffverordnung (see http://www.baua.de/nn_16806/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/Bearbeitungsliste-TRGS-900.pdf, http://www.baua.de/nn_5846/de/Themen-von-A-Z/Gefahrstoffe/Tagungen/GefstoffV-Tagung/pdf/Vortrag-26.pdf). An "acceptable risk" concept seems to be one option for discussion there.

[3] Whether these limit values are binding or indicative.

8. OELs for reprotoxic substances.

Where possible, reference is also made to other sections of the national questionnaires where information relevant to a certain question has been provided.

It is important to note that the report, as requested from the Agency, is based on a one-off questionnaire survey with no accompanying literature review or interviews with the providers of the information.
Therefore the survey results are to be seen as an introductory step for further research on the topic. Where the questionnaires provided only general information and further research would be needed or no conclusions could be drawn, this was mentioned in this report.
Additionally, the tables provided in the report are all preceded by explanatory remarks, which we request readers to consider before extracting information from the tables.

1. Types, legal level and number of OELs for CM substances

There are 2 types of OELs: atmospheric and biological, and 2 main legal levels: constraining (binding) and indicative.
At EU level, constraining OELs are established as atmospheric concentrations of substances to be measured at the workplace in the breathing zone of the worker for five substances:

- benzene, VCM, and hardwood dust (Directive 2004/37/EC);
- asbestos (Directive 2003/18/EC) and
- inorganic lead (Pb) and its compounds (Directive 98/24/EC)[4].

This last group (inorganic lead and its compounds) also has a biological constraining OEL at the European level.

When analysing the number of substances for which atmospheric constraining OELs are set in the EU countries, the following can be concluded:

- most of the Member States who participated listed between 30 and 50 substances or substance groups with atmospheric constraining OELs (Belgium, Czech Republic, Denmark, Estonia, Latvia, Lithuania, the Netherlands, Portugal, Slovakia, Slovenia, and UK);
- Four Member States (Austria, Finland, Poland and Spain) listed a higher number - over 50;
- four Countries listed only three or four atmospheric constraining OELs (for substances with an EU atmospheric constraining OEL) (Cyprus, Greece, Italy, and Luxemburg);
- Germany did not have any OEL in place because of the recent policy change.[2]

Regarding biological – levels of substances measured in the exposed persons´ blood or urine – or constraining OELs, the following can be concluded:

[4] Some lead compounds are classified as carcinogenic (lead chromate, for example), but the EU limit value is laid down in Directive 98/24 on protection of workers against exposure to chemical agents in the workplace.

- three countries have reported one biological constraining OEL for CM substances (Lithuania, and the Netherlands - the EU limit for inorganic lead (Pb) and its compounds, Latvia – for benzene);
- eight other countries report more biological constraining values (two to nine): Austria, Czech Republic, Estonia, Poland, Slovakia, Slovenia, Spain, and UK;
- there was no mention of biological constraining OELs in the answers of Cyprus, Denmark, Finland, Germany, Greece, Italy, Luxemburg, and Portugal.
- Sweden reports to have two biological limit values, for lead and compounds and for cadmium, but does not specify whether constraining or indicative;

At European level two lists of substances with indicative OELs set are established in Directives 2000/39/EC and 2006/15/EC. Finland and Portugal report to have atmospheric indicative OELs, but don't provide further information. Finland reports to have biological indicative limit values as well. Sweden reports to have indicative short-term limit values. Finland also mentions a differentiation between health-based limit values and constraining limit values.

As for the type of limit values adopted (i.e. 8-hour limit values, short-term limit values, ceiling limit values, biological limit values), it is clear that 8-hour limit values are the most common. They are in place in 20 EU countries; Germany, not having specified because the system was under revision at the time of the survey, is not included. Short-term limit values and biological limit values are both reported by 13 Member States, ceiling limit values by eight countries.

2. Selection and prioritisation of CM substances for OEL setting

Seven Member States report to have a specific selection procedure for selecting substances for OEL-setting - Czech Republic, Finland, Greece, Lithuania, Poland, and Slovakia and Spain. In the Netherlands such a procedure is being prepared. Sweden includes CM substances in its selection procedure applied to all substances.

Based on the answers of 11 countries, the most important criteria for the selection of substances for setting of OEL appear to be (in order of priority): (1) epidemiological evidence, including reported cases of ill-health in the workplace, (2) availability of toxicological data, (3) severity of effects, (4) number of persons exposed, (5) availability of data on exposure, and (6) availability of measurement methods.

In five countries – Austria, Cyprus, the Netherlands, Slovakia and Slovenia the process of setting up occupational exposure limits is reported to be initiated by the public authorities.

Nine EU countries (Belgium, Czech Republic, Denmark, Finland, Greece, Italy, Latvia, Poland, and Spain) report that the public authority (Ministry of Labour or Ministry of Health) is one of the bodies that develop proposals for setting up or changing a limit value. In 13 of the 21 countries who participated in the survey (Belgium, Czech Republic, Denmark, Finland, Greece, Italy, Latvia, Luxembourg, Poland, Sweden and Spain), scientific experts are involved in the process. The social partners are reported to be involved in the process in some countries (Belgium, Finland, Greece, Italy, Latvia, Luxemburg, Poland, Spain and Sweden) as well. This needs to be seen in connection with the information on consultation, on the bodies involved in the process, for example scientific committees and the criteria applied to select substances and set the level of exposure limits,. Also, some Member State report to make

extensive use of the resources in other countries and of the scientific evidence already produced by others, which limits their choice of substances to evaluate.

3. Derivation of OELs for CM substances

Ten Member States (Czech Republic, Denmark, Finland, Italy, Latvia, the Netherlands Poland, Spain, Sweden and UK) indicate to have a national system for the derivation of OELs that includes the scientific evaluation of substances and the consideration of feasibility factors. However, some of them also indicate to include CM substances in the general procedure for derivation of OELs.

17 of the 21 participating EU countries consult other parties in the process of derivation of OELs for carcinogenic and mutagenic substances, mostly the social partners and governmental organisations (ministries and other). Two EU countries (Czech Republic and Luxembourg) do not make reference to a consultation process linked to the derivation of OELs. However, the Czech Republic reported in other sections of the questionnaire on its national bodies, and its database of measurements and health surveillance information that is also based on for example “testing” the OEL at the enterprise level before implementing at the national level.
The Czech Republic, Finland, the Netherlands, Poland, Sweden and UK report to have a documented methodology for the scientific evaluation of substances. In nine Member States (Czech Republic, Denmark, Italy, Latvia, Netherlands, Poland, Spain, Sweden and UK) a specific scientific body is set up for the evaluation process. Poland has reported to have a collection of guidelines for assessing health risk from carcinogens” (in Polish language, with a short summary in English), Poland has also given a list of substances for which such guidelines have been set up.

16 of the 21 Member States who participated report to have adopted OELs from other countries (mostly from EU sources and Germany, USA, Scandinavian countries, Netherlands, France, UK and Russia). Two Member States restrict themselves to adapting from EU sources; only 3-4 limit values are implemented in Cyprus and Greece. The Netherlands and Poland indicate in answers to other sections of the questionnaire that they have established their own OELs for carcinogenic and mutagenic substances. Germany was in the process of setting up a new system.

Regarding the criteria for derivation of OELs, information was provided mainly on criteria relating to the exposure situation and the identification of employment sectors where exposures are relevant. To provide an overview of the criteria, it was also important to consider information given in other parts of the national questionnaires.
The questionnaire gauged as well feasibility criteria (technical, socio-economic, and administrative/policy) applied in the national systems for the derivation of OELs:

– *Technical feasibility criteria*

Based on the reporting by Belgium, Czech Republic, Estonia, Finland, Latvia, Poland, Spain, and UK, it can be concluded that different strategies are applied for the identification of employment sectors using CM substances (e.g. via information from social partners, scientific experts, national labour inspectorates, etc.). For the identified sectors, the evaluation of the technical capability to meet the OELs is done as well in different ways (e.g. through a tripartite consultation). Work activity, exposure and product registers are also referred to. According to 12 countries (Czech Republic, Denmark, Estonia, Finland, Italy, Latvia,

Luxembourg, the Netherlands, Poland, Spain, Sweden and the UK), compliance with the OELs in the identified sectors can be achieved by the application of good working practices.

– *Socio-economic feasibility criteria*

Answers were provided by the Czech Republic, Sweden and the UK.
Only UK reports that data on the extent and distribution of economic consequences and on the types of costs (e.g. provision of controls, including local exhaust systems/containment and personal protective equipment) and savings (e.g. expenditure on health care) related to the OEL setting, are taken into consideration. The UK also reported on a tripartite discussion of socio-economic aspects when setting OELs.

In the Czech Republic information on societal and/or individual benefits for health are described in terms other than monetary, the Czech Republic also mentions a “testing phase” for OELs at enterprise level.

In Sweden, an investigation of the cost for the investment that has to be made to comply with the new limit value is performed. Then an impact assessment for the proposal to a new limit value is done. Companies are being contacted in order to get a picture of how they would cope with the new situation.

Other Member states, such as Belgium and the UK, conduct a public consultation and discuss the socio-economic impact in tripartite committees.

– *Administrative and policy criteria*

Latvia, Netherlands, Poland, and Slovakia report to have adopted criteria on the acceptability of risk. The Netherlands and Poland mention levels of acceptability and give a description of the system in place, more extensive for Poland. Germany was discussing such a concept at the time of the survey.

The Czech Republic and Poland reported derogations to OELs for certain employment sectors. When looking at the table of OELs, it appears that a number of Member States have different OELs for a single substance or substance group, but did not report derogations in the questionnaire.

4. Time for OEL setting of a CM substance

The time between the proposal and the adoption of an OEL for a CM substance varies widely: one year for five Member States (Czech Republic, Greece, Lithuania, Sweden and Spain), two years for Finland, three years for five Member States (Belgium, Denmark, the Netherlands, Poland and Slovakia), and more than three years for four countries (Italy, Latvia, Luxembourg and UK). Six other Member States (Austria, Cyprus, Estonia, Germany, Portugal and Slovenia) did not specify how long it takes to establish OELs in their countries. Denmark, Finland and Sweden mentioned it could take longer for some substances.

Nine EU countries (Belgium, Finland, Italy, Latvia, the Netherlands, Slovakia, Spain, Sweden UK) report on difficulties in the process of derivation of OELs for carcinogenic and mutagenic substances, the most common ones being the lack of national exposure data and toxicological data, and problems in reaching a consensus.

5. Revision of OELs for CM substances

Nine Member States (Czech Republic, Denmark, Finland, Italy, Lithuania, the Netherlands, Portugal, Slovakia, and Spain) report having a specific procedure for the revision of OELs for carcinogenic and mutagenic substances. Revision is also reported to be carried out when new toxicological evidence is available or when new EU limit values are being proposed.
The revision occurs with a widely variable frequency: from every year in Spain to every five years in Lithuania, in the Czech Republic when new data are available. The Netherlands mention shorter revision intervals for OELs set above the risk value of 10^{-6}.

6. Monitoring and record-keeping of workers' exposure to CM substances

Eight Member States (Belgium, Finland, Italy, Latvia, Lithuania, Poland, Spain, and UK) report to have specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances.

Exposure monitoring is reported to be mandatory in most (16) of the countries, except for Denmark and the Netherlands. In the UK this exposure monitoring is only mandatory for two substances: vinyl chloride monomer and for hexavalent chromium relating to electrolytic chromium processes.

Specific measurement methods are reported to be laid down or recommended in 12 countries (Belgium, Czech Republic, Estonia, Finland, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Spain, Sweden and UK).
Biological monitoring is reported to be included in the monitoring methods in 12 Member States (Austria, Czech Republic, Estonia, Finland, Italy, Latvia, Luxembourg, the Netherlands, Poland, Slovakia, Spain, and UK). Some Member states have given more detail on the biological monitoring provisions. This information is also provided in this report, which includes a list of substances for which biological limit values have been reported.

Some Member states, such as Austria and Slovakia, have also mentioned the link between measurement or monitoring requirements and risk assessment.

Record-keeping on the results of measurement linked to the OELs for carcinogenic and mutagenic substances is organised at several levels: by the labour inspectorate (e.g. in Austria and Finland) or other authorities (e.g. Regional Authorities of Public Health in Slovakia); by an institute (e.g. FIOH in Finland) and laboratories; individual medical records by the occupational health doctors (e.g. Poland) or services (e.g. Finland and Belgium); and/or by the employer. Some Member States, such as the Czech Republic or Finland, have also mentioned databases of measurements. The Czech Republic mentioned a "trial phase" for OELs at enterprise level before implementation at the national level.

Some of the Member States who provide this information make reference to the obligation set out in the "carcinogens and mutagens" Directive for records to be kept for 40 years after the exposure has stopped.

7. Information and documentation regarding OELs of CM substances

All 21 EU Member States who participated in the survey have documents with OELs for carcinogenic and mutagenic substances available on a webpage. These documents are

available in the own country language(s); Denmark, Sweden and Spain indicate to provide their information in English as well, Latvia is currently translating. Other Member States provide information in additional languages, mostly depending on whether there are several official languages at the national level.

Information on the methodology for OEL setting (prioritisation, derivation, evaluation, measurement, analysis) is publicly available, but to a varying extent, in most countries. The availability of such documentation depends largely on whether specific national procedures are in place and whether assessments are carried out by scientific committees in the Member States. The Czech Republic, Poland, and the Netherlands provide extensive access to this information. On the other hand, while using mainly external sources, Belgium makes them available via the library of the ministry in the course of its public consultation procedure. Some Member States have also provided contact details of national expert committees or chairpersons of those committees. An overview of the documents, titles and Website links is made available in the annex to this report.

8. OELs for reprotoxic substances

14 of the 21 EU Member States who responded (Belgium, Czech Republic, Denmark, Estonia, Finland, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Spain, Sweden, UK) report having OELs for reprotoxic substances. These countries – except Belgium - also report to have a list of reprotoxic substances. On the other hand, Slovakia does not include OELs for reprotoxic substance, but reports having a list of these substances. This information must therefore be addressed together with the information on the documents and legal acts: it appears that in many of the Member States, the limit values are included in the regulation for all OELs, sometimes also in a single table.

Finland reports in its description of documentation to have had a list of reprotoxicants in national legislation since 1991. The Netherlands report to have a non-exhaustive list, which is updated every half-year. Poland makes reference to a specific notation *Ft *– fetotoxicity, which is used in the limit values booklet and a list of substances assigned the notation

Limit values for reprotoxic substances are mostly reported to be applied in the same way as for other substances. On the other hand, seven Member States (Austria, Cyprus, Germany, Greece, Italy, Slovakia, Slovenia) report not having limit values defined for reprotoxic substances.

Some, such as Finland, Luxembourg and Sweden, have also mentioned the link to risk assessment of substances potentially reprotoxic to men and women in the workplace, or specific regulations applied for example to pregnant and breastfeeding workers. Similar regulations are expected to be applied in other Member States, but were not explicitly mentioned in the national answers.

The report provides a non-exhaustive table of substances for which the limit values have been reported to be in place. Some countries have provided separate tables, some have also included the reprotoxic substances in their list.

Based on the data listed by the countries, it can be concluded that the following reprotoxic substances have an OEL in more than three Member States:

– Lead chromate, nickel carbonyl, warfarin: OEL in four different Member States;

- 2-Ethoxyethyl acetate, benzo[a]pyrene, dimethylacetamide, dimethylformamide: OEL in five different Member States;
- 2-Ethoxyethanol, carbon monoxide: OEL in six different Member States.

However, these might not be the priority substances for limit setting, as for example acrylamide has a limit value reported by 14 Member States, but only four labelled it as reprotoxic. For lead compounds and cadmium compounds, there may be ”summary” limit values defined for the metal and its compounds, it is therefore more difficult to assess how many Member Sates have actually defined a limit value for one of these compounds.

9. Additional information

Some Member States have provided additional information which is relevant to how limit values are applied. As an example, Sweden has provided a list of carcinogenic, mutagenic and reprotoxic substances for which there are prohibitions or restrictions in use, for example the use may be subject to prior authorization by the relevant authorities or may only be allowed for research activities.

Also, some Member Sates have provided a list of carcinogenic, mutagenic or reprotoxic substances without limit values. Such information can be found in the national reports or in chapter 7.

This includes information on specific notations; as an example, Poland reported the use of the following notations in the OEL booklet:
C – corrosive, ***I** *– irritation, ***A** *– sensitive, **Carcinogenic categories 1 and 2,** ***Ft** *– fetotoxicity, ***Sk*** – the substance can be absorbed through the skin.
Poland has also mentioned the publication of “Guidelines for assessing health risk from carcinogens” (in Polish language, short summary is in English). A list of substances for which the guidelines were published was attached to the national questionnaire.
All of this additional information has been included in the relevant chapters of this report or is available in the annexes..

1 Introduction

Occupational Exposure Limits (OELs) are concentration limits of hazardous chemicals in workplace air. For most substances, levels are set based on the values for which a No Adverse Health Effects Level (NOAEL) has been observed within the average exposed population. OELs are one of the major exposure evaluation instruments. The measured exposure values compared to the related OELs help assess the existing level of risk to exposed workers.

This project set out to explore more systematically the concepts and criteria applied in the Member States for setting exposure limits for carcinogenic and mutagenic substances.

In 2006, the European Commission's DG EMPL/F/4 had organised in collaboration with the Advisory Committee on Safety and Health at Work (ACSH) a workshop on "Setting OELs for Carcinogens".[5] The key questions addressed during the workshop were the following:

- What is the acceptable/unacceptable level of risk?
- What is the maximum level of risk?
- Is it possible to quantify it in terms of incidence rate versus the number of exposed workers?
- In accepting risk levels should a distinction be made for general public and workers?
- What criteria are used in some Member States and what political decisions have been taken in respect to the OEL setting process for carcinogens?
- What criteria should be used to define the border between the acceptable and unacceptable risk?
- Should the approach to address the risk levels be systematic (quantitative/semi-quantitative) or stochastic (case by case)?
- Should criteria on the acceptability of risks be regulated at EU level?
- Should the workability of the existing EU legal framework be safeguarded versus subsidiarity, in terms of establishment of OELs for carcinogens?

One of the main conclusions of the workshop was that the existing EU OSH legal framework and its supportive administrative, technical and scientific structure should remain in place and be used for the derivation and adoption of OELs at the EU level. However, the derivation of OELs for Carcinogens, Mutagens and Reprotoxic substances (CMRs) - both genotoxic and non-genotoxic - is a demanding task. The availability of sound and sufficient evidence, and in particular the availability of criteria and methodologies for their derivation, is a critical prerequisite for setting OELs for carcinogens.

The European Commission has launched the second stage of consultation of the social partners[6] on the protection of workers from risks related to exposure at work to CMRs in April 2007. The Commission had asked the social partners at European level on the possible direction of a Community initiative aiming to extend the scope of the 'Carcinogens and Mutagens Directive' 2004/37/EC to substances toxic for Reproduction ('CMR' Directive), to revise the occupational exposure limits values (OELs) for carcinogens listed in the Directive, and to establish OELs for some CMRs not yet included in the Directive.

[5] Luxembourg, 25th October 2006, see http://ec.europa.eu/employment_social/health_safety/docs/summary_workshop.pdf
[6] See also: http://ec.europa.eu/employment_social/social_dialogue/docs/carcinogens2_letter_en.pdf, http://ec.europa.eu/employment_social/social_dialogue/docs/carcinogens2_en.pdf.

The Commission's DG EMPL had the intention to make an investigation in all EU MS (EU-27) to increase the Commission's knowledge on the existing situation at national level concerning OELs for CMRs. The European Commission has requested the Agency's assistance in collecting data on existing OELs values for CMRs from the 27 Member States (MSs) and from selected countries outside of the EU. It was agreed to launch a survey aiming at identifying which Carcinogens, Mutagens and Reproductive toxicants have been assigned an OEL at national level and which methodology and criteria (scientific, technical and socio-economic) are used when setting an OEL for a carcinogen or a mutagen.

The significant level of experience in some Member States on setting OELs for carcinogens can provide a helpful source of information for the Commission in considering policy options for setting OELs at EU level. In particular, information is needed on the:

- existing OELs for CMRs classified as Cat. 1 and Cat. 2 in the EU classification and labelling system in every one of the 27 EU Member States;
- methodologies at national level including criteria used for the derivation of OELs for CMRs;
- main sources of information used to derive OELs for CMRs and whether this information is based on the work carried out at national level or it is based on the work done elsewhere (e.g. other EU Member States or international level);
- availability of scientific and technical documents supporting the existing OELs and whether this information is published, and how it could be accessed.

In agreement between the Commission's DG EMPL/F/4 and the Agency, the request covered mainly the OELs for carcinogens and mutagens. Information on reprotoxic substances was collected where available, but dedicated systems for these substances were expected to be in place only in some countries and for a restricted number of substances.

The Agency has asked for assistance of National Focal Points[7] and sent an agreed questionnaire to the network Members. Information for the report was provided by 21 Member States States: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the UK.

The results of the survey are summarised in this report. The structure of the summary report attempts to follow the structure of the questionnaire, and covers the same questions as addressed to the National Focal Points (FOPs). It aims to provide an analysis and overview of the systems in place in the 27 EU Member States as regards OELs for CMR substances.

The information is also complementary to another – larger - project, "Occupational exposure to carcinogens: policies and practices for prevention, control and monitoring", carried out under the Agency's Risk Observatory's work programme 2007.

This report includes:

- A summary of the main results.
- An overview on the above-mentioned issues, after an analysis of the database (overview EXCEL table) and of the FOPs answers to the questionnaire following this structure:

[7] See for more information http://osha.europa.eu/about/partners/focal_points

1. Type of OELs in place, whether binding or indicative, biological or atmospheric limit values;
2. Number of substances for which limits have been set;
3. Selection of substances for limit setting;
4. Description of the limit-setting process (who proposes, who evaluates, who sets the level, consultation): prioritisation, derivation;
5. Basis for the limit values setting – criteria and methodologies;
6. Frequency of revisions of OELs;
7. Measurements and analytical methods for monitoring workers' exposure to CMRs, record-keeping;
8. Availability of and links to supporting documents such as limit values lists and criteria documents, toxicological evaluations, measurement methods (if possible presented by substance);
9. Reprotoxic substances.

– In the Appendix:
    - the FOPs' national reports in a harmonised format.
    - An **overview table of all national and EU limit values identified for CMRs** (Name, CAS nr., EINECS nr, C/M/R categories, OEL's range, 8h-limit, short-term limit values, biological limit values, ceiling limit values, notations (e.g. Skin, sensitiser), remarks and comments (limitation to certain processes, etc.)
    - Detailed tables providing contacts and Website links to documentation (OELs lists, criteria documents, measurement methods.

It is important to note that the fact that an expsosure limit for a substance does not appear does not necessarily mean that there is no limit value set for this substance in the Member State in question. Focal Points were explicitely asked to provide the values for substances that are oficially classified as carcinogens and mutagens. Substances for which this is not so clear-cut include, for example, lead and its compounds - only some of the compounds, namely lead chromate, are classified carcinogens - or crystalline silica.

Some Member States have also provided information on biological limit values, which has been included in the report, but which is by far not to be regarded as exhaustive.

It also needs to be taken into consideration that most countries have submitted the list of CMR substances including only those for which there are occupational exposure standards. That means that the full national lists of CMR substances may include more substances. For example, Slovenia has submitted a list including over 150 substances, while OELs have been established for 45 of them (for some – multiple).

Some Member States have also provided related information, for example on restrictions of use: Sweden has provided lists of substances and procedures for which restrictions of use have been defined or which are subject to prior authorisation. Poland has reported to have a collection of guidelines for assessing health risk from carcinogens (in Polish language, with a short summary in English), and attached to its questionnaire a list of substances for which such guidelines have been set up.

Some Member States have also described how the limit values directly link to provisions on prevention measures: Poland makes reference when describing measurement requirement to specific prevention measures being set at specific levels, while Germany described that its planned new ”risk-based” system directly links (“traffic-light-approach”), depending on the level of risk identified, to prevention measures, the prevention measures being the highest, the higher the assessed risk is – in quantitative proportions.

2 Overview based on the database and FOPs answers

2.1 Overview table of all national and EU OELs

A complete overview table of all national and EU limit values identified for CMRs, containing the substance name, CAS nr, EINECS nr, C/M/R categories, OEL's range, 8h-limit, short-term limit, biological limit, ceiling limit, notation (e.g. skin, sensitiser), remarks and comments (limitation to certain processes, etc.), is presented in Annex 1.

2.2 Type, legal level and number of OELs for carcinogens and mutagens

Questions asked
A) Please list all substances with a national limit value
B2.i) Are limit values indicative or constraining?
C.q) Is biological monitoring included in the monitoring methods?

There are 2 types of OELs: Atmospheric (A) and Biological (B), and 2 main legal levels: binding or Constraining (C) and Indicative (I).

Table 1 provides an overview of the type, legal level and number of OELs for carcinogens and mutagens in the EU and Member States, and shows differences between the Member States in this respect.

The number of European OELs, i.e. OELs specified in European Directives, is very limited; the Scientific Committee on Occupational Exposure Limits (SCOEL) has examined 17 carcinogenic substances: five are subject to binding values (inorganic lead and its compounds[8] (Directive 98/24/EC); benzene, vinyl-chloride monomer (VCM), hardwood dust (Directive 2004/37/EC); and asbestos (Directive 2003/18/EC)), out of a total of 400 substances classified as carcinogens in Annex I of Directive 67/548, of which 250 may be present at the workplaces.[9] These five carcinogenic substances are allocated atmospheric constraining (A-C) OELs; inorganic lead and its compounds also have a biological constraining limit at the European level.

It appears that some Member States set OELs for a large number of substances, while others limit their list to the substances given OELs at the European level. It is worth noting that some Member States mention to have based their system on German (TRK) values, which were revoked in Germany in 2005.[10]

[8] Some lead compounds are classified as carcinogenic (lead chromate, for example) and the EU limit value is laid down in Directive 98/24 on protection of workers against exposure to chemical agents in the workplace.

[9] Figures given by the Commission during the workshop 'Setting Occupational Exposure Limits for Carcinogens', Luxembourg, 25 October 2006. Session 4 - Definition and notification of OELs for carcinogens: framework and options, p. 12. Available at: http://ec.europa.eu/employment_social/health_safety/docs/summary_workshop.pdf.

[10] Germany has revoked the TRK (technische Richtkonzentration) system in 2005 and is currently revising all its technically-based limit values in the AGS (the advisory body for dangerous substances). Some explanation is given in the comments to the updated dangerous substances ordinance Gefahrstoffverordnung (see http://www.baua.de/nn_16806/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/Bearbeitungsliste-TRGS-900.pdf, http://www.baua.de/nn_5846/de/Themen-von-A-Z/Gefahrstoffe/Tagungen/GefstoffV-Tagung/pdf/Vortrag-26.pdf). An "acceptable risk" concept seems to be one option for discussion there.

- Most of the Member States report to have atmospheric constraining and biological constraining limit values, including the EU values. Cyprus, Denmark, Finland, Greece, Italy, Luxemburg and Portugal did not report on biological constraining limit values; Sweden did not specify whether the biological limit values were indicative or constraining..
- Eight Member States have listed several biological constraining limit values (from two to nine: Austria, Czech Republic, Estonia, Poland, Slovakia, Slovenia, Spain and UK), but it is not clear whether the information given is exhaustive.
- Four Member States mention only three or four atmospheric constraining limit values in their OEL list (substances with EU-established OELs): Cyprus, Greece, Italy, and Luxemburg.
- 11 Member States list between 30 and 49 CMRs with an atmospheric constraining OEL: Belgium, Czech Republic, Denmark, Estonia, Latvia, Lithuania, the Netherlands, Portugal, Slovakia, Slovenia and the UK.
- Four Member States mention a number of CMR substances higher than 50 with an atmospheric constraining OEL: Austria, Finland, Poland and Spain.
- Sweden reports to have indicative short-term limit values. Finland reports to have on the one hand health-based and on the other binding limit values.

Table 1: Type of OEL and number of substances for which OELs are set/ number of legal OELs/ for carcinogenic and mutagenic substances
(blank = no answer provided)

Member State	Atmospheric (A)		Biological (B)		Notation
	Constraining (C)	Indicative (I)	Constraining (C)	Indicative (I)	
Austria	68 + compounds / 82 OELs		8 + compounds		Skin notation sensitiser
Belgium	43 + compounds / 43 OELs				Skin notation
Cyprus	3 substances / 3 OELs				Skin notation
Czech Republic	35 + compounds / 35 OELs		3 + compounds		D – Dermal S – Sensitiser P-serious concern about delayed effects
Denmark	46 + compounds / 46 OELs				Skin notation
Estonia	37 + compounds / 38 OELs		2 + compounds		
Finland	58 + compounds / 58 OELs	Yes		Yes	Skin notation
Germany					
Greece	3 compounds /3 OELs				S-Skin notation
Italy	4 + compounds /4 OELs				Skin notation
Latvia	36 + compounds / 36 OELs		Benzene		Skin notation

Member State	Atmospheric (A)		Biological (B)		Notation
	Constraining (C)	Indicative (I)	Constraining (C)	Indicative (I)	
Lithuania	41 + compounds / 46 OELs		Inorganic Lead (Pb) and its compounds		
Luxembourg	4 + compounds / 5 OELs				
Netherlands	39 + compounds / 42 OELs		Inorganic Lead (Pb) and its compounds		H-probably skin notation
Poland	56 + compounds / 61 OELs		4 + compounds		A-sensitising C-corrosive Ft-fetotoxicity I-irritative Sk-can be absorbed through the skin
Portugal	39 + compounds / 40 OELs	Yes			Cutaneous absorption
Slovakia	35 + compounds / 41 OELs		9 + compounds		Skin notation
Slovenia	46 + compounds / 56 OELs		3 + compounds		K-skin notation Y-embryo toxicity notation[11] R_F and R_E for reprotoxic substances
Spain	69 + compounds / 81 OELs		6 + compounds		Skin notation Sensitiser notation Other notations see below (EU limits, biological limit values, etc)
Sweden	23 + compounds / 24 OELs	17 short-term limit values			Skin notation
UK	33+ compounds / 34 OELs		3 + compounds		Skin notation

2.3 Other characteristics of adopted limit values

Questions asked
B2.e) Which kinds of limit values are adopted? (Options: 8-hour limit values; Short-term limit values; Ceiling limit values; Biological limit values; No limit values; Other (please explain)).

The most commonly adopted limit values are (see table 2):
1. 8-hour limit values (20 countries);

[11] there is no danger for embryo when the limit value and biological limit value are respected

2. Short-term (13 countries)
3. Biological limit values (13 countries);
4. Ceiling limit values (eight countries);
5. Other: Some countries reported use of EKA ('exposure equivalent for carcinogenic substances'), and TDK ('technically reachable concentrations'). It is also worth noting that some Member States have based their limit values on the former German TRK values, determined at least partly by technical feasibility (see chapter 3.2.3 Adopting OELs from other sources, table 11).

Table 2 : Type of limit values for CM substances adopted by the EU countries

Member State	8-hour limit values	Short-term limit values	Ceiling limit values	Biological limit values	No limit values	Other
Austria	x	x	x	x		
Belgium	x	x	x			
Cyprus	x					
Czech Republic	x	x		x		
Denmark	x		x			
Estonia	x	x	x	x		
Finland	x	x	x	x		
Germany					x[12]	
Greece	x					
Italy	x					
Latvia	x	x		x		
Lithuania	x	x	x	x		
Luxembourg	x					
Netherlands	x	x	x	x		
Poland	x			x		
Portugal	x	x				
Slovakia	x	x		x		(i)
Slovenia	x	x		x		(ii)
Spain	x			x		
Sweden	x	x	x	x		
UK	x	x		x		
TOTAL	**20**	**13**	**8**	**13**		
(i) EKA - 'exposure equivalent for carcinogenic substances' (ii) TDK - 'technically reachable concentrations'						

Actually there are neither OEL for carcinogenic/mutagenic substances in Germany nor is there a national system for the derivation of such OEL. Such a system was under development but not yet in place at the time of the survey. The concept would be based on a scientific expertise and take into account epidemiological and toxicological data and severity of effects. In addition, social partners (workers and employers) as well as the ministry of labour would be able to comment on those scientific proposals. Based on two separate risk levels regarded as "tolerable" or "acceptable", a splitted OEL would be derived. Exposures below an "acceptable" level would only be related to basic measures such as hygienic measures. Exposures between the "acceptable" level and a "tolerable" level would temporarily be

[12] Germany was revising its OEL setting system for carcinogens and mutagens

tolerated but need to be reduced. Exceeding the "tolerable" level would mean, that these exposures are not tolerable and that risk reduction measures would have to be taken immediately.

2.3.1 Notations

– Almost all Member States reported use of skin notation (see table 1),

Other kinds of notations include such highlighting:

– cutaneous absorption;
– whether there are other limit values set, such as EKA (exposure equivalents), or BAT (biological limits);
– reprotoxicity and whether a substance is teratogenic (Poland Ft fetotoxiciy, Slovenia RE and RF). Latvia mentions in the comments section of the table in the questionnaire specific notations apparently linked to chemicals legislation which include notifications as reprotoxic (see table Latvian national questionnaire);
– Spain highlighted endocrine disruption for one substance.

At least two Member States, Spain and Slovenia, also highlight in their list whether a limit value has been adopted from EU sources, Spain also highlights substances for which proposals for limit values have been made at EU level.

The two most complex examples are described below:

- The following notations are used in the Polish OEL booklet: *C* – corrosive, *I*– irritation, ***A***– sensitising, *Ft*– fetotoxicity, *Sk* – the substance can be absorbed through the skin.
- Apart from C1, C2 and M1, M2, the following notations are used by Spain:

"Skin", "sen" sensitisation, "S" - Means that the biological indicator is an indicator of exposure to the chemical agent in question, but that the quantitative interpretation of its measurement is ambiguous (semiquantitative), "TR1"- harmful for the fertility of human beings or is toxic for their development, "TR2" can and must be considered harmful for the fertility of human beings and toxic for their development, "VLB" - Chemical agent for which a specific Biological Limit Value exists in this document, "VLBa" - Chemical agent to which the Biological Limit Value of cholinesterase inhibitors is applied, "VLBm" - Chemical agent to which the Biological Limit Value of methemoglobin inductors is applied, "VLI" - Chemical agent with an indicative limit value set up by the EU, "VLIp" - Chemical agent with an indicative limit value proposed by the EU. As mentioned above, Spain also marks an endocrine disruptor in the list provided.

3 Description of the OEL- setting process for carcinogenic and mutagenic substances

Table 3 presents an overview of the answers from the 21 Member Sates who participated in the survey. More detail is given in the following chapters.

It is important to read the answers together with the information given on the criteria applied for selection and derivation and on the scientific expert groups in place in the Member State in question. It is also important to consider whether the country mainly bases its OELs on external information sources or whether there are scientific resources available within the Member State. All Member States mention EU Directives and the SCOELs activities as an important resource. It also appears that the assessments are mostly carried out within the procedures set for all OELs and there don't seem to be distinctive procedures for OELs for carcinogens and mutagens. The only apparent exception may be those Member States where a a quantification of risk is one of the criteria applied. For example, the Netherlands mention shorter revision intervals for OELs set above the risk value of 10^{-6}.

Table 3: Overview of the answers - Procedures for selection of carcinogenic and mutagenic substances for OEL setting, derivation and revision of OEL

Member State	Specific procedure for selecting substances for OEL setting	National system for derivation of OEL	Specific procedure For revision of OEL
Austria	No	No	No
Belgium	No	No scientific derivation of OELs for chemical agents is not performed on the national level: OELs , adopted from sources (often ACGIH) that provide a scientific Evaluation are proposed to the High Council for Prevention and Protection at Work Two-stage public consultation procedure.	No
Cyprus	No (makes reference to EU Directive on carcinogens, the only values adopted in Cyprus for CM substances)	No	No

Member State	Specific procedure for selecting substances for OEL setting	National system for derivation of OEL	Specific procedure For revision of OEL
Czech Republic	Yes (priority to inhalation then mutagens and probably genotoxic carcinogens)	Yes General system for derivation of OELs of chemicals incl. CMR substances. Most information on criteria hold for all chemical substances; the specificity of CMR substances is reflected in the phase of risk evaluation and in the mandatory protective measures related to the exposure of workers to carcinogens.	Yes The same general system for derivation of OELs of chemicals incl. CMR substances. Re-evaluation is initiated by new epidemiological or experimental data. Official setting of OELs is bound to the amendment of the Directive.
Denmark	No	Yes	Yes
Estonia	No	No	No
Finland	Yes (priority to EU & new scientific knowledge)	Yes 1)Health based OELs and 2)so called binding limit values	Yes
Germany	No (under discussion)	No Currently, no OEL for carcinogenic or mutagenic substances are derived in Germany. Nevertheless, a new concept for the derivation of OEL is under discussion. This concept is based on two threshold values; an “acceptable threshold” and a “tolerable threshold”, which define three regions representing different risk levels.	No
Greece	Yes (harmonisation with EU directives by introducing the recommended limit values of EU characterized carcinogenic substances as constraining limit values.)	No	No
Italy	No	Yes	Yes
Latvia	No (selected jointly with all substances selected for OEL setting)	Yes OELs for CMR substances are set not separately but within OEL for all chemicals (reference to last update of regulation is given)	No OELs are revised after receiving new imformation from EC (including information from prof. Maija Eglite, participant of EC Scientific Committee for Occupational Exposure Limits) without official specific procedure for revision

Member State	Specific procedure for selecting substances for OEL setting	National system for derivation of OEL	Specific procedure For revision of OEL
Lithuania	Yes (priority to high toxicity, makes reference to EU limit values later in the questionnaire)	No	Yes
Luxembourg	No	No	No
Netherlands	Yes (under discussion; report was due for consultation end 2007)	Yes	Yes Every four years when OEL is set above the risk value of 10-6. • Otherwise when need arises
Poland	Yes (priorities are set based on the following: industrial application; official classification)	Yes	Yes The limits for carcinogens or mutagens are revised as other chemicals for 2-3 years
Portugal	No	No	Yes The revision of OEL's is based on the latest version of the ACGIH values annually
Slovakia	Yes (Technical Exposure Limits TSH from Germany-TRK; EU Dir. & other countries	No	Yes 3 – 5 years according to new toxicologic-epidemiological information or legislative requirements
Slovenia	No	No	No
Spain	Yes (EU-SCOEL procedure)	Yes	Yes As sources, we consider the SCOEL/SUM documents at first, as well as the criteria documents published by MAK, HSE, DECOS and ACGIH.
Sweden	No part of the normal procedure of prioritization of substances for OEL setting, prioritise substances used in a lot of workplaces and when there are problems arising	Yes	No
UK	No	Yes	No

3.1 Selection and prioritisation of substances

3.1.1 Procedure for selection

Question asked:
B1.a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

The Czech Republic, Finland, Greece, Lithuania, Poland, Slovakia and Spain report to have a specific procedure for selecting substances for OEL setting (see table 3). Sweden denies

having a specific procedure, but at the same time mentions it is part of the prioritisation procedure applied to all substances. In the Netherlands, a procedure was being prepared and a report due for consultation end 2007.

This information needs to be addressed together with information provided by the Member States in other sections of the questionnaire, for example on criteria for selection and the procedure for setting limits (see chapter 3.2.2 of this report), with reference to specific expert or tripartite bodies involved directly or more indirectly in selecting and prioritising substances. What also needs to be taken into account is whether or not the Member States used resources of other countries or organisations (see chapter 3.2.3, table 11). In countries where this is the case, that would obviously predetermine to some extent, or limit, the choice of substances for OEL-setting.

The Czech Republic and Poland, for example, gave an extensive description of their procedures in place in several sections of the questionnaire:

The Czech Republic mentions a procedure for the selection of substances: priority is granted to substances to which the workers are exposed predominantly by inhalation, without simultaneous exposure to other CM compounds. Biological availability (i.e. toxicokinetic) criteria are then applied in mutagens and in probably genotoxic carcinogens, while the availability of NOELs for organotoxic effects and their level is decisive in non-genotoxic carcinogens.

The Czech Republic also describes in other sections of the questionnaire more in detail a national register on exposures and results of biological monitoring. The register aims at determining trends in the main exposures and health problems for workers. Reference is also made to a register of work activities where technical criteria for setting limits are described. In yet another section of the questionnaire, the OEL commission is described, which has a broader scope, including toxicological assessment of chemicals and biocides.

Poland appears to be making reference in its criteria for selection of substances to its register of work activities (procedures), which is described more thoroughly in the section on technical feasibility criteria (see chapter 3.2., table 8) This illustrates that it is also not always clear whether such a clear-cut distinction is made between criteria for selection of substances and for setting the level of the OEL, the same source of information obviously being used for both.

On the other hand, Slovakia is affirmative about a procedure, but makes reference to having adopted German TRK values and limit values from other Member States and the EU, not having a national scientific committee in place.

Latvia, while denying there is a specific procedure, stated that the selection is done together with other (non-carcinogenic or mutagenic) substances selected for OEL setting. Later in the questionnaire, while stating the same, Latvia is affirmative about a procedure for setting OELs (that would include scientific evaluation).

Then again, while denying to have a specific procedure in place, Denmark mentions a prominent role of its national scientific (quality) group, which extends its expertise to other related fields of competence such as environmental legislation, and extensively using external sources, including the other Scandinavian countries'.

Also, some Member States make reference to limit values being adopted based on EU Directives. Greece and Spain, while stating they have a procedure in place, mention EU sources, while Portugal denies having a procedure and mentions the same sources.
As described above, some countries, such as Spain, specifically make reference to these EU values in their national lists and thereby highlight the source. Belgium publishes all the proposals, many from external sources, in an open consultation procedure.

Finland mentions a specific procedure, based on proposals of the committee in case of new scientific knowledge - for carcinogens, mutagens and other substances. Finland also makes reference to SCOEL and other EU values requiring selection, the process being explained more in detail later in the questionnaire. In its explanations on revision of OELs, Finland also mentions updating of documentation on the toxicity of substances without necessarily changing the limit values and gives examples of the evolution of OELs for carcinogens and mutagens (see also table 15).

The distinction of whether there is a procedure in place should therefore not be solely based on the Yes/No answers in table 3 and is not so clear-cut.

3.1.2 Criteria for selection

Question asked:
B1.b) Which of the following selection criteria do you use? (Options: Availability of data on exposure, availability of toxicological data, number of persons exposed, severity of effects, epidemiological evidence, including reported cases of ill-health in the workplace, availability of measurement methods, other)

Based on the answers of 11 EU countries (Czech Republic, Denmark, Finland, Italy, Latvia, Poland, Slovakia, Slovenia, Spain, Sweden and UK; see table 4), the most important criteria for the selection of substances for the setting of OELs for carcinogenic and mutagenic substances appear to be, in order of priority:

1. epidemiological evidence, including reported cases of ill-health in the workplace;
2. availability of toxicological data;
3. severity of effects;
4. number of persons exposed;
5. availability of data on exposure;
6. availability of measurement methods.

Some Member States have ticked, but not ranked criteria (marked x in the table below).
The Netherlands reported four selection criteria, without specific priorities allocated to them: availability of toxicological data, severity of effects, number of persons exposed and availability of data on exposure.

Table 4: Criteria for the selection of substances for the setting of limit values in order of priority *(blank = no answer provided)*

Member State	Availability of data on exposure	Availability of toxicological data	Number of persons exposed	Severity of effects	Epidemiological evidence, including reported cases of ill-health in the workplace	Availability of measure-ment methods	Other
Austria							
Belgium							
Cyprus							(i)
Czech Republic	5	3	1		2	6	4 (ii)
Denmark	4	2		3	1		
Estonia							
Finland	6	2	4	3	1	5	7 (iii)
Germany							
Greece							(iv)
Italy	5	3	4	1	2	6	
Latvia	1	3	2	4	5	6	
Lithuania							(v)
Luxembourg		x					
Netherlands	x	x	x	x			
Poland	3	4	2	5	1	6	
Portugal							
Slovakia	5	2	6	3	1	4	7
Slovenia	1	2	4	5	3	6	
Spain	1	2	5	3	4	6	
Sweden	5	1	4	3	2	5	
UK	4	5	3	1	2	6	
MEAN	**3,6**	**2, 6**	**3,5**	**3,1**	**2,1**	**5,6**	

(i) EU directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work (2004/37/EC)
(ii) Read-across, structural alerts, SAR prediction
(iii) National HPV; SCOEL document availability; updates in other countries
(iv) EU directives
(v) OELs are selected according to the requirements of EU directives and the criteria are based on the experience of other EU countries.

3.1.3 Parties involved

Question asked
B1.c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

In 14 EU countries of the 21 countries that participated in the survey (Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, Greece, Italy, Latvia, the Netherlands, Poland, Slovakia, Slovenia, and Spain) public authorities (Ministry of Labour or Ministry of Health) are reported to belong to the group of bodies that make proposals for setting up or changing a limit value. About the same number of countries (13) report that scientific experts are involved in making proposals. As regards the social partners, the workers' organisations are mentioned slightly more often than the employers' as initiators of proposals (nine vs. six) (see table 5).

For five of the Member States which answered - Austria, Cyprus, the Netherlands, Slovakia and Slovenia – solely the public authorities are mentioned as initiators of proposals. It is important in this context also to look at the Member States' answers to questions regarding the criteria for selection of substances and for setting the limits, the additional information given by them on the procedure.

Also, there might be a link to whether Member Sates mainly use other countries resources for the proposals (overview in table 11), because then they would not have so much of an initiating role in the assessment of substances. The starting point for discussions might very well be a summary of other institutions´ or countries´ assessments, prepared by the authorities. Actually, it appears that three of the five Member States mentioning the public authority as sole initiator of proposals, Austria, Slovakia and Slovenia, also use extensively resources from other countries (see table 11). The Netherlands has a scientific committee evaluating at the level of the Ministry of Health. Cyprus only implemented EU limit values, as can be seen from table1, where only the three constraining EU limit values are mentioned for Cyprus.

Table 5: Member States' parties involved in setting up or modifying limit value *(blank = no answer provided)*

Member State	Parties involved in proposals for OELs						
	Scientific experts	Social partners - Employers	Social partners - Workers	Public authority - Ministry of Health	Public authority - Ministry of Labour	Public authority - other	Other
Austria					x		
Belgium	x	x	x		x		
Cyprus					x		
Czech Rep.	x			x			
Denmark	x				x		
Estonia							(i)
Finland	x	x	x	x			
Germany							
Greece	x		x		x	x	(ii)
Italy	x		x	x	x		
Latvia	x	x	x	x	x		
Lithuania	x			x	x		(iii)
Luxembourg	x		x				
Netherlands					x		
Poland	x	x	x	x	x		
Portugal	x						(iv)
Slovakia				x			
Slovenia					x		

Member State	Parties involved in proposals for OELs						
	Scientific experts	Social partners - Employers	Social partners - Workers	Public authority - Ministry of Health	Public authority - Ministry of Labour	Public authority - other	Other
Spain	**x**	**x**	**x**	**x**	**x**	**(v)**	
Sweden	**x**	**x**	**x**				
UK							**(vi)**
TOTAL	**13**	**6**	**9**	**8**	**12**	**2**	

(i) The EU OELs setting, if there will be some new OELs

(ii) The General Directorate of Occupational Health and Safety of the Greek Ministry of Labour, other Ministries, the General Confederation of workers, the Trade Union, the Greek Medical Association, the Technical chamber of Greece, Union of Greek chemists, two experts in Occupational Health & Safety.

(iii) Temporary joint working group of specialists. The specialists are delegated by the Ministry of Health Care and Ministry of Social Security and Labour, State Labour Inspectorate.

(iv) There is a technical Portuguese committee that regularly meets in order to review the Portuguese standard about the OELs.

(v) The Ministry of Industry.

(vi) Proposals for setting a limit or modifying an existing limit are ratified by the Health and Safety Commission.

The answers regarding consultation, which are presented in chapter 3.2.4, are also revealing: 17 EU countries, including the five that only mention public institutions as initiators, reported to consult other parties for the derivation of OELs for carcinogenic and mutagenic substances. These other parties include mostly the social partners and governmental organisations (ministries and other) (see table 12). The same applies for technical feasibility: validation of the technical feasibility may include labour inspection or regional inspection bodies (see table 8), but exposure and product register and "work activity" registers provided by different services are also used in some countries. Several countries also reported to have specific bodies set up for the scientific evaluation process (see table 7). Information provided on the technical feasibility, socio-economic and other administrative criteria also indicates an at least indirect involvement of social partners from specific industrial sectors in the consultation and decision phase (see chapter 3.2.2).

While the official proposal may come from the ministries, several parties may therefore explicitly or implicitly be involved in the selection process.

For example, the UK describes its consultation procedure as a tripartite discussion of scientific evidence (by independent experts nominated by the trade unions, industry and the Health and Safety Executive) followed by tripartite discussion of socioeconomic issues (between individuals representing the trade unions, industry and independent experts) followed by a public consultation exercise. The UK also makes reference to its national body, the Health and Safety Commission (HSC), that ratifies proposals. More extensive comments and other examples are also given in other chapters of this report (for example chapter 3.2.3 on criteria for derivation of OELs).

3.2 Derivation of OELs for carcinogens and mutagens

3.2.1 National system

Question asked:
B2.d) Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors? (Yes/No)

The results from the 21 Member States' answers are summed up in table 3 above, with the answers on the selection procedure and on revision of OELs. 11 Member States, Austria, Belgium, Cyprus, Estonia, Germany, Greece, Lithuania, Luxembourg, Portugal, Slovakia, and Slovenia, indicate that they do not have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors.

As mentioned above, Belgium reports that the scientific derivation of OELs for chemical agents is not performed at national level: OELs, adopted from non-national sources (often ACGIH) that provide a scientific evaluation, are proposed to the High Council for Prevention and Protection at Work (employers' and workers' representatives, experts) and published on the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue[13]. Within two months after publication of the proposed OELs, parties concerned can lodge a notice of objection to these values; within five months after publication, an elaborate file has to be presented for every contested OEL. Based on the above mentioned files, the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work.

Germany reports that currently no OELs for carcinogenic or mutagenic substances are derived. Nevertheless, a new concept for the derivation of OEL is under discussion. This concept would be based on two threshold values; an "acceptable threshold" and a "tolerable threshold", which define three regions representing different risk levels linked to different prevention measures. More detail is provided in the section below on socio-economic criteria (chapter 3.2.2).

It is important to note again in this context that Germany had a number of technical feasibility-based limit values in place, before revoking the "TRK" system in 2005. Several other Member States have based OELs for CMRs on the TRKs in the past and have reported this in the context of this survey.

Member States that indicate to have a national system for setting up of OELs are: the Czech Republic, Denmark, Finland, Italy, Latvia, the Netherlands, Poland, Spain, Sweden and the UK. However there is no clear indication as to what the differences are to the general system of setting OELs. In the Czech Republic**,** for example, the general system for derivation of OELs of chemicals was reported to include CMR substances. The specificity of CMR substances is reflected in the phase of risk evaluation and in the mandatory protective measures related to the exposure of workers to carcinogens. Latvia also reports that OELs for CMR substances are set not separately but within OEL for all chemicals. In other parts of the questionnaire, other Member States have also reported that assessments are similar to the ones conducted for other limit values (see the following chapters): for example, Poland has also

[13] http://www.werk.belgie.be or http://www.emploi.belgique.be.

provided an extensive description of how the assessment of scientific evidence is carried out at national level, which is provided in the following chapters.

To assess whether there is a specific procedure in place, it is therefore also important to consider information given in other parts of the national questionnaires.

3.2.2 Criteria for the key components of the national system

The table below provides an overview over the answers from the 21 Member States who participated in the survey.

Table 6: Derivation of OEL –procedure and criteria
(blank = no answer provided)

Member State	National system for derivation of OEL	Documented methodology for scientific evaluation	Scientific body for the evaluation process	Technical feasibility criteria	Socio-economic criteria	Administrative and policy criteria (e.g. acceptability of risk)
Austria	N					
Belgium	N			(i)	(i)	N
Cyprus	N	N	N	N	N	N
Czech Republic	Y	Y	Y	Y	N except societal /individual benefits for health	Y, but not acceptability of risk
Denmark	Y	N	Y	Y	N	N
Estonia	N	N	N	Y	N	N
Finland	Y	Y	N	x		
Germany	N					
Greece	N					
Italy	Y	N	Y	x	N	N
Latvia	Y	N	Y	x	N	N
Lithuania	N	N	N			Acceptability of risk, no detail
Luxembourg	N	N	N	x	N Except individual/societal benefits	N
Netherlands	Y	Y	Y	x	N	Y Acceptability of risk
Poland	Y	Y	Y	x	N	Y Acceptability of risk
Portugal		N	N			
Slovakia	N	N	N	N	N	Y Acceptability of risk
Slovenia	N	N	N	N	N	N
Spain	Y	N	Y	x	N	N

Member State	National system for derivation of OEL	Documented methodology for scientific evaluation	Scientific body for the evaluation process	Technical feasibility criteria	Socio-economic criteria	Administrative and policy criteria (e.g. acceptability of risk)
Sweden	Y	Y	Y	x	Y compliance costs, economic benefits	
UK	Y	Y	Y	x	Y	N
(i) mentioned in description of procedure x information provided, mainly about exposure situation and sectors affected						

3.2.2.1 SCIENTIFIC EVALUATION PROCESS

Questions asked
B2.g) Where a national system exists, does it contain criteria for the key components of the system, including scientific evaluation? (Yes/No)

(i) Do you have a documented methodology for the scientific evaluation of substances? (Yes/No)
- Answered 'yes': Czech Republic, Finland, the Netherlands, Poland, Sweden and UK
- Answered 'no': Cyprus, Denmark, Estonia, Italy, Latvia, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia and Spain
- No answer: Austria, Belgium, Germany, Greece

(ii) Other approach, please describe?
Three countries indicate to have another approach, namely:
- Denmark – evaluation of available material
- Latvia - evaluation of existing toxicological data according to OECD guidelines, evaluation of OEL values in other countries, consultation within partners, agreement on indicative or constraining value
- Spain - risk assessment following the SCOEL criteria.

(iii) Are there specific scientific bodies set up for the scientific evaluation process? (Yes/No) If yes, please provide the name, address and website details.
- Answered 'yes': Czech Republic, Denmark, Italy, Latvia, the Netherlands, Poland, Spain, Sweden and the UK (see table 7)
- Answered 'no': Cyprus, Estonia, Finland, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia
- No answer: Austria, Belgium, Germany, Greece

Belgium reports in its answer to question 2d) that, while using scientific evaluations from other countries (often ACGIH), it has a 2-stage consultation procedure involving experts: publication of the values and open consultation at first, more thorough dossiers to be prepared for those OELs where objections are received, and consultation in a body where experts are reported to be represented (High Council for Prevention and Protection at Work) after that.

The Czech republic also mentions in its answer about socio-economic feasibility criteria its Registry of Subjects Occupationally Exposed to Carcinogens (REGEX) which collects

analysed data such as length, intensity, route of exposures to known occupational carcinogens collected at individuals' level and provided by the Regional Hygienic Stations and/or Public Health Institutes to the National Institute of Public Health at Prague. The major objectives include the analysis of trends in levels and types of exposures to carcinogens, the evaluation of effects of past and current exposures to carcinogens on workers' health and the identification of factors associated with elevated exposures and/or elevated incidence of cancer.

Poland has given an extensive description of assessment of scientific evidence in its answer on administrative criteria (see table 10).

For carcinogenic agents, the national Polish commission has adopted the socially accepted risk at the level of 10^{-3} to 10^{-5}. The experts propose the MAC for carcinogenic for those two levels and the Commission opts on one of them. The risk assessment from animal experiments or human data is estimated by the Group of Experts for Risk Assessment of Carcinogenic Compounds. It is included in documentation prepared by experts. When preparing draft MAC values for carcinogenic substances, health risk assessment resulting from human exposure to the carcinogens can be also used. Uniform documentation for each compound includes:

1. Contents
2. Summary
3. Substance characterisation, uses and occupational exposure
4. Toxic effects on human
5. Toxic effects on laboratory animals
6. Carcinogenicity, mutagenicity, teratogenicity, embryotoxicity, and effects on reproduction
7. Toxicokinetics
8. Mechanism of toxicity
9. Combined effects
10. Dose-effect and dose-response relationships
11. Bases for existing MAC or MAI values and biological tolerance limits
12. Bases for proposed MAC or MAI values and biological tolerance limits
13. Methods of determining the agents harmful to health in the air and in biological material
14. Pre-employment and periodical medical examinations

    Documentations of MAC values are published quarterly in a publication of the Interdepartmental Commission "Principles and Methods of Assessing the Working Environment".

Poland has also reported to have a collection of guidelines for assessing health risk from carcinogens (in Polish language, with a short summary in English), and attached to its questionnaire a list of substances for which such guidelines have been set up (see national questionnaire).

Denmark gives a more detailed description of the competencies represented in the scientific body in its answer on the consultation of parties. It appears that there is a wide representation in the group, apparently also competent, maybe also active, in related policy fields (e.g. environmental issues). More detail is given in the table below.

A similar impression is given by the Czech Republic's answer, where a broader expertise (e.g. biocides-related) is represented.

Denmark also specifies that a prominent role is given to the scientific committee, an involvement of social partners mainly being when limit values would be contested.

Inversely, Belgium mentions that a more thorough scientific evaluation would only be conducted when there are objections filed in the public consultation process.

In its answer on consultation Italy mentions a Committee, the "Commissione Consultiva permanente per la prevenzione degli Infortuni e l'igiene del lavoro" at the Ministry of Labour and Social Security, composed by scientific experts from different Institutions (Ministry of Labour and Social Security, ISPESL, ISS, INAIL, CNR, UNI, CEI, ANPA, Ministry of Health)

The UK describes its consultation procedure as a tripartite discussion of scientific evidence (by independent experts nominated by the trade unions, industry and the Health and Safety Executive) followed by tripartite discussion of socioeconomic issues (between individuals representing the trade unions, industry and independent experts) followed by a public consultation exercise.

Sweden provides detailed information on its scientific bodies too:

- The Swedish criteria group which produces risk assessment documents used for setting legally binding occupational exposure limits;
- The Nordic expert group for Criteria Documentation of Health Risks from Chemicals (NEG) consisting of scientific experts from the Nordic countries representing different fields of science, such as toxicology, occupational hygiene and occupational medicine. The main task is to produce criteria documents to be used by the regulatory authorities of the Nordic countries as the scientific basis for setting occupational exposure limits (OELs) for chemical substances.

The actual setting of an OEL is regarded to be a national concern.

Table 7: EU countries reporting to have specific scientific bodies set up for the scientific evaluation process

Member State	Scientific bodies and contact details
Czech Republic	OEL commission at the National Institute of Public Health in Prague; members of the commission are appointed also to assess health risk of chemicals and biocides. Website (http://www.szu.cz) is now under reconstruction.
Denmark	Denmark gives more detail in its answer on the consultation of parties see 2.2.4: A group called The Quality Group consisting of scientific experts from the following research institutes: National Research Centre for Working Environment, Danish Working Environment Authority, Danish Veterinary and Food Administration, Department of Environmental Medicine – Odense University, Department of Working Medicine, Aarhus, Danish Environmental Protection Agency,.

Member State	Scientific bodies and contact details
Italy	– ISPESL -Via Urbana 167, 00184 Roma, website www.ispesl.it ; – ISS - Viale Regina Margherita 299, 00161 Roma, website www.iss.it ; – AIDII - Via Morgagni Giovanni Battista 32, 20129 Milano, website www.aidii.it – SIMLII - website www.simlii.net In its answer on consultation Italy mentions a Committee, the "Commissione Consultiva permanente per la prevenzione degli Infortuni e l'igiene del lavoro" at the Ministry of Labour and Social Security, composed by scientific experts from different Institutions (Ministry of Labour and Social Security, ISPESL, ISS, INAIL, CNR, UNI, CEI, ANPA, Ministry of Health)
Latvia	Technical Committee No 19 "Work Environment" of National Standardisation body "Latvijas Standarts"; http:/www.lvs.lv/lv/tc/tc_EP.html
Netherlands	Health Council, http://www.gr.nl
Poland	– Group of Experts for Chemical and Dust Agents Interdepartmental Commission for MAC and MAI, Central Institute for Labour Protection – National Research Institute www.ciop.pl – Group of Expert for Risk Assessment of Carcinogenic Compounds, Nofer Institute of Occupational Medicine www.imp.lodz.pl
Spain	INSHT Occupational Exposure Limits Working Group, c/ Torrelaguna 73, MADRID 28027, SPAIN; http://empleo.mtas.es/insht/index.htm
Sweden	– The Swedish criteria group which produces risk assessment documents used for setting legally binding occupational exposure limits: http://www.av.se/teman/hygieniska/kriteriegruppen/ (only Swedish) Contact details were also provided for the chairman (available from national questionnaire). – The Nordic expert group for Criteria Documentation of Health Risks from Chemicals (NEG) consists of scientific experts from the Nordic countries representing different fields of science, such as toxicology, occupational hygiene and occupational medicine. The main task is to produce criteria documents to be used by the regulatory authorities of the Nordic countries as the scientific basis for setting occupational exposure limits (OELs) for chemical substances. The actual setting of an OEL is a national concern. The chairman of the Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals (NEG) is also a member of the Swedish criteria group and the scientific committee of occupational exposure of limit values (SCOEL) in EU. Contact details were also provided in the national questionnaire. Website: http://www.av.se/arkiv/neg/
UK	Scientific evaluation is performed by a tripartite committee, the Working Group on Action to Control Chemicals (WATCH). Information about this committee can be found at: http://www.hse.gov.uk/aboutus/hsc/iacs/acts/watch/index.htm

3.2.2.2 TECHNICAL FEASIBILITY CRITERIA

Questions asked
B2.g) Where a national system exists does it contain criteria for the key components of the system, including technical feasibility criteria? (Yes/No)

i) How do you identify which employment sectors use carcinogenic and mutagenic substances?

(ii) For the identified employment sectors how do you evaluate the technical capability to meet the OEL?

Most of the Member States only gave answers to these questions and not in the other sections on criteria. A summary of the answers is provided in table 8.

The technical feasibility assessment may involve labour inspections and regional inspections. National lists of priority substances, product registries and exposure measurement registers also seem to be used as an important information source.

Other sources include "working conditions or work activity registers", which apparently specify work procedures and provide information on potential exposures.

For example, in the Czech Republic, an evaluation by regional centres of public health is mentioned. More detail is provided in the answer to the questions on policy and administrative criteria (see table 10): an OEL value is set at first for an individual enterprise ('private OEL') through the Regional Public Health Authority, and feedback information (on feasibility, compliance and specified health issues) is required also through the medium of this regional centre. If there is no feedback, the OEL is recommended as a value for national implementation.

The Czech republic also mentions in its answer about socio-economic feasibility criteria its Registry of Subjects Occupationally Exposed to Carcinogens (REGEX) which collects analysed data such as length, intensity, route of exposures to known occupational carcinogens collected at individuals' level and provided by the Regional Hygienic Stations and/or Public Health Institutes to the National Institute of Public Health at Prague. The major objectives include the analysis of trends in levels and types of exposures to carcinogens and the identification of factors associated with elevated exposures and/or elevated incidence of cancer.

Poland specifies that when using substances, preparations and agents or processes that are carcinogenic or mutagenic in the working environment, each employer is obliged at the start of the activity to send information concerning the manufacturing process to the State Sanitary Inspection and the National Labour Inspectorate. A central register of exposure to carcinogenic and/or mutagenic substances, preparations or technological processes has been compiled at the Nofer Institute of Occupational Medicine in Łódź, Poland.

The Central Statistical Office collects information on working conditions: registers on working conditions cover workers by enterprise and the risks factors deriving from the work process, physical factors (e.g. lighting, noise, micro-climate), chemical (e.g. toxic substances) and biological (e.g. bacteria), at the workplace as well as the space surrounding the

establishment, for example when concentrations exceed the constraining MAC (maximum admissible concentration) and MAI (maximum admissible intensity). Exposures are also taken into account when an occupational disease is suspected to occur and data on exposures are notified to the Nofer Institute.

The UK and other Member States also mention the tripartite consultation after the scientific evaluation as an information source on technical feasibility. Belgium refers to its answer to question 2 d) about its two-stage public consultation procedure, where it is possible to file objections to proposals, that the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work. The Netherlands make reference to a national tripartite socio-economic (assessment) committee (SER (Sociaal-Economische Raad)).

Table 8: Technical feasibility criteria
(Countries not listed did not answer the questions)

Member State	Information provided
Identification of employment sectors using carcinogenic and mutagenic substances	
Belgium	Information is provided by the social partners, scientific experts, and if possible tested against inspection data.
Czech Republic	Information is extracted from: 1. The National Registry of Working Activities representing national system of mandatory work categorisation; 2. The National List of Priority Substances; 3. HEDSET (Harmonized Electronic Data SET)
Estonia	Via Chemical Notification Centre, National Labour Inspectorate, Estonian Technical Inspectorate.
Finland	Contribution from employers' and employees' organizations, FIOH, common knowledge, national registry of chemical products, etc.
Latvia	Information from State Labour Inspection and Department of Chemical Substances of Ministry of Environment State agency "Latvian Environment, geology and meteorology agency"
Poland	1. According to the Regulation of the Minister of Health of 20 April 2005 on substances, preparations and agents or processes that are carcinogenic or mutagenic in the working environment, each entrepreneur is obliged at the start of the activity to send information concerning the manufacturing process to the State Sanitary Inspection and the National Labour Inspectorate. The central register of exposure to carcinogenic and/or mutagenic substances, preparations or technological processes has been compiled at the Nofer Institute of Occupational Medicine in Łódź, Poland. 2. The basis for registers on working conditions is the regulation of the Council of Ministers of 13 June 2005 concerning public statistical surveys for 2005. The Central Statistical Office collects information on working conditions using the form Z-10 "Work conditions". Registers on working conditions cover entities with 9 employees and over. Work environment factors consist of: physical factors (e.g. lighting, noise, micro-climate), chemical factors (e.g. toxic substances) and biological factors (e.g. bacteria), occurring within work place (e.g. factory room, work station) as well as the space surrounding the establishment. Hazard related to work environment exposures exceeding the constraining MAC (maximum admissible concentration) and MAI (maximum admissible intensity), Polish standards or other hygienic standards. 3. Occupational diseases are reported on a special form. The form contains detailed data including diagnosis, job description, causal agent of the disease, exposure level and duration, patient's name, date of birth, home address, name of enterprise with its code

Member State	Information provided
Identification of employment sectors using carcinogenic and mutagenic substances	
	number and postal address, industrial branch, name of health service unit that diagnosed the disease, date of issue of medical certification. The models of forms are given in the Regulation of the Minister of Health of 1 August 2002 on documentation of occupational diseases and the effects of these diseases. For biological and allergic agents not the exposure levels are required, but the type of agent, the kind of contact and its duration [regulation of the Council of Ministers of 30 July 2002 on occupational diseases index, specific procedures concerning reporting doubts, identification and recognition of occupational diseases and subjects that are appropriate for these cases. This information should be sent to the Nofer Institute of Occupational Medicine in Łódź and to the State Sanitary Inspection. The same applies to farmers, but they send information about occupational diseases to the Agricultural Social Insurance Fund (KRUS).
Spain	Normally, employment sectors are obtained from the information provided by the interested parties.
Sweden	In the Nordic countries, the product register where the suppliers and users must make an announcement of the use and the amount of the substance in question.
UK	Track chemicals through the supply chain, track process generated carcinogens through industry and trade union consultation.
Evaluation of the technical capability to meet the OEL for the identified employment sectors	
Czech Republic	General technical feasibility is one of criteria used in the process of OEL derivation; compliance in individual enterprises is evaluated by regional centres of public health.
Estonia	Via inspection visits.
Finland	Employer/employee consultation; national measurement registries; literature
Latvia	According to results of risk assessment made by Competent Organisations (at present accepted 31 CO in Latvia)
Netherlands	Via advice of the tripartite SER (Sociaal-Economische Raad).
Spain	During the consultation process, the affected employment sectors evaluate their own technical capability to meet the proposed OEL and report the results to the INSHT Occupational Exposure Limits Working Group.
Sweden	Perform an investigation of the cost for the investment that has to be made to comply with the new limit value. Then an impact assessment for our proposal to a new limit value has to be done. Also take contact with the companies in order to get a picture of how they will coup with the new situation.
UK	Tripartite consultation on the ability of industry to control exposures after the scientific evaluation has been completed.

(iii) Compliance can be achieved by the application of good working practices in the identified employment sectors (Yes/No)

- Answered 'yes': Czech Republic, Denmark, Estonia ("partly"), Finland, Italy, Latvia, Luxembourg, the Netherlands, Poland, Spain, Sweden, UK
- Answered 'no': Cyprus, Slovenia, Slovakia
- No answer: Austria, Belgium, Germany, Greece, Lithuania, Portugal

3.2.2.3 SOCIO-ECONOMIC FEASIBILITY CRITERIA

Member states' answers to the questions on socio-economic criteria are presented in table 9. Again, Belgium refers to its answer to question 2 d) about its two-stage public consultation procedure, where it is possible to file objections to proposals, that the technical and socio-

economic evaluation is performed within the High Council for Prevention and Protection at Work.

Sweden states in its answer on technical feasibility criteria that it performs an investigation of the cost for the investment that has to be made to comply with the new limit value, then an impact assessment for the proposal to a new limit value. Sweden also mentions contacts with the companies in order to assess how they will cope with the new situation.

As mentioned above, the UK describes its consultation procedure as a tripartite discussion of scientific evidence (by independent experts nominated by the trade unions, industry and the Health and Safety Executive) followed by tripartite discussion of socioeconomic issues (between individuals representing the trade unions, industry and independent experts) followed by a public consultation exercise. The UK mentions here that costs for provision of controls, including LEV/containment and PPE are considered and that expenditure on healthcare is also taken into consideration. The Netherlands make reference to a national tripartite socio-economic (assessment) committee (SER (Sociaal-Economische Raad)).

Questions asked:
Do you have data on the extent and distribution of economic consequences and the types of costs and savings? (Yes/No)
- Answered 'yes': UK
- Answered 'no': Cyprus, Czech Republic, Denmark, Estonia, Finland, Italy, Latvia, Luxembourg, the Netherlands, Poland, Spain, Slovakia, Slovenia
- No answer: Austria, Belgium, Germany, Greece, Lithuania, Portugal

In particular:
(i) Data on compliance costs to employers that are manufacturers or users of chemicals. (Yes/No)
If yes, please specify.
- Answered 'yes': UK
- Answered 'no': Cyprus, Czech Republic, Denmark, Estonia, Finland, Italy, Latvia, Poland, the Netherlands, Spain, Slovakia, Slovenia
- No answer: Austria, Belgium, Germany, Greece, Lithuania, Luxembourg, Portugal

(ii) Data on economic benefits stemming from avoiding costs e.g. less expenditure for health care. (Yes/No)
If yes, please specify.
- Answered 'yes': UK
- Answered 'no': Cyprus, Czech Republic, Denmark, Estonia, Italy, Latvia, the Netherlands, Poland, Slovakia, Slovenia
- No answer: Austria, Belgium, Finland, Germany, Greece, Lithuania, Luxembourg, Portugal, Spain.

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? (Yes/No)
If yes, please specify.
- Answered 'yes': Czech Republic, Luxembourg, UK,
- Answered 'no': Cyprus, Denmark, Estonia, Italy, Latvia, the Netherlands, Poland, Slovenia, Slovakia,

– No answer: Austria, Belgium, Finland, Germany, Greece, Lithuania, Portugal, Spain

Table 9: Socio-Economic Feasibility criteria
(Member States not listed did not provide information)

Member States	Information provided
Belgium	Information is provided by the social partners, scientific experts. Belgium refers to its answer to question 2 d) about its two-stage public consultation procedure, where it is possible to file objections to proposals, that the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work.
Sweden	States in its answer on technical feasibility criteria (question 2 g)) that it performs an investigation of the cost of the investment that has to be made to comply with the new limit value, then an impact assessment for the proposal to a new limit value. Sweden also mentions contacts with the companies in order assess of how they will cope with the new situation.
Data on compliance costs to employers that are manufacturers or users of chemicals	
UK	Costs for provision of controls, including LEV/containment and PPE are considered
Data on economic benefits stemming from avoiding costs e.g. less expenditure for health care	
UK	Expenditure on healthcare is taken into consideration
Information on societal and/or individual benefits for health	
Czech Republic	Information extracted from 1) National Registry of Occupational Diseases, and 2) Registry of Subjects Occupationally Exposed to Carcinogens In 1998 the Registry of Subjects Occupationally Exposed to Carcinogens (REGEX) has been established in the Czech Republic. The major objective of the REGEX is to collect, centralise, and analyze data collected by the Hygienic Service for sake of supervision of risky works. The data such as length, intensity, route of exposures to known occupational carcinogens is collected at individuals' level and provided by the Regional Hygienic Stations and/or Public Health Institutes to the National Institute of Public Health at Prague. The major objectives of the REGEX follow: 1) Analysis of trends in levels and types of occupational exposures to carcinogens in the Czech Republic 2) Evaluation of effects of past and current exposures to carcinogens on workers' health 3) Identification of factors associated with elevated exposures and/or elevated incidence of cancer. 4) Delivery of health care to subjects at risk of occupational cancer. Also mentions in answers to other questions an evaluation of the costs to enterprises and a "testing phase" in enterprises
UK	The benefits of reducing ill health are taken into consideration

(iv)Other criteria: please describe them.
The Member States did not indicate using any other criteria.

3.2.2.4 ADMINISTRATIVE AND POLICY CRITERIA

Questions asked

- ***(i) Do you have a criteria on the acceptability of risk?***
- ***(ii) For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/No and where applicable please state factor used:***

– Aswered 'yes': Latvia, the Netherlands, Poland, Slovakia

- Answered ‘no’: Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Italy, Luxembourg, Slovenia, Spain, Sweden, UK
- No answer: Austria, Germany, Greece, Lithuania, Portugal

(iii) Are derogations to the OEL possible for certain employment sectors? (Yes/No)
(iv) For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

- Answered ‘yes’: Czech Republic, Poland
- Answered ‘no’: Belgium, Cyprus, Denmark, Estonia, Finland, Italy, Latvia, Luxembourg, the Netherlands, Slovakia, Slovenia, Spain, Sweden and UK
- No answer: Austria, Germany, Greece, Lithuania, Portugal

Some Member States have not reported derogations or answered this question, but, when looking at the information given in the table of OELs (see table 1 and Annex 1), it comes clear that in some countries, such as Austria, different limit values might be set for different work processes.

(iii) Other administrative or policy criteria?
Information is provided in table 10.

Table 10: Administrative or policy criteria
(Member States not listed did not provide information)

Member State	Information provided
EU countries having reported to adopt criteria on the acceptability of risk	
Germany	Reports in another section of the questionnaire on a concept currently being discussed based on the acceptability of risk and linked to provisions on prevention measures. This concept would be based on two threshold values; an "acceptable threshold" and a "tolerable threshold", which define three different risk levels. Exposures below an "acceptable" level would only be related to basic measures. Exposures between the "acceptable" and a "tolerable" level would temporarily be tolerated but need to be reduced. Exceeding the tolerable" level would mean that hat risk reduction measures have to be taken immediately.
Latvia	Data in Register of Occupational Diseases (CA cases, exposure); Data in State Cancer Register (CA cases without analyse of data in connection with exposure and job)
Netherlands	OELs are set on a level of excess cancer death of 10^{-6}, but this value must be underscored when technically possible
Poland	For carcinogenic agents, the Commission has adopted the socially accepted risk at the level of 10^{-3} to 10^{-5}. The experts propose the MAC for carcinogenic for those two levels and the Commission decides for one of them. When preparing draft MAC values for carcinogenic substances, health risk assessment resulting from human exposure to the carcinogens can be also used. The following considerations have been valid when performing the assessment based on the results of animal studies: The relationship between dose (expressed in suitable units) and tumour frequency in animals is determined from the results of biological research on animals; The dose-response relationship is the same in humans and in the animals; Both mg/kg body weight and mg/m2 body surface area per diem may by used as the suitable units of the equivalent dose; The carcinogenic activity after received small doses is linear. The risk assessment from animal experiments or human data is estimated by the Group of Expert for Risk Assessment of Carcinogenic Compounds. It is included in documentation, which prepares experts. Uniform documentation for each compound includes: Contents Summary Substance characterisation, uses and occupational exposure Toxic effects on human Toxic effects on laboratory animals Carcinogenicity, mutagenicity, teratogenicity, embriotoxicity, and effects on reproduction Toxicokinetics Mechanism of toxicity Combined effects Dose-effect and dose-response relationships Bases for existing MAC or MAI values and biological tolerance limits Bases for proposed MAC or MAI values and biological tolerance limits Methods of determining the agents harmful to health in the air and in biological material Pre-employment and periodical medical examinations References Documentations of MAC values published quarterly in a publication of the Interdepartmental Commission "Principles and Methods of Assessing the Working Environment".
Slovakia	At assessment and prediction of risks in a process of decision making dealing with risk control measures which is responsibility of employers, local authorities, etc.

Member State	Information provided
EU countries reporting other administrative or policy criteria	
Czech Republic	Usually, an OEL value is set at first for an individual enterprise ('private OEL') through the Regional Public Health Authority, and feedback information (on feasibility, compliance and specified health issues) is required also through the medium of this regional center. If there is no feedback, the OEL is recommended as a value with national force.
EU countries reporting other administrative or policy criteria	
Lithuania	The criteria on the acceptability of occupational risk are set in normative document Order of Ministry of Social Security and Labour and Ministry of Health Care, 16 October 2003 on the approval of regulations on occupational risk. Official gazette (2003, No. 100–4504).
Netherlands	OELs are set on a level of excess cancer death of 10^{-6}, but this value must be underscored when technically possible
Poland	The representatives of employers and employees can report these difficulties on the meeting of the Interdepartmental Commission.

Table 10 shows countries' answers reporting either criteria on the acceptability of risk or other administrative or policy criteria. A few Member States (Latvia, Netherlands, Poland, and Slovakia) have reported to apply criteria on acceptability of risk. The Netherlands and Poland mention levels of acceptability and give a description of the system in place, more extensive for Poland. Germany is currently discussing such a system.

The Netherlands report that OELs are set on a level of excess cancer death of 10^{-6}, but this value must be underscored when technically possible.

In Poland, for carcinogenic agents, the relevant Commission has adopted the socially accepted risk at the level of 10^{-3} to 10^{-5}. The experts propose the MAC for carcinogenic for those two levels and the Commission opts for one of them. When preparing draft MAC values for carcinogenic substances, health risk assessment resulting from human exposure to the carcinogens can be also used.

Germany did not answer questions in this section of the questionnaire, but reports that currently a new concept for the derivation of OEL is under discussion, although no OELs for carcinogenic or mutagenic substances are derived yet. This concept would be based on two threshold values; an "acceptable threshold" and a "tolerable threshold", which define three regions representing different risk levels. Within this "traffic light" approach:

- exposures below an "acceptable threshold" would be associated with risks that are regarded acceptable. Besides basic measures such as standard hygiene or risk communication no further risk reduction measures are necessary.
- risks that result from exposures between the "acceptable threshold" and the "tolerable threshold" would be regarded as tolerable. Predominantly measures are requested that reduce these exposures and therefore risks.
- in those cases where the "tolerable threshold" would be exceeded, risks would be considered as intolerable and risk reduction measures as immediately necessary.

The derivation of limit values within this concept would primarily be based on toxicological and epidemiological data and take into account the severity of the effect(s). The adopted values would be defined as 8-hour values.

3.2.3 Adopting OELs from other sources

Question asked
B2.h) Do you ever adopt OELs from other sources? (Yes/No)
If yes, from which sources e.g. other national limit setting organisation. Please specify them.

16 of the Member States who responded reported to have adopted OELs from other countries. Five Member States responded to this question 'NO' (Cyprus, Germany, Greece, Netherlands, and Poland) (see table 11). Table 1 shows that Cyprus and Greece adopted only 3-4 limit values, including the constraining EU values. The Netherlands and Poland thoroughly described their scientific assessment procedures in their questionnaires. Germany had no system in place at the time of the survey.

To assess whether resources from other countries are used when setting limit values, it is also useful to have a look at other sections of the questionnaire, such as the ones referring to the procedure in place for deriving OELs (section B2d) of the questionnaire, outlined in the previous chapters, section D on availability of background documents and specific substance-related information (see chapter 5 and annex 3), or section E on limit values for reprotoxic substances (see chapter 6 and annex 4), where Member States have provided information on other documents they use. Some Member States have also given more detail when describing the bodies within which they consult OELs (chapter 3.2.4. of the report).

Some of the responding Member States systematically use sources and (scientific or other) evaluations from other countries. For example, Latvia and Slovakia reported the use of EU documents or other documents from data bases (NIOSH, OSHA, IOM, EPA).

Belgium has described in its answer to question 2d) its two-stage procedure for deriving OELs, while stating that the scientific derivation of OELS is not performed at the national level: OELs, adopted from sources (often ACGIH) that provide a scientific evaluation are proposed to the High Council for Prevention and Protection at Work (employers' and workers' representatives, experts) and published on the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be).

- Within 2 months after publication of the proposed OELs, parties concerned can lodge a notice of objection to these values;
- within 5 months after publication, an elaborate file has to presented for every contested OEL.

Based on the above mentioned files, the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work.

Belgium has also mentioned to make available the documents via the library of the authorities (question on available documents).

Some Member States have also made reference in the chapter on documentation to other areas of legislation (e.g. environmental or chemicals legislation outside the area of occupational safety and health).

Table 11: Adoption of OELs for carcinogenic and mutagenic substances from other countries
(blank = no answer provided)

Member State	OELs adopted from other countries (Y/N)	Which sources?
Austria	Y	OELs from German sources, namely DFG (German research society, deriving 'MAK Values') or from AGS (Committee hazardous substances), have been adopted in the past Specific EU legislation – carcinogens Directive and directives listing indicative occupational limit values – has been implemented
Belgium	Y	– The American Conference of Industrial Hygienists (ACGIH) – Other Member States In another section of the questionnaire, Belgium mentions a 2-stage open consultation procedure; proposed OELs from other sources are published on authorities' Website and documentation is used throughout the consultation process.
Cyprus	N	
Czech Republic	Y	All available OEL values are used as one source of supportive data; in case of discrepancies, preference is given to: – values supported by available background documents; – more recently updated values; – values based on biological inference; – values recommended by EC, – technically-based limits (e.g., Germany TRKs) are used as tentative estimates of feasibility.
Denmark	Y	EU (SCOEL), USA (ACGIH, NIOSH, OSHA, IARC), Germany (MAK), The Netherlands (DECOS), the Scandinavian countries, the Nordic Expert group (NEG) and UK
Estonia	Y	From other national set of standards (Sweden)
Finland	Y	e.g. European Union limit values. They are not necessarily adopted as such, but Finland would produce national documents on them also for the discussion in the OEL committee
Germany	N	
Greece	N	
Italy	Y	ACGIH, CEN, WHO
Latvia	Y	– Scientific Board of Nordic Countries (OEL setting in Sweden, Norway, Denmark and Finland); – Russian Commission on Occupational Health and OEL setting; – 'MAK values' from Germany.
Lithuania	Y	OELs are adopted on the legal basis of other EU countries. This procedure is laid down in a normative document (Order of Ministry of Health Care and Ministry of Social Security and Labour),, to be replaced to Hygiene Norm HN 23:2007 Concentration limit values of chemical substances in the air of working environment (Draft). Usually there are quite strict values of OELs adopted. The majority are adopted from Statute Book of the Swedish work Environment Authority (AFS 2005:17).

Member State	OELs adopted from other countries (Y/N)	Which sources?
Luxembourg	Y	OELs established in other countries (France, Germany)
Netherlands	N	
Poland	N	
Portugal	Y	OELs are based on the ACGIH values (2006), except for those that have specific European legislation
Slovakia	Y	Most OELs have been adapted from MAK (Germany), UK or Czech Republic
Slovenia	Y	TRGS 905 - German technical standard
Spain	Y	As sources, the SCOEL/SUM documents are considered first, as well as the criteria documents published by MAK, HSE, DECOS and ACGIH
Sweden	Y	Implement the limit values in EU Commission directives.
UK	Y	EU limits Historically the UK has adopted Threshold Limit Values from the ACGIH
TOTAL	**Y: 16** **N: 5**	

3.2.4 Consultation of other parties

Questions asked
B2.f) Is there a consultation for the derivation of OELs for carcinogenic and mutagenic substances? (Yes/No)
If yes, with which parties?

17 EU countries report to consult other parties for the derivation of OELs for carcinogenic and mutagenic substances. These other parties include mostly the social partners and governmental organizations (ministries and other) (see table 12). Two EU countries (Czech Republic and Luxembourg) indicate that there is no consultation process with other parties for the derivation of OELs. However, the Czech Republic reported in other sections of the questionnaire on its national bodies, and its database of measurements and health surveillance information that is also based on for example “testing” the OEL at the enterprise level before including into national legislation.

Therefore, it is important to consider answers to other sections of the questionnaire, for example on the procedures in place, national bodies for evaluation or on documentation available.

Poland has reported in its answer related to other administrative and policy criteria that the representatives of employers and employees can report difficulties at meetings of the Interdepartmental Commission.

Germany did not answer this question, but reports in another section of the questionnaire that a concept is being discussed that is based on scientific expertise. In addition, social partners (workers and employers) as well as the ministry of labour shall be able to comment on those scientific proposals.

Some of the respondents have made reference to the national scientific expert groups (Denmark, Italy, the Netherlands) and some have mentioned tripartite consultation at the expert level (for example UK). The UK also mentioned an open consultation procedure as a last step in its procedure.

Denmark specifies that a prominent role is given to the scientific committee, an involvement of social partners mainly being when limit values would be contested.
Inversely, Belgium mentions as outlined above that a more thorough scientific evaluation would only be conducted when there are objections filed in the public consultation process. Belgium reports (in its answer about the national system for derivation of OELs) that the scientific derivation is not performed at the national level, but that OELs adopted from other sources are proposed to the body established at the national level (High Council for Prevention and Protection at work), where experts and employers and workers representatives are represented. Also these proposals are reported to be published on the official Website of the authorities (Belgian Federal Public Services Employment, Labour and Social Dialogue) for public consultation. Within a certain period after publication, parties concerned can object to the proposals, an elaborate file has to be presented to the committee when there is an objection presented within a period of 5 months. Based on the above mentioned files, the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work.

Table 12: Consultation of other parties for the derivation of OELs for carcinogenic and mutagenic substances *(blank: no answer provided)*

Member State	Consultation (Y/N)	Which parties are consulted?
Austria	Y	Social partners, AUVA (Austrian accident insurance board), experts, chaired by ministry of economy and labour
Belgium	Y	Employers' and workers' representatives, scientific experts Belgium refers to answer to question B2d), where it has reported about a public consultation procedure that foresees a two-stage process: - publication of the proposal on the authorities' Website and 2 months time to file objections; - presentation of a more elaborate file for OELs for which an objection is received within a 5-month period; Based on the above mentioned files, the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work, where social partners and experts are represented.
Cyprus	Y	Social partners for the adoption of relevant EU legislation
Czech Republic	N	Answered negatively, but reported in other sections of the questionnaire on its national bodies, and its database of measurements and health surveillance information that is also based on for example "testing" the OEL at the enterprise level.

Member State	Consultation (Y/N)	Which parties are consulted?
Denmark	Y	A group called The Quality Group consisting of scientific experts from the following research institutes: – National Research Centre for Working Environment – Danish Working Environment Authority – Danish Veterinary and Food Administration – Department of Environmental Medicine – Odense University – Department of Working Medicine, Aarhus – Danish Environmental Protection Agency The social partners of workers and employers are only involved when a protest is given.
Estonia	Y	Confederations of employers and trade unions (on general matters only).
Finland	Y	Employers, employees, various ministries, various agencies
Germany		Did not answer this question, but reports in another section of the questionnaire that actually there are no OEL set for carcinogenic/mutagenic. Currently, a new concept is being discussed, that will involve scientific experts. In addition, social partners (workers and employers) as well as the ministry of labour will be able to comment on those scientific proposals.
Greece	Y	The General Directorate of Occupational Health and Safety of the Greek Ministry of Labour, other Ministries, the General Confederation of workers, the Trade Union, the Greek Medical Association, the Technical chamber of Greece, Union of Greek chemists, two experts in Occupational Health & Safety.
Italy	Y	1. The "Commissione Consultiva permanente per la prevenzione degli Infortuni e l'igiene del lavoro" at the Ministry of Labour and Social Security, composed by scientific experts from different Institutions (Ministry of Labour and Social Security, ISPESL, ISS, INAIL, CNR, UNI, CEI, ANPA, Ministry of Health), 2. Delegates of the Standing Conference for the Relationships between State and Regions, 3. Experts nominated by workers' and employers' representatives.
Latvia	Y	Governmental organisations (Ministry of Welfare, Ministry of Health, Ministry of Environment), Social partners (Employers' Confederation, Free Trade Union Confederation), NGOs
Lithuania	Y	Ministry of health care, social security and labour and the State labour inspectorate
Luxembourg	N	
Netherlands	Y	For the value as advised by the Health Council: everybody For the value advised by the SER (Sociaal-Economische Raad): employers and employees

Member State	Consultation (Y/N)	Which parties are consulted?
Poland	Y	It is a consultation for representatives of health and labour administration, various sectors of industry, trade unions and research institutes in the fields of occupational safety and medicine on the forum of the Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment. The main responsibility of the Commission is to consider, evaluate and adopt exposure limits for chemical and physical agents in the working environment and to submit them to the Minister of Labour and Social Policy, who is responsible for introducing those values into legislation. The secretariat of the Commission is based at the Central Institute for Labour Protection – National Research Institute.
Portugal		
Slovakia	Y	Ministry of Labour, employers
Slovenia	Y	All social partners
Spain	Y	Interested parties, employers, workers and public authorities
Sweden	Y	The consultation is with the labour unions organisations and the employers organisations
UK	Y	Tripartite discussion of scientific evidence (by independent experts nominated by the trade unions, industry and the Health and Safety Executive) followed by tripartite discussion of socioeconomic issues (between individuals representing the trade unions, industry and independent experts) followed by a public consultation exercise.
TOTAL	**Y: 17** **N: 2** **no answer: 2**	

3.2.5 Time from the proposal to adoption

Question asked:
B2.j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL? (Options: 1 Year; 3 Years; longer time period)

The reported time between the proposal and the adoption of an OEL for a CMR substance varies widely (see table 13):

- 1 year for five Member States (Czech Republic, Greece, Lithuania, Spain and Sweden);
- 2 years for Finland;
- 3 years for five Member States (Belgium, Denmark, the Netherlands, Poland and Slovakia);
- more than 3 years for four Member States (Italy, Latvia, Luxembourg and UK).

Six other Member States (Austria, Cyprus, Estonia, Germany, Portugal and Slovenia) did not specify how long it takes to establish OELs in their countries; Denmark, Finland and Sweden mentioned it could take longer for some substances.

Table 13: Time from the proposal to adoption
(blank: no answer provided)

Member State	Time from proposal to adoption (Options: 1 Year, 3 Years, longer time period)
Austria	
Belgium	3 years
Cyprus	
Czech Republic	1 year
Denmark	3 years or more, setting of an OEL for carcinogens and mutagens takes at least three years
Estonia	Mentions OELs being adopted from other countries
Finland	1-3 years, usually 2 years
Germany	
Greece	1 year
Italy	> 3 years
Latvia	> 3 years
Lithuania	1 year
Luxembourg	> 3 years
Netherlands	3 years (depends on the substance)
Poland	3 years
Portugal	
Slovakia	3 years
Slovenia	
Spain	1 year
Sweden	1 year, Sometimes the time is longer if the industry needs more time for the adjustment.
UK	> 3 years

3.2.6 Difficulties encountered

Question asked:
B2.k) In your experience, which elements of the process are the most complex to manage during the process of derivation of OELs for carcinogenic and mutagenic substances? Please give a brief description of the difficulties encountered.

Nine EU Member States reported difficulties. The most common problems, as listed in the table below, are the lack of national exposure data and toxicological data and difficulties in reaching a consensus.

Austria, Cyprus, Czech Republic, Denmark, Estonia, Germany, Greece, Lithuania, Luxembourg, Poland, Portugal and Slovenia did not specify any problems in the process of derivation of OELs for carcinogenic and mutagenic substances.

Table 14: Difficulties encountered during the OELs derivation process in some EU Member States.
(Member States not listed did not provide information)

Member State	Difficulties encountered
Belgium	Agreement between the social partners on the eventual OELs.
Finland	– Reaching consensus on proposals – Lacking measurement methodology or national exposure data.
Italy	To combine the different requirements of interested parties
Latvia	– Experiment evaluation of toxicity – Epidemiological study of impact of chemicals on health (uncertainty within groups exposed and co-factors).
Netherlands	– Actual exposure information – Trends in exposure and use.
Slovakia	Approval procedure: there is not any specific expert committee or commission for the adoption of an OEL.
Spain	Data on exposure and on the adverse effects occurred are difficult to obtain, especially from certain settings in SMEs or employment sectors with a lot of SMEs. Therefore, in most of the cases, available information about epidemiological studies is insufficient.
Sweden	When dose-response data and dose-effect data are not available and we still have to present a limit value
UK	Generally most difficulties are encountered during tripartite discussions on the socioeconomic impact of a new or revised limit, particularly for substances that have many different uses.

3.3 Revision of OELs

Question asked
B3.l) Is there a specific procedure for the revision of OELs for carcinogenic and mutagenic substances? (Yes/No)
B3.m) If yes, how often are limit values revised? Please specify time period.

An overview of the answers by the 21 Member States who responded is presented in table 15 below. 12 Member States deny having a specific procedure for revision of OELs (Austria, Belgium, Cyprus, Estonia, Germany, Greece, Latvia, Luxembourg, Poland, Slovenia, Sweden and UK); such a procedure does exist in nine other countries (Czech Republic, Denmark, Finland, Italy, Lithuania, the Netherlands, Portugal, Slovakia and Spain).

The revision occurs with a widely variable frequency:
- every year in Portugal and in Spain;
- every 2 years in Denmark;
- every 2-3 years in Finland and Poland;

- every 3 years in Italy;
- every 3-5 years in Slovakia;
- every 4 years in the Netherlands;
- every 5 years in Lithuania.

More details were given by Finland, including some examples of the development over time of limit values for selected carcinogens.

In other sections of the questionnaire, revision is also reported to be carried out when new toxicological evidence is available or when new EU limit values are being proposed. This is also the case for those countries which rely heavily on limit values published by other countries or scientific expert groups. For example, Portugal mentioned that it was revising its OELs when new values were published by the ACGIH. Please refer to chapter 3.2.3.and table 11 for an overview of the external sources.

Table 15: Specific procedures and frequency of revision for OELs of carcinogenic and mutagenic substances *(blank: no answer)*

Member State	Specific Procedure	Frequency
Austria	No	
Belgium	No	
Cyprus	No	
Czech Republic	Yes	Re-evaluation by new data
Denmark	Yes	Every 2 years
Estonia	No	
Finland	Yes	Every 2-3 years (since 1993)*
Germany	No	
Greece	No	
Italy	Yes	Every 3 years
Latvia	No	After receiving new info from EU-SCOEL
Lithuania	Yes	Every 5 years
Luxembourg	No	
Netherlands	Yes	Every 4 years when OELs set > risk value = 10-6; otherwise when need arises
Poland	No	Every 2-3 years (as for other chemicals)
Portugal	Yes	Every year (revision is based on ACGIH-TLVs)
Slovakia	Yes	Every 3-5 years (new data/legislation)
Slovenia	No	
Spain	Yes	Every year
Sweden	No	
UK	No	

* Finland:

- The target lately has been to revise the list of limit values every 2 years. The list of 2007 has 15 new substances with OEL, for 29 substances there was a change in OEL, and for another 19 substances the documentation was updated without the need to change the existing OEL.
- The list has been revised at least in 1962, 1972, 1981, 1987, 1993, 1996,1998, 2000, 2002, 2005, and 2007
- As for changes of OELs for specifically C/M/R substances, either due to this C/M/R property or some other undesired effect, a look at first 11 substances in table A above showed that for these substances between year 1962 and the present, a median value of 1 change and an arithmetic mean of ca. 1,5 changes was made. For one substance (asbestos) four changes had taken place, for another one three changes (benzene), for three substances two changes (arsenic, butadiene and ethylene dibromide). Some examples:
- For butadiene the limit value of year 1962 was 1000 ppm and the present one 1 ppm
- For asbestos the limit value of 1972 was 5 fibres/ml and the present 0,1 fibres/ml
- For ethylene dibromide the limit value of 1962 was 25 ppm and the present 0,1 ppm.

4 Measurements and analytical methods for monitoring workers´ exposure - record-keeping

Questions asked
C.n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances? (Yes/No)
C.o) Is exposure monitoring mandatory? (Yes/No)
C.p) Are there specific measurement methods laid down, or recommended? (Yes/No)
C.q) Is biological monitoring included in the monitoring methods? (Yes/No)

Germany and Portugal did not provide information in relation to these issues.
An overview of the answers received to the four questions is given in table 16. For a detailed overview of the answers to all five questions in section C of the questionnaire, including the question on organisation of record-keeping, see Annex 2.

Table 16: Overview of national protocols for measurements
('x' = yes; blank = noCountries that provided no information are not listed)

Member State	*(n) Specific measurement requirements*	*(o) Exposure monitoring mandatory*	*(p) Specific measurement methods laid down or recommended*	*(q) Biological monitoring included in the monitoring methods*
Austria		**x**		**x**
Belgium	**x**	**x**	**x**	
Cyprus		**x**		
Czech Republic		**x**	**x**	**x**
Denmark				
Estonia		**x**	**x**	**x**
Finland	**x**	**x**	**x**	**x**
Greece		**x**		
Italy	**x**	**x**	**x**	**x**
Latvia	**x**	**x**		**x**
Lithuania	**x**	**x**	**x**	
Luxembourg		**x**	**x**	**x**
Netherlands			**x**	**x**
Poland	**x**	**x**	**x**	**x**
Slovakia		**x**		**x**
Slovenia		**x**		
Spain	**x**	**x**	**x**	**x**
Sweden		**x**	**x**	
UK	x		x	x
	Y: 8 N: 11	**Y: 16 N: 3**	**Y: 12 N: 7**	**Y: 12 N: 7**

11 EU Member States (Austria, Cyprus, Czech Republic, Denmark, Estonia, Greece, Luxembourg, the Netherlands, Slovakia, Slovenia and Sweden) indicate not to have specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances. Eight Member States (Belgium, Finland, Italy, Latvia, Lithuania, Poland, Spain and UK) report to have such specific requirements (for more details, see Annex 3.).

Monitoring of exposure to carcinogenic and mutagenic substances in general is reported to be mandatory in 16 EU countries; in Denmark and the Netherlands it is not. In the UK the

exposure monitoring is only mandatory for two substances: vinyl chloride monomer and for hexavalent chromium relating to electrolytic chromium processes.
Slovakia mentioned the link to risk assessment, while stating that exposure monitoring was mandatory.

In Sweden, besides general monitoring requirements depending on whether there is reason to suspect that an occupational exposure limit is being exceeded, monitoring is always mandatory for a number of work procedures and substances used (unless, having regard to the nature and extent of the work, it is clearly apparent that the concentration of these compounds are less than 1/10 of the applicable exposure limit values).

In Poland, a similar limit is set: the employer does not have to determine a carcinogenic agent in workplace air when its concentration was below 0.1 of MAC in two rounds of measurement. Measurements should be done:

1) every 3 months if in the last measurements the concentrations of them was below 0.5 of MAC;
2) every 6 months if in the last measurements the concentrations of them was above 0.1 to 0.5 of MAC;

12 Member States (Austria, Czech Republic, Estonia, Finland, Italy, Latvia, Luxembourg, the Netherlands, Poland, Slovakia, Spain and UK) report that biological monitoring is included in the monitoring methods.

In a footnote to the table from Austria, health surveillance (incl. biological monitoring) was reported to be mandatory if workers are exposed more then one hour a day to a number of substances (e.g. heavy metals like lead, mercury, and their compounds, welding fumes, fluorine and inorganic fluoric compounds, a certain number of aromatic and halogenated solvents and other aromatic compounds) or without time limit to some C1 or C2 carcinogens. This is also depending on risk assessment results. In general, in case of exposure to carcinogenic substances (Cat 1 or 2), employers have to make sure that exposed workers have access to appropriate medical surveillance.

More details and an overview of the answers is given in Annex 3. In chapter 5, a table with the information on biological monitoring from the participating Member states is provided.

Regarding the measurement methods, seven EU Member States (Austria, Cyprus, Denmark, Greece, Latvia, Slovakia, and Slovenia) report to have none specified.

However, Member States do mention standards and methods to be applied or recommended for measurements and monitoring. 12 Member States (Belgium, Czech Republic, Estonia, Finland, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Spain, Sweden and UK) report to have designated specific measurement methods or to recommend certain methods. For example, Lithuania mentions a detailed list of orders and standards to be applied, some of these standards being identical to ISO standards. Also, the Netherlands mention non-binding methods elaborated by the SER (Sociaal-Economische Raad) committee and the use of CEN standards, and Finland methods of the Finnish Institute for Occupational Safety and Health (FIOH) recommended, Sweden mentions a collection of methods published in an OSH publication (Arbete och Hälsa). Luxembourg and Italy make reference to standards used in other Member States (BGIA methods and DIN standards for Luxembourg and ISO EN standards for Italy).

Regarding biological monitoring, similar information is given, for example from Poland, which refers to the Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment and has provided a list of criteria documents annexed to its questionnaire. Other Member States, such as Sweden, also specify that they have recommended methods for biological monitoring.

It therefore appears that Member Sates do make use of recommended methods for measurement requirements at workplaces, but from the questionnaires it can not be assessed to which extent this is the case. For a detailed listing of answers, see Annex 3.

Question asked:
C.r) How is record-keeping on the results of such measurements organised?

The Czech Republic, Denmark, Germany, Greece, the Netherlands, Luxembourg and Portugal did not provide specific information in relation to keeping records. The record-keeping in the other Member States is reported to be done at several levels:

- At the authority level for example by the labour inspectorate (e.g. in Austria, Finland and Sweden, where a database is kept) or other authorities (e.g. Regional Authorities of Public Health in Slovakia);
- by an institute (e.g. FIOH in Finland, who keeps a registry of air and biological monitoring measurements) and laboratories that perform measurements;
- occupational health services or individual medical records by the occupational health doctors (e.g. Poland) or services (e.g. Finland and Belgium);
- by the employer (has to keep a list with the names of all workers who can be exposed and data on the exposure to which they have been subjected, and/or the results of measurements), or in the risk assessment documents, when there are changes to the workplace or when an occupational disease occurs;

However, it is not always clear from the answers whether the record-keeping mentioned is additional to record-keeping as foreseen in the “carcinogens and mutagens ” Directive (Article 15.1 of Directive 2004/37/EC), which sets a 40 years period. Belgium, Cyprus, Latvia, Slovenia and Spain make reference to records having to be kept for 40 years from the end of exposure. The Netherlands have indicated that, while they do not foresee extensive measurement requirements following specific measurement methods and biological monitoring is foreseen only for selected substances, the requirements of the “chemical agents” and “carcinogens and mutagens” Directives still apply.

The information provided in other sections of the national questionnaires can also be useful: for example, the Czech Republic also mentions in its answer about socio-economic feasibility criteria its Registry of Subjects Occupationally Exposed to Carcinogens (REGEX) which collects analysed data such as length, intensity, route of exposures to known occupational carcinogens collected at individuals’ level and provided by the Regional Hygienic Stations and/or Public Health Institutes to the National Institute of Public Health in Prague. The aims of the registry include the analysis of trends in levels and types of occupational exposures to carcinogens, the evaluation of effects of past and current exposures to carcinogens on workers’ health, and the identification of factors associated with elevated exposures and/or elevated incidence of cancer. A “testing phase” of OELs at the enterprise level is also mentioned, with a feedback of information through the regional centres.

For the detailed answers on national requirements for record keeping please see Annex 3.

5 Biological limit values

The previous section gave an overview of the answers to the questions about monitoring and measurements, and the record-keeping linked to that. 12 EU countries (Austria, Czech Republic, Estonia, Finland, Italy, Latvia, Luxembourg, the Netherlands, Poland, Slovakia, Spain and the UK) report to have biological monitoring included in the monitoring methods. Additionally, some Member States have also provided information about the biological limit values set for the substances they reported about. Table 17 gives an overview of biological limit values reported by some of these EU countries in the national questionnaires and OEL tables. It is important to note that these apply to all there categories considered: carcinogens, mutagens and reprotoxicants. More detail about the information provided on biological monitoring can also be found in Annex 2.
These limit values are also included in the overview table of limit values in Annex 1. for more information it is best to refer to this overview table and the "substance sheets".

How to read this table
- This table does not represent an exhaustive list of all biological limit values set in the Member states who have participated in the survey.
- It is merely a summary table of information provided by the Member states in their questionnaires.
- The table refers to carcinogenic, mutagenic and reprotoxic substances.

Table 17: Biological limit values in some EU countries

Substance name	CAS number	EINECS number	Country and Biological limit value established
Acrylonitrile	107-13-1	203-466-5	Slovakia: cyanoethylvaline 420 mg/L in blood (erythrocyte)
Arsenic & compounds, except arsine (as As) Include: Arsenic acid Arsenic pentoxide Arsenic trioxide	7440-38-2 7778-39-4 1303-28-2 1327-53-3	231-148-6 215-481-4	- Austria: for arsenious acid, arsenic acid and its salts: As in urine 100 µg/L - Poland: As + monomethylarsonic acid + dimetylarsinic acid in urine at the end of working week- 35 µg/L - Slovakia: As in urine - 130 µg/L - Spain: for As elemental and soluble inorganic compounds: As inorganic and methymetabolites in urine - 35 µg/L at the end of working week
Asbestos	12172-67-7 12172-73-5 77536-66-4 77536-67-5 77536-68-6 132207-32-0 132207-33-1 1332-21-4		→LU: 25 fiber years / 0,1 f/cm3
Benzene	71-43-2	200-753-7	– Austria: t,t-Muconic acid in urine - 1,6 mg/L – Czech Republic: S-Phenylmercapturic acid in urine - 0,024 µmol/mmol creatinine

Substance name	CAS number	EINECS number	Country and Biological limit value established
			– Latvia: Phenol in urine - 25 µg/g creatinine at the end of work – Poland: S-Phenylomercapturic acid in urine at the end of shift - 25 µg/g creatinine; T,t-Muconic acid in urine - 0,5 mg/g creatinine – Slovakia: Benzene in blood - 5 µg/L; S-Phenylmercapturic acid in urine - 0,045 mg/g creatinine; t,t-Muconic acid in urine - 2 mg/L – Spain: S-Phenylmercapturic acid in urine at the end of shift - 120µg/g creatynine; t,t-Muconic acid in urine at the end of shift - 4.5mg/g creatynine
Cadmium Include: Cadmium chloride Cadmium fluoride Cadmium oxide Cadmium sulphate Cadmium sulphide	7440-43-9 10108-64-2 7790-79-6 1306-19-0 101-24-36-4 1306-23-6	231-152-8	– Austria: Cd in blood - 5 µg/L – Czech Republic: Cd in urine - 0,005 µmol/mmol creatinine; Cd in blood - 0,045 µmol/L – Poland: Cd inorganic compounds in urine - 5 µg/g creatinine; in blood - 5 µg Cd/L – Spain: - Cd in urine - 5 µg/g creatynine; Cd in blood - 5 µg/l; total p-chlorophenol in urine at the end of shift - 25mg/g creatynine – Sweden: value not provided;
Chromium(VI)-compounds Include: Ammonium dichromate Chromium III chromate Chromium trioxide Chromyl chloride Lead chromate Lead chromatemolybdate Potassium chromate Potassium dichromate Potassium hydroxichromate Sodium chromate Sodium dichromate Strontium chromate Zinc chromate	 7789-09-5 24613-89-6 1333-82-0 14977-61-8 7758-97-6 1344-37-2 12656-85-8 7789-00-6 7778-50-9 11103-86-9 7772-11-3 10588-01-9 7789-06-2 37300-23-5	 231-846-0 215-693-7 235-759-9 231-906-6 234-329-8 231-889-5 234-190-3 232-142-6	– Austria: Cr in blood - 9 µg/L; in urine - 12 µg/L – Czech Republic: total Cr - 0,065 µmol/mmol creatinine – Poland: Cr(VI) in urine before and at the end of shift- 10 µg/g creatinine; water-soluble fume in urine at the end of shift and end of working week - 30 µg/g creatinine – Slovakia: 35 µg Cr/L erythrocyte in whole blood; 40 µg Cr / L in urine – Spain: total chromium in urine – 10 µg/g creatinine –increased during shift; 30 µg/g creatinine – end of working week – UK: Cr in urine - 10 µmol/mol creatinine
Cobalt	7440-48-4	231-158-8	→Austria: Co 10 µg/L in urine
Dimethylformamide	68-12-2	200-679-5	Czech Republic: N-Methyl formamide in urine – 0,25mmol/L creatynine
Dinitrotoluene, technical Includes: 2,4-Dinitrotoluen 2,6-Dinitrotoluen	25321-14-6 121-14-2 606-20-2	246-836-1 204-450-0 210-106-0	Spain: BLV of methemoglobin inductors is applied
Ethylene oxide	75-21-8	200-849-9	Slovakia: hydroxyethylvaline in blood 90 µg/L

Substance name	CAS number	EINECS number	Country and Biological limit value established
Hydrazine	302-01-2	206-114-9	Slovakia: hydrazine in urine - 380 µg/g creatinine; hydrazine in blood - 340 µg/L
Lead and inorganic compounds Includes: Lead arsenate Lead azide Lead chromate Lead chromatemolybdate Lead phosphate	7439-92-1 7784-40- 13424-46-9 7758-97-6 344-37-2 12656-85-8 7446-27-7	231-100-4 232-064-2 236-542-1 231-846-0 215-693-7 235-759-9 231-205-5	– Belgium: 70 µg Pb/100 ml in blood – Czech Republic: delta-aminolevulinic acid in urine - 13 µmol/mmol creatinine or coproporphyrin in urine - 0,035 µmol/mmol creatinine, or plumbaemia 0,4 mg/L – The Netherlands (value not provided) – Spain: Pb in blood - 70 µg/dL; – Sweden – value not provided
4,4'-Methylene (bis(2-chloro aniline)) = 2,2'-Dichloro-4,4'-methylene dianiline (MbOCA)	101-14-4	202-918-9	→UK: total MbOCA in urine - 15µmol/mol creatynine
4,4'-Methylene dianiline = 4,4'-Diaminodiphenylmethane	101-77-9	202-974-4	→UK: total MDA in urine 50 µmol/mol creatinine
Nickel Include: Nickel carbonyl Nickel (II) oxide	7440-02-0 13463-39-3 1313-99-1	231-111-4 236-669-2 215-215-7	– Austria: Ni in urine - 7 µg/L – Czech Republic: 0,077 µmol/mmol creatynine – Slovakia: Ni in urine - 45 µg/L
o-Nitrotoluene	201-853-3 606-20-2	88-72-2 210-106-0	Spain: value not provided
o-Toluidine	202-429-0	95-53-4	Spain: value not provided
Trichlorethene	79-01-6	201-167-4	– Czech Republic: Trichloroacetic acid in urine - 70 µmol/mmol creatinine at the end of the working week, or trichloroethanol in urine - 150 µmol/mmol creatinine at the end of shift – Poland: Trichloroacetic acid in urine at the end of shift – 20mg/L – Slovakia: trichloroacetic acid in urine - 100 mg/L – Spain: measured at the end of working week: Trichloroacetic acid in urine - 100 mg/g creatinine; Trichloroacetic acid plus trichloroethanol in urine - 300 mg/g creatinine; free trichlorethanol in blood - 4 mg/L
Vinyl chloride	75-01-4	200-831-0	Slovakia: thiodiglycolic acid in urine - 4 mg/24h

6 Availability of and links to supporting documents

Questions asked
D.s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered)
In which languages are these documents available?
Is it/are they linked to other texts (for example legal documents)?

All EU countries from which an answer was received have documents regarding OEL available on a webpage. These documents are available in the own country language(s); Denmark, Sweden and Spain indicate to provide their information in English as well, Latvia is currently translating. Other Member States provide information in additional languages as well, mostly depending on whether there are several official languages at the national level:
- for Belgium, in Dutch and French;
- for Finland, in Finnish and Swedish.

Most of the Member States have mentioned at least some of the related legislation.
The information is compiled in a text table in Annex 3

Questions asked
D.t) Which of the following types of information is publicly available:
- ***Methodology for identifying priority substances for OEL setting? (Yes/No)***
- ***Methodology for developing measurement and analytical methods? (Yes/No)***
- ***Methodology for the derivation of OELs? (Yes/No)***
- ***Evaluation documents for individual substances? (Yes/No)***
- ***Measurement and analytical methods for individual substances? (Yes/No)***

Table 18 presents an overview of the answers to the five questions regarding the types of information that are made publicly available by the EU Member States who sent answers to the questionnaire.

This information is not always consistent with that given in other sections of the questionnaire and must therefore be addressed with caution and read together with the information about available information for reprotoxic substances (section E of the questionnaire, chapter 7 and Annex 4 of this report) and with information provided on the committees in place (section B, question g iii) of the questionnaire, chapter 3.2.2.1 of this report, table 7).

The information is also varying in the level of detail. The availability of such documentation depends largely on whether specific procedures are in place and whether assessments are carried out by scientific committees in the Member states. The Czech Republic, Poland, and the Netherlands provide extensive access to this information. On the other hand, Cyprus, Germany, Italy and Portugal did not answer this question. For Germany, as already mentioned, the procedures are currently under revision, with a perspective of being modified considerably as compared to the past.

The answers may also reflect resources available and should be read with answers to other sections in the questionnaire, for example related to whether resources of other countries are made use of in the national OEL setting procedures (question B2h)). Some Member States

have made reference to background documents produced by others. For example, Belgium explicitly mentioned to make available via the public authority's (ministry's) library the documents produced by others and considered throughout the public consultation procedure.

Annex 3 gives a more detailed overview of the documents, titles and website links to the documents, and of the languages in which these documents are available. Some Member States have also provided contact details of national expert committees or chairpersons of those committees. Please refer to the national questionnaires for further details.

Table 18: Information publicly available
('Y' = yes; 'N'=: no; blank = no answer provided
Countries who did not answer any of the questions are not included).

Member State	General Information			Specific Information	
	Methodology for identifying priority substances for OEL setting	*Methodology for developing measurement and analytical methods*	*Methodology for the derivation of OELs*	*Evaluation documents for individual substances*	*Measurement and analytical methods for individual substances*
Austria	**N**	**N**	**N**	**N**	**N**
Belgium	**N**	**[14]**	**[15]**	**Y**	**Y**
Cyprus					
Czech Republic	**Y**	**Y**	**Y**	**Y**	**Y**
Denmark				**Y**	**N**
Estonia	**N**	**Y**	**N**	**Y**	
Finland	**N**	**N**	**N**	**Y**	**Y**
Germany					
Greece	**N**	**N**	**N**	**N**	**N**
Italy					
Latvia	**N**	**N**	**N**	**N**	**N**
Lithuania	**Y**	**Y**	**Y**		**Y**
Luxembourg	**N**	**N**	**N**	**Y**	**Y**
The Netherlands	**Y**	**Y**	**Y**	**Y**	**Y**
Poland	**Y**	**Y**	**Y**	**Y**	
Portugal					
Slovakia	**N**	**N**	**N**	**Y**	**Y**
Slovenia	**N**	**N**	**N**	**N**	**N**
Spain	**N**	**N**	**N**	**Y**	**Y**
Sweden	**N**	**N**	**N**	**Y**	**No answer, but link provided**
UK	**N**	**N**	**Y**	**Y**	**Y**

[14] Reference was made to EN standards available from the Ministry
[15] A description of the procedure was reported to be available on the Ministry's Website and included in the questionnaire (section B2d))

7 Limit values for reprotoxic substances

Questions asked
E.u) Are there any limit values defined for reprotoxic substances? (Yes/No)
If yes, how are these limit values applied in practice?
E.v) Are there any lists of reprotoxic substances? (Yes/No)

14 of the 21 EU Member States who responded (Belgium, Czech Republic, Denmark, Estonia, Finland, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal[16], Spain, Sweden and the UK) report having OELs for reprotoxic substances. When these limit values are set, they seem to be applied in the same way as a limit value for any other type of substance. Seven countries (Austria, Cyprus, Germany, Greece, Italy, Slovakia, Slovenia) report not to have limit values defined for these substances.

14 countries report having a list of reprotoxic substances, while the other seven (Austria, Belgium, Cyprus, Germany, Greece, Italy, Slovenia) don't (see table 19).

This information must be considered together with the information given in other sections of the questionnaire, for example about available documents and legal acts (section D of the questionnaire), summarised in the previous chapter and listed in a text table in the annex. It appears that in many of the Member States, the limit values for reprotoxic substances are included in the regulation for all OELs, sometimes also in a single table.

For example, Belgium provides a list of substances with limit values which are included in the list of OELs, but denies having a list of reprotoxic substances. On the other hand, Slovakia does not include OELs for reprotoxic substance, but reports having a list of these substances. Estonia mentions to have lists of reprotoxic substances, but has not labelled any of the substances as such in the questionnaire. The Netherlands report to have a non-exhaustive list, which is updated every half-year. Poland makes reference to a specific notation *Ft *– fetotoxicity, which is used in the limit values booklet, and a list of substances assigned the notation. Slovenia also uses specific notations for reprotoxic substances (R_F , R_E). The same applies to Spain (see chapter 2.2, types of limit values and notations).

The Netherlands have provided a separate list of limit values for reprotoxic substances.
Finland reports in its description of documentation to have had a list of reprotoxicants in national legislation since 1991.

Some of the Member States, such as Finland, Luxembourg and Sweden, have also mentioned the link to risk assessment in the workplace for reprotoxicity to men and women, or specific regulations applied for example to pregnant and breastfeeding workers. In Finland, to achieve a special maternity leave right, a risk assessment at workplace may be carried out, which takes into account, for chemical reprotoxicants, OELs. For some, exceeding OEL is the limit, for some a specified fraction of the OEL may be the action level to stop working during pregnancy depending on how reprotoxicity originally has been taken into account at the OEL setting of a specific substance. A guidance document is available from the national OSH institute, FIOH.

[16] Mentioned in answer to question i)

Similar regulations are expected to be applied in other Member States, but were not explicitly mentioned in the national answers.

Table 19: Availability of lists of reprotoxic substances, related limit values and their application *('Y' = yes; 'N' = no; blank = no answer provided).*

	u) Are there any limit values defined for reprotoxic substances?	*Application of OELS for reprotoxic substances (blank = no answer provided)*	*v) Are there any lists of reprotoxic substances?*
Austria	N		N
Belgium	Y	There are OELs defined for certain reprotoxic substances (Table E). Similar to the carcinogenic and mutagenic substances, they are listed in annex I of the Royal Decree of March 11th 2002, but their reprotoxic nature it is not specified in this list. For lead, a biological limit value is defined (70 µg Pb/100 ml blood) These limit values are constraining.	N
Cyprus	N		N
Czech Republic	Y	Referred to answer for CM substances (section D s) of the questionnaire): OELs of all substances (CMR and hazardous substances) - IOELVs, BOELVs and national OELs - are in the same document: Government Regulation No. 178/2001 Coll., determining conditions for occupational health protection as amended by Government Regulation No: 523/2002 Coll. and Government Regulation No: 41/2004 Coll. (In Czech: Nařízení vlády č. 178/2001 Sb., kterým se stanoví podmínky ochrany zdraví zaměstnanců při práci, ve znění Nařízení vlády č. 523/2002 Sb. a Nařízení vlády č. 441/2004 Sb.) They are available only in Czech. http://www.mvcr.cz/sbirka/2001/sb068-01.pdf http://www.mvcr.cz/sbirka/2002/sb180-02.pdf http://www.mvcr.cz/sbirka/2004/sb145-04.pdf A new Government Regulation is prepared and will come into force probably in April 2008.	Y
Denmark	Y	Limit values are often applied because of other effects i.e. allergies or other acute effects. Only later it is discovered that the compounds are reprotoxic.	Y
Estonia	Y	These limit values are applied in the same way as all limit values - levels of applications are quite different in different enterprises	Y[17]

[17] no substances labelled as reprotoxic in the list of Estonia

	u) Are there any limit values defined for reprotoxic substances?	*Application of OELS for reprotoxic substances (blank = no answer provided)*	*v) Are there any lists of reprotoxic substances?*
Finland	Y	– As the other OELs – Also to achieve a so-called special maternity leave right, a risk assessment at workplace may be carried out. For chemical reprotoxicants, OELs are used. For some, exceeding OEL is the limit, for some a specified fraction of the OEL may be the action level to stop working during pregnancy depending on how reprotoxicity originally has been taken into account at the OEL setting of a specific substance.	Y[18]
Germany	N		N
Greece	N		N
Italy	N		N
Latvia	Y	OELs are defined for all Chemical substances within the Regulation of the Cabinet of Ministers No 325/2007; in t his regulation reprotoxic substances are included.	Y
Lithuania	Y		Y[19]
Luxembourg	Y	Luxembourg lists here a number of chemical substances and makes reference in the table to the regulations for pregnant and breastfeeding worker in the next column referring to a list of reprotoxic substances.	Y[20]
Netherlands	Y	In the same way as non-carcinogenic substances.	Y
Poland	Y	These limits are applied in the same way as MAC for other chemicals by Group of Experts for Chemical and Dust Agents Interdepartmental Commission for MAC and MAI.	Y[21]
Portugal	Y[22]		Y[23]
Slovakia	N		Y[24]
Slovenia	N		N
Spain	Y	These limit values are applied as the rest of the OELs established.	Y[25]
Sweden	Y	They are used in the risk assessment. For example if you are planning to have a baby you should avoid exposure to these substances. These substances can be a danger for both men and women. There is a special ordinance for pregnant or breastfeeding women with more detail (AFS 2007:5[26])	Y
UK	Y	Where a limit has been set for a reprotoxic substance it will be applied in the same way as a limit value for any other type of substance.	Y[27]
TOTAL	**Y: 14** **N: 7**		**Y: 14** **N: 7**

[18] Finland makes reference in the table to regulations for pregnant and breastfeeding workers
[19] no substances labelled reprotoxic in the Lithuanian list
[20] no substances labelled as reprotoxic in the list of Luxembourg
[21] Poland makes reference in this column to a notation qualifying substances as fetotoxic (Ft)
[22] Mentioned in answer to question i)
[23] Portugal makes reference to regulations of the Ministry of Environment
[24] no substances labelled reprotoxic were included in the Slovakian list
[25] no substances labelled as reprotoxic in the list of Spain
[26] AFS 2007:05 - Gravida och ammande arbetstagare, http://www.av.se/lagochratt/afs/afs2007_05.aspx
[27] The UK mentions here that certain reproductive toxicants have been assigned a limit value in the list of limit values EH 40

Table 20 provides a list of reprotoxic substances with the number of Member States having reported an OEL for these respective substances and the names of countries which have labelled the substances explicitly as reprotoxic in their answers.

This information needs to be addressed with caution: not every Member State with an OEL for a potentially reprotoxic substance or known reprotoxicant has labelled that substance explicitly as “R” in the questionnaire. Examples for this are lead and its compounds, and a number of organic solvents.

Also, not all Member States who responded have included the limit values for these substances in the OEL table, some of them have provided information on reprotoxic substances in a separate list, and additionally some have also provided information about their limit values. The information about classification was also not exhaustive. For example, the Netherlands provided a table of OELs for carcinogenic compounds and a separate table of OELs for reprotoxic compounds, without specifying the categorisation. On the other hand, the Czech Republic included in its list reprotoxic substances, but did not include limit values for all these substances. As a consequence, for example, for a single substance, such as cadmium sulphate, there is a limit value included in the list provided by the Netherlands, but the substance is not labelled as reprotoxic, while for the Czech Republic, there is no limit value included, but the substances is labelled as reprotoxic.

Where the class (1,2,3) is not mentioned, the information is marked with an asterisk (*)

The list in table 20 should therefore not be seen as an exhaustive list for all limit values for substances considered as reprotoxic in the Member States who have replied to the questionnaire. Based on the data of the table, it can be concluded that the following reprotoxic substances have an OEL in more than three Member States:

- 2-Ethoxyethanol, carbon monoxide: OEL in six different Member States
- 2-Ethoxyethyl acetate, benzo[a]pyrene, dimethylacetamide, dimethylformamide: OEL in five different Member States;
- Lead chromate, nickel carbonyl, warfarin: OEL in four different Member States.

However, these might not be the priority substances for limit setting, as for example

- Acrylamide has a limit value reported by 14 Member States, but only four labelled it as reprotoxic;

For lead compounds and cadmium compounds, there may be ”summary” limit values defined for the metal and its compounds, it is therefore more difficult to assess how many Member States have actually defined a limit value for the substance in question.

How to read the table

- **This table is not to be read as an exhaustive table of all potentially reprotoxic substances with OELs.** The table only includes substances labelled "R" explicitly by the Member states in the questionnaire, it does not refer to carcinogenic and mutagenic substances in the national questionnaires which are potentially reprotoxic but have not been labelled as such.
- Consequently, potentially reprotoxic substances with a limit value that none of the Member States have labelled as reprotoxic in the questionnaire, will not be included in this table.
- However, where a substance is categorised C, M **and** R, it has been included. See other sections of the report for limit values for carcinogenic and mutagenic substances.

For all limit values provided in the national questionnaires see the overview table, Annex 1

Table 20: List of substances recognised as reprotoxic at the national level
(Not exhaustive, see above)

Substance name	CAS number	EINECS number	C/M/R	N° of Member States that report having an OEL for substance	Member States labelling substance as reprotoxic in the national report
Acrylamide (Prop-2-enamide)	79-06-01	201-173-7	C*-C2 M*-M2 R*-R3 R_F3	14[28]	Slovenia, Sweden, UK Fetotoxic-Poland
Ammonium dichromate	7789-09-5		C2 M2 R2	4[29]	Czech Republic, Finland, Slovenia
Benomyle	17804-35-2	241-775-7	M2 R*	4[30]	Finland
Benzo[a]pyrene	50-32-8	200-028-5	C2-C* M2-M* R2-R*[31]	5	Czech Republic, Finland, Latvia, Slovenia, Sweden
Bis(2-ethylhexyl) phthalate = Di- (2-ethylhexyl) phthalate	117-81-7	204-211-0	R2-R*[32]	3	Belgium, Czech Republic, Sweden
Benzyl butyl phthalate	85-68-7	201-622-7	R*[33]	1	Sweden
1-Bromopropane	106-94-5	203-445-0	R2	2	Belgium, Finland
Cadmium and inorg. Compounds Respirable dust Total dust[34]	7440-43-9		C*/M*/R*[35]	1	Sweden
Cadmium chloride[36]	10108-64-2		C2 M2 R2	3[37]	Czech Republic, Slovenia

[28] Austria, Belgium, Denmark, Finland, Latvia, Lithuania, Portugal, Slovakia, Sweden and Spain have reported an OEL, but not labelled R
[29] Spain has reported an OEL, but not labelled R
[30] Spain, Belgium, Denmark, have OELs for benomyle; only Finland labels it also with an 'R'
[31] Category not specified for Sweden
[32] Category not specified for Sweden
[33] Category not specified for Sweden
[34] Two limit values defined for Sweden, for respirable dust and for total dust
[35] Category not specified for Sweden
[36] Substance is in the Czech list of OELs, but no value is given

Substance name	CAS number	EINECS number	C/M/R	N° of Member States that report having an OEL for substance	Member States labelling substance as reprotoxic in the national report
Cadmium fluoride[38]	7790-79-6		C*-C2 M*-M2 R*-R2	3[39]	Czech Republic, Finland, Slovenia
Cadmium oxide fume (as Cd)	1306-19-0	215-146-2	C2 M3 R3	1	UK
Cadmium sulphide and cadmium sulphide pigments (as Cd)	1306-23-6	215-147-8	C2 M3 R3	1	UK
Cadmium sulphate	10124-36-4		C*-C2, M*-M2 R*-R2[40]	3[41]	Czech Republic, Finland
Carbendazim	10605-21-7	234-232-0	M2 R2	1	Poland
Carbon monoxide	630-08-0	221-128-3	R*-R1	6	Belgium, Czech Republic, Finland, Latvia, Netherlands, Portugal
CI Pigment yellow	1344-37-2	215-693-7	R1		Czech Republic[42]
Copper and inorganic Copper compounds	7440-50-81		R *	1	Netherlands
1,2-Dibrom-3-chloropropan	96-12-8	202-479-3	C2 M2 R1	2[43]	Slovenia
Dibutylphtalate	84-74-2	201-557-4	R*-R2[44]	4[45]	Belgium,, Latvia, Sweden
1,2-Dimethoxyethane	110-71-4	203-794-9	R2	1	Latvia

[37] Not labelled R by Finland
[38] Substance is in the Czech list of OELs and labelled R, but no value is given
[39] Spain and Slovakia did not label substance as R
[40] Category not specified for Finland
[41] Not reported as reprotoxic by the Netherlands, is in the Czech list of OELs and labelled R, but no value is given
[42] is in the Czech list of OELs, but no value is given
[43] not reported reprotoxic by Denmark
[44] Category not specified for Sweden
[45] Not reported as reprotoxic by the Czech Republic

Substance name	CAS number	EINECS number	C/M/R	N° of Member States that report having an OEL for substance	Member States labelling substance as reprotoxic in the national report
Dimethylacetamide	127-19-5	206-826-4	R2	5	Belgium, Czech Republic, Finland, Latvia, Netherlands
Dimethylformamide	68-12-2	200-679-5	R2	5	Belgium, Czech Republic, Finland, Latvia, Portugal
Dinitrotoluene	25321-14-6	246-836-1	R_F3		Slovenia[46]
2,3-Dinitrotoluene	602-01-7	210-013-5	R_F3		Slovenia
2,4-Dinitrotoluene	121-14-2	204-450-0	R_F3		Slovenia
2,5-Dinitrotoluene	619-15-8	210-581-4	R_F3		Slovenia
2,6-Dinitrotoluene	606-20-2	210-106-0	R_F3	1	Slovenia
3,4-Dinitrotoluene	610-39-9	210-222-1	R_F3	1	Slovenia
3,5-Dinitrotoluene	618-85-9	210-566-2	R_F3		Slovenia
2,3-Epoxy-1-propanol	556-52-5	209-128-3	C2 R2	7[47]	Denmark, Finland, Slovenia
(R) 2,3-Epoxy-1-propanol (Glycidol)	57044-25-4	404-660-4	R_F2		Slovenia
2-Ethoxyethanol = Ethylene glycol	110-80-5	203-804-1	R*-R2[48]	6	Belgium, Czech Republic, Finland, Latvia, Portugal, Sweden
2-Ethoxyethyl acetate = Ethylene glycol monoethylether acetate	111-15-9	203-839-2	R*-R2[49]	5	Belgium, Czech Republic, Finland, Portugal, Sweden
Ethylene thiourea	96-45-7		R*	1	Finland
2-Ethylhexanoic acid	149-57-5	205-743-6	R2	1	Belgium

[46] Substance is in the Slovenian list of OELs and labelled R, but no value is given for some isomers, for 2,6-Dinitrotoluene and 3,4- Dinitrotoluene, a limit value is defined (different from each other).
[47] Austria, Poland, Portugal, Spain have an OEL for this substance, but don't label it as reprotoxic
[48] Category not specified for Sweden
[49] Category not specified for Sweden

Substance name	CAS number	EINECS number	C/M/R	N° of Member States that report having an OEL for substance	Member States labelling substance as reprotoxic in the national report
Formamide	75-12-7	200-842-0	R*-R2[50]	2	Belgium, Finland
n-Hexane	110-54-3		R *	1	Netherlands
Lead (II) methanesulfonate	17570-76-2	401-750-5	R1	1	Czech Republic
Lead 2,4,6-trinitro-m-phenylene dioxide	15245-44-0	239-290-0	R1	1	Czech Republic
Lead acetate	1335-32-6	215-630-3	R*	1	Finland
Lead and inorganic compounds (total dust, respirable dust)[51,52]	7439-92-1	231-100-4	R*-R1[53]	4[54]	Belgium, Czech Republic, Netherlands, Sweden
Lead arsenate	7784-40-9	232-064-2	C1 R1 R_F3, R_E1	2[55]	Czech Republic[56], Slovenia
Lead azide	13424-46-9	236-542-1	R*-R1		Czech Republic, Finland
Lead chromate[57]	7758-97-6	231-846-0	R1	5[58]	Belgium, Czech Republic, Finland, Portugal[59]
C.I. Pigment Red 104 [Colour Index Constitution Number, C.I.77605.]	12656-85-8	235-759-9	R*-R1	2	Czech Republic, Finland
Lead diacetate	301-04-2	206-104-4	R*-R1	2	Czech Republic, Finland
Lead hexafluorosilicate	25808-74-6	247-278-1	R*-R1	2	Czech Republic, Finland

[50] Category not specified for Finland
[51] For lead many Member states have limit values, but many of them label the substance neither C, M, nor R
[52] two different limit values defined for Sweden, total dust and respirable dust
[53] Category not specified for Sweden
[54] not reported as reprotoxic by Spain, no value given by NL
[55] No limit value defined in Czech Republic
[56] not labelled as reprotoxic by Spain
[57] Partly defined under lead compounds in the national lists
[58] NL does nor label the substance as reprotoxic
[59] no value given in Finland

Substance name	CAS number	EINECS number	C/M/R	N° of Member States that report having an OEL for substance	Member States labelling substance as reprotoxic in the national report
Lead phosphate	7446-27-7	231-205-5	R*-R1	1	Czech Republic
Lead tetraethyl	78-00-2		R*-R1	2	Belgium, Finland
Lead tetramethyl	75-74-1		R*-R1	2	Belgium, Finland
Methanol	67-56-1		R *	1	Netherlands
2-Methoxyethyl acetate	110-49-6	203-772-9	R*-R2	3	Belgium, Finland, Portugal
2-Methoxyethanol	109-86-4	203-713-7	R*-R2	3	Belgium, Finland, Portugal
2-(2-Methoxyethoxy)- ethanol	111-77-3		R *	1	The Netherlands
Methylazoxymethanol acetate	592-62-1	209-765-7	R_E2		Slovenia
1-Naphthalenesulfonic acid, 3,3'-(4,4'-biphenylenebis(azo)) bis(4-amino-, disodium salt, (C.I. Direct Red 28)	573-58-0	209-358-4	R_E3		Slovenia
2,7-Naphthalene-disulfonic acid, 4-amino-3-((4'-((2,4-diaminophenyl) azo) (1,1'-biphenyl)-4-yl) azo)-5-hydroxy-6-(phenylazo)-, disodium salt, (CI Direct Black 38)	1937-37-7	217-710-3	R_E3		Slovenia
2,7-Naphthalene-disulfonic acid, 3,3'-((4,4'-biphenylylene) bis(azo)) bis(5-amino-4-hydroxy-, tetrasodium salt (C.I. Direct Blue 6)	2602-46-2	220-012-1	R_E3		Slovenia
Nickel carbonyl	13463-39-3	236-669-2	R*-R2	7[60]	Czech Republic, Finland, Latvia, Portugal

[60] not labelled R in Austria, Estonia and Slovakia

Substance name	CAS number	EINECS number	C/M/R	N° of Member States that report having an OEL for substance	Member States labelling substance as reprotoxic in the national report
Nitrofen	1836-75-5	217-406-0	R_E2		Slovenia
Nitrobenzene	98-95-3	202-716-0	C3 R3	1	Netherlands
Potassium dichromate	7778-50-9	231-906-6	C*-C2 M*-M2 R*-R2	4[61]	Finland
Sodium chromate	7775-11-3	231-889-5	C*-C2 M*-M2 R*-R2	3[62]	Czech Republic, Finland
Sodium dichromate	10588-01-9	234-190-3	C*-C2 M*-M2 R*-R2	3[63]	Finland
Toluene	108-88-3	203-625-9	R3	1	Netherlands
Trichloromethane (chloroform)	67-66-3	200-663-8	C*-C3 R*	3[64]	Netherlands
1,2,3-Trichloropropane	96-18-4	202-486-1	C*-C2 R*-R2 Ft[65]	5[66]	Denmark, Finland, Latvia Fetotoxic - Poland
Vanadium pentoxide	1314-62-1		R *	1	Netherlands
Warfarin	81-81-2	201-377-6	R1	4	Belgium, Finland, Latvia, Portugal
Xylene	1330-20-7		R *	1	Netherlands

C*, M*, R*: category not specifed

[61] Not labelled R by Czech Republic, Slovenia, Spain
[62] not labelled R by Belgium and Spain
[63] not labelled R by Czech Republic and Spain
[64] Not labelled R by Estonia, Lithuania,
[65] labelled as fetotoxic in Poland
[66] Not labelled R by the Netherlands

8 References

- Bundesministerium für Arbeit und Soziales (Germany). OELs for Hazardous Substances-Healthy working conditions in a global economy. Conference under the German Presidency of the European Council, Dortmund, 7-8 May 2007. Information available at the BAuA Website
- EC DG EMPL F4. Setting OELs for Carcinogens. Workshop report, Luxembourg, 25 October 2006. Available at: http://ec.europa.eu/employment_social/health_safety/docs/summary_workshop.pdf.
- European Agency of Occupational Safety and Health (Bilbao). Carcinogens and Occupational Cancers: literature survey, case studies, policy & practice overview (EU-27) (in publication).
- Institute for Occupational Safety and Health of the German Social Accident Insurance (BGIA). GESTIS database ('GefahrSToffInformationsSystem der gewerblichen Berufsgenossenschaften'). Available at: http://www.hvbg.de/e/bia/gestis/stoffdb/index.html.

Relevant Directives

- Council Directive 89/391 of 12 June 1989 on the introduction of measures to encourage improvements on the safety and health of workers at work, Official Journal n° L 183, 29 June1989.
- Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work, Official Journal n° L 196 of 26 July 1990.
- Council Directive 97/42/EC of 27 June 1997 amending for the first time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work, Official Journal L 179 of 8 July 1997, p.4.
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, Official Journal L 131, 5 May1998, p. 11 - 23.
- Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, Official Journal L 142 , 16 June 2000, p. 47 - 48.
- Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (codified version), Official Journal of the European Union L 158 of 30 April 2004, p.23-34.
- Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC, Official Journal L 38, 9 February 2006, p. 36-39.

9 Annexes

9.1.1 Annex 1: Overview table of all national and EU limit values identified for CMRs

(Click here to see table in EXCEL format)

Note: The fact that an exposure limit for a substance does not appear in the table does not necessarily mean there is no limit value set for this substance in the Member State in question. Focal Points were explicitly asked to provide the values for classified carcinogens and mutagens. Substances for which this is not so clear-cut are for example lead and its compounds, only some of the compounds, namely lead chromate, being classified carcinogens, or crystalline silica.

How to read this table

- This table provides an overview of the limit values for carcinogens, mutagens and reprotoxicants based on information provided by the 21 Member States in their questionnaires.
- This table is not to be read as an exhaustive table of all potentially reprotoxic substances with OELs. The table only includes substances labelled “R” explicitly by the Member states in the questionnaire.
- This table also does not represent an exhaustive list of all biological limit values set in the Member states who have participated in the survey. It is merely a summary table of information provided by the Member states in their questionnaires.
- Where OELs relate to groups of substances (for example heavy metals and their compounds (Pb, Cr, Cd)), cross-references were included in the table as far as information was available, as separate information was also provided for some of these compounds by some Member States. The same applies to polycyclic aromatic hydrocarbons and mixtures derived from mineral oil (petrol, gasoline, etc.).
- The number of countries who report to have limit values for a given substance (column 5 of the table) is related to athmospheric limit values.

Abbreviations:

C*, M*, R*: category not specified
CAS: Chemical Abstracts Service
EINECS: European Inventory of Commercial Chemical Substances

9.1.2 Annex 2: Measurements and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances - record-keeping

Measurements and record-keeping

See also the information provided on the availability of documents related to measurement methods in the following annexes

Member State	(n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?	(o) Is exposure monitoring mandatory?	(p) Are there specific measurement methods laid down, or recommended ? If yes, please specify:	(r) How is record keeping on the results of such measurements organised?
Austria	no	yes	no	Authority level: Results of measurements are kept at the labour inspectorate Enterprise level: documentation of measurements is obligatory in context of risk assessment at the workplace (safety and health documentation).
Belgium	yes The following methods are used in order of preference: - reference methods - normalised methods - methods published by institutes, specialised in occupational hygiene - in house validated methods If relevant for the analysis, the following standards are applied: EN 481, EN 13205, EN 482, EN 689, EN 838, EN 1076, EN 1231, EN 1232, EN 1540. Furthermore standard EN 689 (Workplace atmospheres. Guidance for the assessment of	Whenever a carcinogen or mutagen is used, the employer shall use existing appropriate procedures for the measurement of these substances, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident.	Yes cfr. point C. n) For the measurement of the concentration of asbestos fibres in air, the use of the standard NBN T96-102 is mandatory.	All data on exposure to chemical agents are added to the individual medical records of the workers. These medical records are kept by the service, assigned to perform the medical surveillance. In case of exposure to carcinogens/ mutagens, these medical records have to be kept for at least 40 years following the end of the exposure. Furthermore, the employer has to keep a register with a list with the names of all workers who can be exposed to carcinogens/mutagens and the exposure to which they have been subjected.

Member State	(n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?	(o) Is exposure monitoring mandatory?	(p) Are there specific measurement methods laid down, or recommended ? If yes, please specify:	(r) How is record keeping on the results of such measurements organised?
	exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) is applied.			
Cyprus	no	yes	no	In cases where health surveillance monitoring is established health records must be kept for at least 40 years.
Czech Republic	no	yes	yes Recommended	
Denmark	no There is no request on making measurements, but if measurements are made, a procedure from an Executive Order has to be followed	no	No See column 1	
Estonia	no	yes	yes The different specific measurement labs are using different applicable methods – no universal national methods.	Record keeping on the results of such measurement (as for all measurements in the context of OSH) is a task of employer.
Finland	yes European standards/norms	Yes and no If it is possible to assess the exposure otherwise, there need not be monitoring by measurements	yes The FIOH methods are recommended for other parties as well	– FIOH maintains a registry of air and biological monitoring measurement results which they have carried out – Employers themselves – Occupational health care services – Labour inspectorate
Greece	no	yes	no	
Italy	yes	yes	Yes	The results of such measurements are

Member State	(n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?	(o) Is exposure monitoring mandatory?	(p) Are there specific measurement methods laid down, or recommended ? If yes, please specify:	(r) How is record keeping on the results of such measurements organised?
			ISO UNI EN Harmonized Norms	reported in the Document of risk assessment and in the Register of the exposed workers.
Latvia	Yes Substances at Workplaces" Cabinet Regulation No. 539 Adopted 27 December 2001 „Regulations regarding Requirements for Labour Protection When in Contact with Carcinogenic Substances at Workplaces"	yes	no	According to Regulations of Cabinet of Ministers No 325/2007 and No 539/2001 is defined time of data keeping (40 years) and after archiving in connection with law.
Lithuania	Yes	yes	yes A detailed list of orders and standards on the determination of concentration of airborne asbestos fibres, vinylchloride, vaporous aromatic/chlorinated hydrocarbons, particulate lead and lead compounds is cited in the national questionnaire. Some of those standards are identical to ISO standards.	The records are keeping by the measurements' laboratories and the employer or customer
Luxembourg	no	yes	yes Different sources are used, e.g. BGIA (D) for chemicals, NBN and DIN for asbestos, documented in the quality procedures of the test laboratories	Occupational health services recordings, Company files, Labour inspectorate archives
Netherlands	No However, the requirements of the Directives on chemical agents and carcinogenic and	No However, the requirements of the Directives on chemical agents and carcinogenic and mutagenic	yes Non-binding methods as elaborated by the tripartite body of the SER (Sociaal-Economische Raad).	Not specified.

Member State	(n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?	(o) Is exposure monitoring mandatory?	(p) Are there specific measurement methods laid down, or recommended ? If yes, please specify:	(r) How is record keeping on the results of such measurements organised?
	mutagenic substances do of course apply.	substances do of course apply.	Moreover, CEN methods are recommended.	
Poland	Yes In Poland the employers are obliged to carry out measurements of chemical substances at the workplace area and to make the results available to the workers (Regulation of the Minister of Health of 20 April 2005 on the detection and measurement of harmful agents in working environment Dziennik Ustaw 2005, No. 73, item 645). In the case of carcinogens or mutagens the measurements should be done: 1) every 3 months if in the last measurements the concentrations of them was below 0.5 of MAC; 2) every 6 months if in the last measurements the concentrations of them was above 0.1 to 0.5 of MAC; 3) in every case if there is any change in the use of those agents. The employer does not have to determine carcinogenic agent in the workplace air when its	yes	yes According to Regulation of the Minister of Health of 20 April 2005 on the detection and measurement of harmful agents in working environment (Dziennik Ustaw 2005, No. 73, item 645) the measurement methods definite Polish Standards and international standards or others equivalent. They are recommended.	The employer is obliged to approach the State Sanitary Inspection and the National Labour Inspectorate in each case of recognised or suspected occupational disease. The obligation also applies to the physician, who recognises such a disease. The employer is obliged to: - Establish the cause of the occupational disease, its nature and extent together with the State Sanitary Inspection. - Immediately eliminate the agents responsible for the occupational disease and apply necessary preventive means. - Guarantee the realisation of the physician's recommendations. - Keep a list of occupational diseases. - Analyze the causes of occupational diseases and apply necessary preventive means. Employers cover costs of hygienic measurements and prophylactic examinations. The results of BEI measurements are being kept by physicians specialised in occupational health or industrial medicine.

Member State	(n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?	(o) Is exposure monitoring mandatory?	(p) Are there specific measurement methods laid down, or recommended ? If yes, please specify:	(r) How is record keeping on the results of such measurements organised?
	concentration was below 0.1 of MAC in two rounds of measurement.			
Slovakia	no	yes Employers are obliged to make a risks assessment in compliance with Governmental Order of the Slovak Republic No. 356/2006 Coll. of Laws (this Governmental Order adapts requirements of the relevant Directive 2004/37/EC.	no	Results are kept by employers and occupational health services. Since measurements in the Slovak Republic are performed and organised also by Regional Authorities of Public Health, copies of all records and documentation are kept and archived by these authorities.
Slovenia	no	yes	no	The employer must keep the list of all workers exposed together with the factors of exposure (name of the substance, duration of exposure, concentration of the substance) at least 40 years after the end of exposure
Spain	yes	yes	yes Please visit the website: http://empleo.mtas.es/insht/mta/mta.htm	As the Royal Decree 665/1997 describes, the employer is obliged to keep the monitoring results, the measurements and analytical methods used, as well as a list of the employees affected, during 40 years after exposure.
Sweden	no	When there is reason to suspect that an occupational exposure limit is being exceeded, exposure measurement shall be carried out in order to make clear whether and to what extent this is the case. When it is obvious that the air	Yes The methods are published in a scientific series called Arbete och Hälsa: https://gupea.ub.gu.se/dspace/bitstream/2077/4231/1/ah2000_23.pdf also updated database with this	The measurement reports that the Swedish work environment authority performs and those received from the employers are stored in a data base at the authority.

Member State	(n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?	(o) Is exposure monitoring mandatory?	(p) Are there specific measurement methods laid down, or recommended ? If yes, please specify:	(r) How is record keeping on the results of such measurements organised?
		contaminants are causing exposure which is unacceptable with reference to the occupational exposure limit values, measures shall, however, be taken immediately to reduce the exposure to an acceptable level. The results of the measures taken shall if necessary be verified by means of exposure measurement. In connection with handling of ethylene oxide, propylene oxide, cadmium, silica, lead, radon and in the handling of reactive monomer (styrene and vinyl toluene) during production of ester plastics the employer shall always see to it that an exposure measurement is carried out, unless, having regard to the nature and extent of the work, it is clearly apparent that the concentration of these compounds are less than 1/10 of the applicable exposure limit values. Exposure measurement shall be carried out promptly and not more than three months after handling has commenced or been altered, in such a way that a previous measurement is not applicable. Measurement shall subsequently be carried out once per calendar year.	information that is under construction for internet	
UK	yes	No.	yes	Dutyholders (employers) have the responsibility to maintain monitoring

Member State	(n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?	(o) Is exposure monitoring mandatory?	(p) Are there specific measurement methods laid down, or recommended ? If yes, please specify:	(r) How is record keeping on the results of such measurements organised?
		In most cases exposure monitoring is not mandatory but there are two situations where exposure monitoring is mandatory: for vinyl chloride monomer and for hexavalent chromium relating to electrolytic chromium processes.	Methods for measuring the concentration of substances in the air are described in the Methods for Determination of Hazardous Substances (MDHS) series of publications.	records in accordance with the UK COSHH regulations.

9.1.3 Biological monitoring

Member State	(q) Is biological monitoring included in the monitoring methods? If yes, please specify.
Austria	yes Methods to ensure consistent performance of health surveillance and biological monitoring are laid down in the Austrian regulation on health surveillance at the workplace, Annex 2. In general, health surveillance has to be taken into account in the process of risk assessment at the workplace (Austrian workers safety and health act). Concretely the regulation on health surveillance at the workplace foresees that employers have to scrutinize existing risk assessment according to the results of health surveillance (including results of biological monitoring). Austria has specified in a footnote to the OEL table: In Austria, health surveillance is mandatory if workers are exposed more then one hour a day to the substances listed below, (except carcinogenic substances C1 or 2 – no time limit): lead, lead alloys or compounds; mercury, - compounds; manganese, - compounds; cadmium, - compounds; arsenic, - compounds; chromium VI – compounds; cobalt, -compounds; nickel, -compounds; asbestos- or silicium dioxide containing dust, hard metal dust; aluminium, aluminium containing welding fume; welding fumes; fluorine and inorganic fluoric compounds; benzene; toluene; xylenes; trichloromethane, trichloroethylene, tetrachloromethane, tetrachloroethane, perchloroethene, or chlorobenzenes; carbon disulfide; dimethylformamide; aromatic amines and nitro compounds; nitroglycoles and nitroglycerines; phosphoric acid esters; crude paraffine, tar, tar oils, anthracene, pitch, soot, (depending on risk assessment results); crude cotton, flax or hemp; isocyanates. In general, in case of exposure to carcinogenic substances (Cat 1 or 2), employers have to make sure that exposed workers have access to appropriate medical surveillance.
Belgium	No

Member State	(q) Is biological monitoring included in the monitoring methods? If yes, please specify.
Cyprus	No
Czech Republic	Yes Number of chromosomal aberrations is used as a group test either as a cross-section test or as a dynamic test, namely 1) in workers exposed to many potentially genotoxic substances or to a genotoxic substance through more than one route; 2) to verify the carcinogenic risk in dependence on the exposure level (airborne concentrations).
Denmark	no
Estonia	yes It depends on substance – it exists for some substances.
Finland	yes FIOH methods are recommended
Greece	no
Italy	yes Biomarkers of dose and effect: Guidelines for medical surveillance of workers occupationally exposed to carcinogens, set up by the Italian Society (SIMLII) in the year 2003 Guidelines for biological monitoring of workers occupationally exposed to chemical agents, set up by the Italian Society (SIMLII) in the year 2005
Latvia	yes According to Regulation of Cabinet of Ministers No 325/2007 biological exposure indices (BER) for benzene, chromium, cadmium are defined.
Lithuania	no
Luxembourg	yes BAT values
Netherlands	Yes Only in special cases, see answer to previous questions.
Poland	yes

Member State	(q) Is biological monitoring included in the monitoring methods? If yes, please specify.
	The Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment in Poland also proposes BEI values, but only as recommendation values. They are published in a Commission booklet "Harmful agents in the working environment – limit values". The Commission established BEIs for 26 chemical substances. Only workers exposed to lead in the working environment must have blood tests to determine how much lead there is in their blood – this is so in accordance with regulation of the Minister of Health and Social Welfare of May 30, 1996 on medical examinations of workers, the scope of preventive health care and on expert medical opinions for purposes provided for in the Labour Code. Biological monitoring entails the measurement of substances and/or metabolites in biological media, and the measurement of biological effects induced by the substance. BEIs for some chemical substances are listed with details on sampling methodologies in a table provided with the national questionnaire: Arsenic and inorganic compounds, benzene, chromium(VI), cadmium and inorganic compounds, trichloroethylene
Slovakia	yes As for carcinogens with established biological limit value there are available methods for biological monitoring.
Slovenia	no
Spain	Yes The biological monitoring is described in legislation in the Royal Decree 665/1997, which is the regulation brought into force to comply with Council Directives 90/394/EEC, 97/42/EC and 1999/38/EC.
Sweden	No They are published in an ordinance called Medicinska kontroller i arbetslivet (medical controls in the working life) AFS 2005:6[67].
UK	yes Biological monitoring may be included for those carcinogens for which a biomarker has been identified.

[67] http://www.av.se/lagochratt/afs/afs2005_06.aspx, AFS 2005:06 - Medicinska kontroller i arbetslivet

9.2 Annex 3: Availability of documentation - Supporting documents

See also information provided in annex 4. below.

9.2.1 Publicly available documents - OELs lists

	s)In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered).	In which languages are these documents available?	Is it/are they linked to other texts (for example legal documents)?
Austria	OELs are published in Austria as part of a regulation ("Grenzwerteverordnung"). They are therefore legally binding values. The regulation and its Annexes containing OELs can be found at the webpage of the Austrian labour inspection: http://www.arbeitsinspektion.gv.at/AI/Arbeitsstoffe/Grenzwerte/default.htm		
Belgium	The OEL's for chemical agents (including the carcinogenic and mutagenic substances) are listed in Annex I of the Royal Decree of March 11th 2002, published in the "Belgisch Staatsblad" (http://www.juridat.be/cgi_loi/wetgeving.pl) . They can also be found on the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be) with links to further explanation and legislation.	Dutch French	On the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be) the list of OELs is linked to further explanation and legislation texts.
Cyprus	OELs, for carcinogenic and mutagenic substances are published in the Safety and Health at Work (Carcinogens and Mutagens Agents) Regulations of 2001 and 2004. These documents are available on the website (http://www.mlsi.gov.cy/dli) of the Department of Labour Inspection.	Greek	
Czech Republic	OELs of all substances (CMR and hazardous substances) - IOELVs, BOELVs and national OELs - are in the same document: Government Regulation No. 178/2001 Coll., determining conditions for occupational health protection as amended by Government Regulation No: 523/2002 Coll. and Government Regulation No: 41/2004 Coll. (In Czech: Nařízení vlády č. 178/2001 Sb., kterým se stanoví podmínky ochrany zdraví zaměstnanců při práci, ve znění Nařízení vlády č. 523/2002 Sb. a Nařízení vlády č. 441/2004 Sb.) http://www.mvcr.cz/sbirka/2001/sb068-01.pdf http://www.mvcr.cz/sbirka/2002/sb180-02.pdf http://www.mvcr.cz/sbirka/2004/sb145-04.pdf A new Government Regulation is prepared and will come into force probably in April 2008.	Czech	

	s)In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered).	In which languages are these documents available?	Is it/are they linked to other texts (for example legal documents)?
Denmark	In WEA-Guideline nr. C.0.1. Limit values for substances and materials The Guideline is published on www.at.dk.	Danish English	The guideline is linked to Consolidated Act No. 268 of 18 March 2005 Danish Working Environment Act
Estonia	List of OELs for carcinogenic and mutagenic substances has been published in "Limit values for chemical hazards in the working environment" (Regulation N0 239 of the Government of Estonia of 18 September 2001 (enclosed)[68]. Availability of these documents is high (via web sites of the Ministry of Social Affairs and official governmental information bulletin (as a booklet too).	Estonian English	It is linked to Chemical Act.
Finland	A biennial booklet is published on OELs ; also published legislation (especially for binding limit values) Also in web	Finnish Swedish	yes They are linked to legal documents
Greece	In the gazette of Government as presidential decrees. In the ministry's webpage.	Greek	
Latvia	Cabinet Regulation No. 325 Adopted 15 May 2007 „Labour Protection Requirements when in Contact with Chemical Substances at Workplaces" http://osha.lv/legislation	Latvian (translation is in process and will be available soon.)	
Lithuania	– Order of Ministry of Health Care and Ministry of Social Security and Labour, 13 December 2001 on the Hygiene Norm HN 23:2001 Concentration limit values of harmful chemical substances in the air of working environment. Official gazette (2001, No. 110–4008). Must be replaced to Hygiene Norm HN 23:2007 Concentration limit values of chemical substances in the air of working environment (Draft). Available from : http://www.lrs.lt/DPaieska.html [in Lithuanian] – Order of Ministry of Social Security and Labour and Ministry of Health Care, 24 July 2001 on the approval of regulation on the protection of workers from risks related to exposure to carcinogens or mutagens at work. Official gazette (2005, No. 55-1907). Available from : http://www.lrs.lt/DPaieska.html [in Lithuanian]	Lithuanian	
Luxembourg	Legal documents		

[68] The list was made available with the questionnaire (in English)

	s)In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered).	In which languages are these documents available?	Is it/are they linked to other texts (for example legal documents)?
Netherlands	Annex XIII B Arbeidsomstandighedenregeling Web page SER (Sociaal-Economische Raad) http://www.ser.nl/sitecore/content/Internet/en/OEL%20database.aspx	Dutch	
Poland	Documentations of MAC values are published quarterly in a publication of the Interdepartmental Commission "Principles and Methods of Assessing the Working Environment" (in Polish language, short summary is in English, Central Institute for Labour Protection – National Research Institute www.ciop.pl - publication - Principles and Method of Assessing the Working Environment). Risk assessments for carcinogens and/or mutagens are published by IMP, Lodz in a publication "Guidelines for assessing health risk from carcinogens" (in Polish language, short summary is in English). The list of substances for which the guidelines were published is annexed in the national questionnaire. In the basic Legal Act – the Regulatory of the Minister of Labour and Social Policy – there is no information about the effect of chemical substances. So, the Interdepartmental Commission decided to put these notations in a booklet "Harmful agents in the working environment – limit values" (only in Polish language, Central Institute for Labour Protection – National Research Institute www.ciop.pl) to make them more easily accessible for the industry, hygienists and occupational inspectors (only in Polish). The following notations are used in the booklet: *C* – corrosive, *I *– irritation, *A *– sensitive, Carcinogenic categories 1 and 2, *Ft *– fetotoxicity, *Sk* – the substance absorb through the skin	Polish	
Portugal	The OELs for carcinogenic and mutagenic substances are published on the Portuguese Standard NP1796 of 2007, available on the Portuguese Standardization Body – Portuguese Institute for Quality – www.ipq.pt (available only in Portuguese) The OEL's for Benzeno (benzene – CAS 71-43-2), cloreto de vinilo (vinyl chloride – CAS 75-01-4) and amianto (asbestos) are published on national Decret-laws – DL 301/2000, of 18th November and DL 266/2007, of 24th July, available on http://www.dgert.msst.gov.pt/Arquivo/seguranca/Indice%20das%20directivas%20comunitarias.htm	Portuguese	
Slovakia	Law No. 355/2007 Coll. of Laws on protection, promotion and development of public health (in force from 1. Sept. 2007) Governmental Order of the Slovak Republic No. 356 Coll. of Laws on the health protection of workers from the risks related to exposure to carcinogens or mutagens at work as amended These legislative documents are published in printed version of Collection of Laws and also	Slovak	

	s)In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered).	In which languages are these documents available?	Is it/are they linked to other texts (for example legal documents)?
	published at www.zbierka.sk.		
Slovenia	OELs for carcinogens and mutagens are listed in the Rules on the protection of the workers from the risks related to exposure to carcinogens and/or mutagens (Official Gazette of the Republic of Slovenia, No. 101/2005). Rules are available on the Webpage of the Government Office for Legislation and on the Webpage of the Ministry of Labour, Family and Social Affairs: http://zakonodaja.gov.si/rpsi/r09/predpis_PRAV6839.html http://www.mddsz.gov.si/si/zakonodaja_in_dokumenti/veljavni_predpisi	Slovene	
Spain	In the document Occupational Exposure Limits for Chemical Agents in Spain. Published by INSHT and annually updated. http://empleo.mtas.es/insht/practice/vlas.htm	Spanish English	Yes, it is linked to Safety and Health legislation in force.
Sweden	They are published in the scientific series Arbete och Hälsa: http://www.medicine.gu.se/avdelningar/samhallsmedicin_folkhalsa/amm/aoh/	Swedish English	
UK	The HSE publication EH40 provides a list of limit values, called Workplace Exposure Limits (WELs). Supporting data is published in EH64 summaries. These are available in English. The list of WELs is available at: http://www.hse.gov.uk/coshh/index.htm EH40/2005 Workplace Exposure Limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended) (ISBN 0-7176-2977-5) is available via HSE Books at: http://www.hsebooks.co.uk/Books/. EH64 summaries can be obtained from the ACTS Secretariat at the address below and will be made available via the HSE website	English	WELs take their legal force from the Control of Substances Hazardous to Health Regulations 2002 (as amended) (ISBN 0-7176-2981-3).

9.2.2 Specific Information - Criteria documents and measurement methods

Member State	Evaluation documents for individual substances Available from (contact point address or web site)	Measurement and analytical methods for individual substances Available from (contact point address or web site)
Belgium	Copyrighted documents (e.g. ACGIH criteria documents): can be consulted at the library of the Belgian Federal Public Service Employment, Labour and Social Dialogue	Copyrighted documents (standards): can be consulted at the library of the Belgian Federal Public Service Employment, Labour and Social Dialogue
Czech Republic	OEL commission at National Institute of Public Health in Prague	OEL commission at National Institute of Public Health n Prague, NRL for Biological Monitoring of Occupational Exposure to Chemical Compounds Centre of Occupational Health NIPH NRL for Analysis of Toxic Gases in Workplace Air Centre of Occupational Health NIPH NRL for Monitoring and Evaluation of Dust and Microclimate at Workplaces Centre of Occupational Health NIPH See answer to Section E of the questionnaire: Documentation of MAC in Czechoslovakia – Czechoslovak committee of MAC. Prague, 1969. 166 p. Editor: Institute of Industrial Hygiene and Occupational Diseases (in English) The same documentation in Czech: “Návrh nejvýše přípustných koncentrací chemických škodlivin v průmyslovém ovzduší, Praha, 1969, 162 s.” From 1994 all documentations are as internal documents Centre of Occupational Health The National Institute of Public Health (NIPH)
Denmark	The documents are not available at www.at.dk but can be ordered by contacting the Danish Working Environment Authority.	It is possible that the National Research Centre for Working Environment can provide some information
Estonia	Chemical Notification Centre (Gonsiori 29, Tallinn 1502) ; www.ktk.ee	Chemical Notification Centre
Finland	Contact: Asko Aalto, Ministry of Social Affairs and Health, OSH Department Web site exists	Finnish Institute of Occupational Health FIOH

Member State	Evaluation documents for individual substances Available from (contact point address or web site)	Measurement and analytical methods for individual substances Available from (contact point address or web site)
Latvia	See information provided fro documents related to reprotoxic substances (answer to section E of the questionnaire): Directive 76/769 EEK and Regulations of Cabinet of Ministers within implementation (Cabinet Regulation No. 158 Adopted 25 April 2000 „Regulations regarding Restrictions and Prohibitions on Use and Marketing of Dangerous Chemical Substances and Dangerous Chemical Preparations") - Materials of EC Scientific Committee for Occupational Exposure Limits; - Criteria documents of Nordic Council; - Scientific literature in different data bases (NIOSH, OSHA, IOM, EPA).	
Lithuania	See also information provided above	Institute of Hygiene of Ministry of Health Care www.hi.lt
Luxembourg	Occupational health services, AAA, risk analysis at work	
The Netherlands	Health Council www.gr.nl SER (Sociaal-Economische Raad): http://www.ser.nl/sitecore/content/Internet/en/OEL%20database.aspx	SER (Sociaal-Economische Raad) http://www.ser.nl/
Poland	The Interdepartmental Commission for MAC and MAI Central Institute for Labour Protection – National Research Institute, Warsaw www.ciop.pl The secretary of Commmission Jolanta Skowroń Ph. D., e-mail josko@ciop.pl	The member of the Commission Central Institute for Labour Protection – National Research Institute, Warsaw www.ciop.pl; Małgorzata Pośniak Ph.D., mapos@ciop.pl Nofer Institute of Occupational Medicine, IMP Łódź; www.imp.lodz.pl Jan. P Gromiec Ph.D. jpgrom@imp.lodz.pl
Slovakia	Selected Regional Public Health Authorities with laboratories at the Slovak Republic.	Selected Regional Public Health Authorities with laboratories at the Slovak Republic.
Spain	http://empleo.mtas.es/insht/practice/dlep.htm#presentacion	http://empleo.mtas.es/insht/mta/mta.htm
Sweden	http://www.av.se/dokument/inenglish/reports/2006_10.pdf http://www.medicine.gu.se/avdelningar/samhallsmedicin_folkhalsa/amm/aoh/ See also answer to the questions in section E, annex 3 below	https://gupea.ub.gu.se/dspace/bitstream/2077/4231/1/ah2000_23.pdf Also updated database with this information under construction for the internet.
United Kingdom	ACTS secretariat, can be contacted at: Health & Safety Executive, Floor 9SW, Rose Court, 2 Southwark Bridge, London SE1 9HS or email: androulla.michael@hse.gsi.gov.uk	MDHS series Documents in the MDHS series are available via the HSE website at http://www.hse.gov.uk/pubns/mdhs/index.htm

9.3 Annex 4: Reprotoxic substances – answers to the questionnaires

See also information provided in Annex 3. above

Member State	u) Are there any limit values defined for reprotoxic substances?	If yes, how are these limit values applied in practice?	v) Are there any lists of reprotoxic substances?	w) Availability of scientific and technical documents supporting establishing the OEL (list of limit values, criteria documents, explanatory notes)
Austria	no		no	
Belgium*	yes	There are OELs defined for certain reprotoxic substances (Table E). Similar to the carcinogenic and mutagenic substances, they are listed in annex I of the Royal Decree of March 11th 2002, but their reprotoxic nature it is not specified in this list. For lead, a biological limit value is defined (70 µg Pb/100 ml blood) These limit values are constraining.	yes (included in the general table of OELs)	The document also referred to section D of the questionnaire on availability of documents for CM substances: "The OEL's for chemical agents […] are listed in Annex I of the Royal Decree of March 11th 2002, published in the "Belgisch Staatsblad" (http://www.juridat.be/cgi_loi/wetgeving.pl) . They can also be found on the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be) with links to further explanation and legislation."
Cyprus	no		no	
Czech Republic	yes	Referred to answer for CM substances (section D s) of the questionnaire): OELs of all substances (CMR and hazardous substances) - IOELVs, BOELVs and national OELs - are in the same document: Government Regulation No. 178/2001 Coll., determining conditions for occupational health protection as amended by Government Regulation No: 523/2002 Coll. and Government Regulation No: 41/2004 Coll.	yes (referred to appendices in Directive ?)	Documentation of MAC in Czechoslovakia – Czechoslovak committee of MAC. Prague, 1969. 166 p. Editor: Institute of Industrial Hygiene and Occupational Diseases (in English) The same documentation in Czech: "Návrh nejvýše přípustných koncentrací chemických škodlivin v průmyslovém ovzduší, Praha, 1969, 162 s." From 1994 all documentations are as internal documents Centre of Occupational Health The National Institute of Public Health (NIPH)

Member State	u) Are there any limit values defined for reprotoxic substances?	If yes, how are these limit values applied in practice?	v) Are there any lists of reprotoxic substances?	w) Availability of scientific and technical documents supporting establishing the OEL (list of limit values, criteria documents, explanatory notes)
		(In Czech: Nařízení vlády č. 178/2001 Sb., kterým se stanoví podmínky ochrany zdraví zaměstnanců při práci, ve znění Nařízení vlády č. 523/2002 Sb. a Nařízení vlády č. 441/2004 Sb.) They are available only in Czech. http://www.mvcr.cz/sbirka/2001/sb068-01.pdf http://www.mvcr.cz/sbirka/2002/sb180-02.pdf http://www.mvcr.cz/sbirka/2004/sb145-04.pdf A new Government Regulation is prepared and will come into force probably in April 2008.		
Denmark	yes	Limits values are often applied because of other effects i.e. allergies or other acute effects. Only later it is discovered that the compounds are reprotoxic.	yes (The reprotoxic substances are included on the list of dangerous compounds and materials)	Material can be provided by contacting the Danish Working Environment Authority
Estonia	yes	These limit values are applied in practice in same way as all limit values – levels of applications are quite different in different enterprises.	yes	Level of availability is relatively high, especially through the Internet. See also information provided from Estonia for general availablility of documents: List of OELs for carcinogenic and mutagenic substances has been published in "Limit values for chemical hazards in the working environment" (Regulation N0 239 of the Government of Estonia of 18 September 2001 (enclosed). Availability of these documents is high (via web sites of the Ministry of Social Affairs and official

Member State	u) Are there any limit values defined for reprotoxic substances?	If yes, how are these limit values applied in practice?	v) Are there any lists of reprotoxic substances?	w) Availability of scientific and technical documents supporting establishing the OEL (list of limit values, criteria documents, explanatory notes)
				governmental information bulletin (as a booklet too). Languages – Estonian, English. It is linked to Chemical Act. The list was made available with the questionnaire (in English)
Finland	yes	– As the other OELs – Also to achieve a so-called special maternity leave right, a risk assessment at workplace may be carried out. For chemical reprotoxicants, OELs are used. For some, exceeding OEL is the limit, for some a specified fraction of the OEL may be the action level to stop working during pregnancy depending on how reprotoxicity originally has been taken into account at the OEL setting of a specific substance	yes – EU Classification for reprotoxicity – Special maternity leave (social security) legislation – OSH legislation from year 1991 contains lists of reprotoxicants	– For list of limit values see table A above for R substances – Criteria documents available in a similar way as for other substances with OEL – Guidebook for risk assessment for need of special maternity leave published by FIOH in co-operation with the ministry – recently updated
Germany	no		no	
Greece	no		no	
Italy	no		no	
Latvia	yes	OELs are defined united for Chemical substances within Regulation of Cabinet of Ministers No 325/2007 and in this regulation reprotoxic substances are included. In section D of the national questionnaire, this regulation was reported to be available	yes	– Directive 76/769 EEK and Regulations of Cabinet of Ministers within implementation (Cabinet Regulation No. 158 Adopted 25 April 2000 „Regulations regarding Restrictions and Prohibitions on Use and Marketing of Dangerous Chemical Substances and Dangerous Chemical Preparations") – Materials of EC Scientific Committee for Occupational Exposure

Member State	u) Are there any limit values defined for reprotoxic substances?	If yes, how are these limit values applied in practice?	v) Are there any lists of reprotoxic substances?	w) Availability of scientific and technical documents supporting establishing the OEL (list of limit values, criteria documents, explanatory notes)
		from the following Website: http://osha.lv/legislation Latvian version available now, but translation is in process and will be available soon.		Limits; – Criteria documents of Nordic Council; – Scientific literature in different data basis (NIOSH, OSHA, IOM, EPA).
Lithuania	yes		yes	Order of Ministry of Health Care and Ministry of Social Security and Labour, 13 December 2001 on the Hygiene Norm HN 23:2001 Concentration limit values of harmful chemical substances in the air of working environment. Official gazette (2001, No. 110–4008). Must be replaced to Hygiene Norm HN 23:2007 Concentration limit values of chemical substances in the air of working environment (Draft). Available from : http://www.lrs.lt/DPaieska.html [in Lithuanian]
Luxembourg	yes	Hg, antimitotics, CO, Pb no exposure percutanous penetration + cancerogenic substances	yes (Loi du 1ier aôut 2001 concernant la protection des travailleuses enceintes, accouchées et allaitantes[69])	
Netherlands	yes	In the same way as non-carcinogenic substances.	yes (List updated regu-larly, and not limita-tive. Every half year)	Annex XIII A Arbeidsomstandighedenregeling Health Council www.gr.nl SER (Sociaal-Economische Raad): http://www.ser.nl/sitecore/content/Internet/en/OEL%20database.aspx
Poland	yes	Are applied in the same way as MAC for other chemicals by Group of Experts for Chemical and Dust Agents	yes (In a booklet "Harmful agents in	Documentations of MAC values for reprtotoxic substances are published in a publication of the Interdepartmental Commission "Principles and Methods of Assessing the Working Environment".

[69] Legislation relating to pregnant and breastfeeding workers

Member State	u) Are there any limit values defined for reprotoxic substances?	If yes, how are these limit values applied in practice?	v) Are there any lists of reprotoxic substances?	w) Availability of scientific and technical documents supporting establishing the OEL (list of limit values, criteria documents, explanatory notes)
		Interdepartmental Commission for MAC and MAI www.ciop.pl	the working environment – limit values" there are signed *Ft *– fetotoxicity.)	The list of substances with singed "Ft" are published in booklet "Harmful agents in the working environment – limit values" (only in Polish language). Extensive information on the availability of documents was also given in the answers to section D of the questionnaire, which provides contacts for the documents.
Portugal			yes (On legislation published by the Ministry of Environment)	
Slovakia	no		yes	Information and documents are available, e.g. from SCOEL reports (Scientific Committee on Occupational Exposure Limits); Advisory Committee on Safety and Health at Work; Working Group on Chemicals at Work of EC.
Slovenia	no		no	
Spain	yes	These limit values are applied like the rest of the OELs established.	yes	Limit values established for reprotoxic substances are included in the Document Occupational Exposure Limits for Chemical Agents in Spain (http://empleo.mtas.es/insht/practice/vlas.htm) .
Sweden	yes	They are used in the risk assessment. For example if you are planning to have a baby you should avoid exposure to these substances. These substances can be a danger for both men and women. There is a special ordinance for pregnant or breastfeeding women with more detail (AFS 2007:5).	yes	There are published criteria documents of all limit values at http://www.medicine.gu.se/avdelningar/samhallsmedicin_folkhalsa/amm/aoh/ There are also a report of the impact assessments of the proposals of the limit values that are published on the web site: http://www.av.se/dokument/inenglish/reports/2006_10.pdf More information on the availability of documents was given in the national questionnaire in the answer to section D (see annex 3 above)

Member State	u) Are there any limit values defined for reprotoxic substances?	If yes, how are these limit values applied in practice?	v) Are there any lists of reprotoxic substances?	w) Availability of scientific and technical documents supporting establishing the OEL (list of limit values, criteria documents, explanatory notes)
UK	yes	Where a limit has been set for a reprotoxic substance it will be applied in the same way as a limit value for any other type of substance.	yes (Certain reproductive toxicants are assigned limit values in EH40)	Where a limit has been set, the documentation will be available from the ACTS secretariat. for more details on the availability of documents see the answers to section D of the questionnaire, annex 3above: The list of WELs is available at: http://www.hse.gov.uk/coshh/index.htm Supporting data is published in EH64 summaries. These are available in English. ACTS Secretariat can be contacted at: Health & Safety Executive, Floor 9SW, Rose Court, 2 Southwark Bridge, London SE1 9HS or email: androulla.michael@hse.gsi.gov

9.4 Annex 5: Questionnaire on OELs for CMRs: answers/contributions of 21 Member States (2007-2008)

TC RO P 07-11

Occupational Exposure Limits (OELs) for Carcinogens, Mutagens and Reprotoxic substances (CMRs) at EU Member States (MSs) level (EU-27)

Overview of the questionnaires

Elke Schneider
Joanna Kosk-Bienko
Willy De Craecker
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Steve Van Herpe
Rik Op de Beeck
Carine Meeus

13 June 2008

Background

The European Commission has requested the Agency's assistance in collecting data on existing occupational exposure limit (OELs) values for carcinogens, mutagens and substances toxic for reproduction (CMRs) from the 27 Member states.

DG Employment, Social Affaires and Equal Opportunities, in April 2003 had requested from the 15 EU MSs some basic information on OELs for carcinogens. This questionnaire complements this earlier work and seeks more detailed information on this issue.

Furthermore, DG EMPL had organised a workshop in October 20061 with the aim to discuss the legal, scientific and current practical experiences in Europe and to investigate methodologies including objective criteria and options for setting and communicating OELs for carcinogens and mutagens. According to the conclusions of the workshop, OELs continue to play an important role as a risk management tool.

Furthermore, the significant level of experience in some MSs on setting OELs for carcinogens can provide a helpful source of information for the Commission in considering policy options for setting OELs at EU level. In particular, it was agreed to launch a survey aiming at identifying which carcinogens and mutagens have been assigned an OEL at national level and which methodology and criteria (scientific, technical and socio-economic) are used when setting an OEL.

On the basis of the above-mentioned considerations, DG EMPL in addressing the identified need for more specific information is launching an initiative to consult the 27 EU Member States on the sensitive issue of setting OELs for carcinogens and mutagens.

[1] http://ec.europa.eu/employment_social/health_safety/docs/summary_workshop.pdf, Presentations accessible by clicking on the name of the speaker

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Austria

27 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Acrylamide	[79-06-1]	201-173-7	C2	0,06 E[3] 0,03 E		0,24 E 0,12 E				✓	– handling of solid acrylamide – other uses
Acrylonitrile	[107-13-1]	203-466-5	C2	4,5	2	18	8			✓	Sensitizer (skin)
Antimonytrioxide (assessed on the basis of Sb)	[1309-64-4]	215-175-0	C2	0,3 E 0,1 E		1,2 E 0,4 E					– manufacture of antimonytrioxide, manufacture of antimonytrioxide-masterbatches and -pasts (weigthing and mixing of antimonytrioxide-powder) - other uses
Arsenictrioxide + -pentoxid, arsenious acid, arsenic acid + its salts (assessed on the basis of As)	[1327-53-3]	215-481-4	C1	0,1 E		0,4 E		100 µg/l (As in Urine)			
Asbestos chrysotil- and amphibole) (actinolite, amosite, anthophyllite, crocidolite, tremolite)	[1332-21-4] asbestos dust, asbestos containing dust		C1	250 000 F/m³ 250 000 F/m³		1 000 000 F/m³ 1 000 000 F/m³					Definition fiber (F): length > 5 µm diameter < 3 µm l/d > 3 : 1 – all uses except demoliton, reconstruction + maintainance

[1] Please specify
[2] Please specify
[3] E: inhalable fraction to be measured

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Auramin and auramin salts	[492-80-8]	207-762-5	C2	0,08 E		0,32 E					
Benzene	[71-43-2]	200-753-7	C1	3,2	1	12,8	4	1,6 mg/l t,t-Muconic acid (Urine)		✓	
Benzo[a]pyrene	[50-32-8]	200-028-5	C2	0,005 0,002		0,02 0,008					– certain uses in coking plants – other uses
Beryllium and Be - compounds (assessed on basis of Be)	[7440-41-7]	231-150-7	C2	0,005 E 0,002 E		0,02 E 0,008 E					– grinding Be-metal + Be-alloys – all other uses; Sensitizer (skin)
1,3-Butadiene	[106-99-0]	203-450-8	C2	34 11	15 5	136 44	60 20				– handling after polymerisation, loading – other uses
Cadmium and Cd-compounds (assessed on basis of Cd)	[7440-43-9]	231-152-8	C2	0,03 E 0,015 E		0,12 E 0,06 E		5 µg/l Cd (Blood)			- manufacture of batteries, thermic extraction of zinc, lead and copper, welding of Cd-containing alloys - other uses
p-Chloroaniline	[106-47-8]	203-401-0	C2	0,2	0,04	0,8	0,12			✓	
1-Chloro-2,3-epoxy-propane (Epichloro-hydrine)	[106-89-8]	203-439-8	C2	12	3	48	12			✓	Sensitizer (skin, respiratory tract)
Chlorinated Dibenzodioxins and -furans[4]			C2	50 pg TE/m³		200 pg TE/m³					

[4] [4]Chlorinated Dibenzodioxines + -furans: Toxicity equivalence factors (NATO/CCMS 1988):

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value [2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
α-Chlorotoluene	[100-44-7]	202-853-6	C2	0,2		0,8					
Chromium(VI)-compounds, (including leadchromate, except compounds unsoluble in water, e.g. barium-chromate; assessed on basis of CrO_3 aerosols)			C2	0,1 E 0,05 E		0,4 E 0,2 E		9 µg/l Cr (Blood); 12 µg/l Cr (Urine)			– certain welding procedures, manufacture of soluble Cr(VI)- compounds – other uses; Sensitizer (skin)
4,4'-Diamino-diphenyl-methane	[101-77-9]	202-974-4	C2	0,1		0,4				✓	Sensitizer (skin)
1,2-Dibromo-ethane	[106-93-4]	203-444-5	C2	0,8	0,1	3,2	0,4			✓	
3,3'-Dichloro-benzidine + its salts	[91-94-1]	202-109-0	C2	0,03	0,003	0,12	0,012			✓	Sensitizer (skin)
1,4-Dichloro-2-butene	[764-41-0]	212-121-8	C2	0,05	0,01	0,2	0,04			✓	

PCDD-Kongenere	Toxicity equivalence factor	PCDF-Kongenere	Toxicity equivalence factor
2,3,7,8-Tetrachlordibenzodioxin	1,0	2,3,7,8-Tetrachlordibenzofuran	0,1
1,2,3,7,8-Pentachlordibenzodioxin	0,5	1,2,3,7,8-Pentachlordibenzofuran	0,05
		2,3,4,7,8- Pentachlordibenzofuran	0,5
1,2,3,4,7,8-Hexachlordibenzodioxin	0,1	1,2,3,4,7,8-Hexachlordibenzofuran	0,1
1,2,3,6,7,8- Hexachlordibenzodioxin	0,1	1,2,3,6,7,8- Hexachlordibenzofuran	0,1
1,2,3,7,8,9- Hexachlordibenzodioxin	0,1	1,2,3,7,8,9- Hexachlordibenzofuran	0,1
		2,3,4,6,7,8- Hexachlordibenzofuran	0,1
1,2,3,4,6,7,8-Heptachlordibenzodioxin	0,01	1,2,3,4,6,7,8-Heptachlordibenzofuran	0,01
		1,2,3,4,7,8,9-Heptachlordibenzofuran	0,01
Octachlordibenzodioxin	0,001	Octachlordibenzofuran	0,001

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
1,2-Dichloro-ethane	[107-06-2]	203-458-1	C2	20	5	80	20				
Diethyl sulfate	[64-67-5]	200-589-6	C2	0,2	0,03	0,8	0,12			✓	
3,3'-Dimethoxy-benzidin and its salts	[119-90-4]	204-355-4	C2	0,03	0,003	0,12	0,012			✓	
3,3'-Dimethyl-benzidine and its salts	[119-93-7]	204-358-0	C2	0,03	0,003	0,12	0,012			✓	
3,3'-Dimethyl-4,4'-diamino-diphenyl-methan	[838-88-0]	212-658-8	C2	0,05		0,2				✓	Sensitizer (skin)
Dimethylsulfa-moylchloride	[13360-57-1]	236-412-4	C2	0,1		0,4				✓	
Dimethyl sulfate	[77-78-1]	201-058-1	C2	0,1 0,2	0,02 0,04	0,4 0,8	0,08 0,16			✓	– manufacture – other uses
2,6-Dinitrotoluene	[606-20-2]	210-106-0	C2	0,05	0,007	0,2	0,028				
3,4-Dinitrotoluene	[610-39-9]	210-222-1		1,5		6					
1,2-Epoxy-propane	[75-56-9]	200-879-2	C2	6	2,5	24	10			✓	
2,3-Epoxy-1-propanol	[556-52-5]	209-128-3	C2	150	50	150	50			✓	Sensitizer (skin, respiratory tract)
Ethylenimine	[151-56-4]	205-739-9	C2	0,9	0,5	3,6	2			✓	
Ethylenoxide	[75-21-8]	200-849-9	C2	2	1	8	4			✓	
Hydrazine	[302-01-2]	216-114-9	C2	0,13	0,1	0,52	0,4			✓	Sensitizer (skin)
p-Kresidin	[120-71-8]	204-419-1	C2	0,5		2				✓	
2-Methoxy-aniline	[90-04-0]	201-963-1	C2	0,5	0,1	1	0,2			✓	
4,4'-Methylen-bis(2-chloroaniline) and its salts	[101-14-4]	202-918-9	C2	0,02		0,08				✓	
4,4'-Methylene-bis(N,N-di-methylaniline)	[101-61-1]	202-959-2		0,1 E		0,4 E					

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value [2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Nickel (Ni-metal, Ni-sulfid and sulfidic ores, Ni-oxide und Ni-carbonate, dust of Ni-alloys; assessed on basis Ni)	[7440-02-0]	231-111-4	C1	0,5 E		2 E		7 µg/ Ni (Urine)			Sensitizer (skin, respiratory tract)
Ni- compounds (inhalable droplets)			C1	0,05 E		0,2 E		7 µg/ Ni (Urine)			assessed as Ni (entire inhalable fraction); Sensitizer (skin, respiratory tract)
2-Nitro-naphthalene	[581-89-5]	209-474-5	C2	0,25	0,035	1	0,14				
2-Nitropropane	[79-46-9]	201-209-1	C2	18	5	72	20				
o-Nitrotoluene	[88-72-2]	201-853-3	C2	0,5		2				✓	
o-Toluidine	[95-53-4]	202-429-0	C2	0,5	0,1	2	0,4			✓	
o-Toluidine, salts			C2	0,5 E		2 E				✓	
2,4-Toluylene-diamine	[95-80-7]	202-453-1	C2	0,1	0,02	0,4	0,08			✓	Sensitizer (skin)
α,α,α-Trichloro-toluene	[98-07-7]	202-634-5	C2	0,1	0,012	0,4	0,048				
Vinylchloride	[75-01-4]	200-831-0	C1	5	2	20	4				

Substances/OELs regarded carcinogenic in Austria, additional to classification in EU classifications system (acc to Dir 67/548/EG)

Diesel exhaust				0,3 A[5] 0,1 A		1,2 A 0,4 A					– mining (below ground) and construction work below ground – other uses
Artificial mineral fibers (if carcinogenic, provisions -> annex IIIC)				500000 F/m³		2000000 F/m³				✓	Definition fiber (F): length > 5 µm diameter < 3 µm l/d > 3 : 1 Construction sites: OEL (500 000 F/m³) considered as met when total number of fibers is found below 1 000 000 F/m³ (using light microscope)
N-Nitrosamine: N-Nitrosodi-n-butylamine N-Nitrosodi-ethanolamine N-Nitrosodi-methylamine N-Nitrosodi-i-propylamine N-Nitrosodi-n-propylamine N-Nitrosoethylphenylamine N-Nitrosomethylethylamine N-Nitrosomethyl-phenylamine N-Nitroso-morpholine N-Nitrosopiperidine N-Nitroso-pyrrolidine				 0,0025 0,0025 0,0025 0,001		 0,01 0,01 0,01 0,004					OEL to be applied on sum of N-Nitrosamines - Vulcanisation and following processes including storage of rubber products, storage places for tires, used before 1992 - Manufacture of polyacrylnitrile dry spinning process (using dimethylformamide) – Filling of vessels and reactors with amines – other uses
Wood dust			Dir. 2004/37/EG	2 E							Sensitizer (skin, respiratory tract)

[5] A : respirable fraction to be measured

Substances/OELs regarded carcinogenic Cat 1 or 2 in Austria, differing from EU classification system (acc to Dir 67/548/EG)

2-Amino-4-nitrotoluene	[99-55-8]	202-765-8		0,5		2				✓	
2-Butenal (cis/trans isomers)	[123-73-9], [15798-64-8], [4170-30-3]	224-030-0 (trans isomere)		1	0,34	4	1,36			✓	
Chloroethane	[75-00-3]	200-830-5		25	9	100	36			✓	
Chlorofluoro-methane	[593-70-4]	209-803-2		1,4	0,5	5,6	2				
Cobalt (Co-metal, Co-oxide and Co-sulfide, dust of Co- alloys ; assessed on basis of Co)	[7440-48-4]	231-158-8		0,5 E 0,1 E		2 E 0,4 E		10 µg/l Co (Urine)			– manufacture of Co-powder and catalysts, heavy metals and magnets (handling of powders, pressing and mechanical conditioning of not sintered components) – other uses; Sensitizer (skin, respiratory tract)
3,3'-Diaminoben-zidin + its salts	[91-95-2]	202-110-6		0,03 E	0,003	0,12 E	0,012			✓	
1,4-Dichloro-benzene	[106-46-7]	203-400-5		122	20	306	50			✓	
1,3-Dichloro-propene (E-, Z-; technical mixtures)	[542-75-6]	208-856-5		0,5	0,11	2	0,44			✓	Sensitizer (skin)
α,α-Dichloro-toluene	[98-87-3]	202-709-2		0,1	0,015	0,4	0,06				
Iodmethane	[74-88-4]	200-819-5		2	0,3	8	1,2			✓	
1-Naphthyl-amine	[134-32-7]	205-138-7		1 E	0,17	4 E	0,68			✓	
Ni tetracarbonyl	[13463-39-3]	236-669-2		0,35	0,05	1,4	0,2	7 µg/ Ni (Urine)		✓	
o-Phenylene-diamine	[95-54-5]	202-430-6		0,1		0,4				✓	Sensitizer (skin)
2,3,4-Trichloro-1-butene	[2431-50-7]	219-387-9		0,035	0,005	0,14	0,02				
N-Vinyl-2-pyrrolidone	[88-12-0]	201-800-4		0,5	0,1	2	0,4			✓	
2,4-Xylidine	[95-68-1]	202-440-0		25	5	100	20			✓	

Biological Monitoring:

In Austria, health surveillance is mandatory if workers are exposed more then one hour a day to the substances listed below, (except carcinogenic substances C1 or 2 – no time limit):
lead, lead alloys or compounds; mercury, - compounds; manganese, - compounds; cadmium, - compounds; arsenic, - compounds; chromiumVI – compounds; cobalt, -compounds; nickel, -compounds; asbestos- or silicium dioxide containing dust, hard metal dust; aluminium, aluminium containing welding fume; welding fumes; fluorine and inorganic fluoric compounds; benzene; toluene; xylenes; trichloromethane, trichloroethylene, tetrachloromethane, tetrachloroethane, perchloroethene, or chlorobenzenes; carbon disulfide; dimethylformamide; aromatic amines and nitro compounds; nitroglycoles and nitroglycerines; phosphoric acid esters; crude paraffine, tar, tar oils anthracene, pitch, soot, (depending on risk assessment results); crude cotton, flax or hemp; isocyanates.

In general, in case of exposure to carcinogenic substances (Cat 1 or 2), employers have to make sure that exposed workers have access to appropriate medical surveillance.

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No X

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☐ Availability of data on exposure
- ☐ Availability of toxicological data
- ☐ Number of persons exposed
- ☐ Severity of effects
- ☐ Epidemiological evidence, including reported cases of ill-health in the workplace
- ☐ Availability of measurement methods
- ☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☐ Scientific experts
- ☐ Social partners – Employers
- ☐ Social partners – Workers
- ☐ Public authority - Ministry of Health

X Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	X

e) Which kind of limit values are adopted?

X 8-hour limit values

X Short-term limit values

X Ceiling limit values

X Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
X	☐

If yes, with which parties?

Social partners, AUVA (Austrian accident insurance board), experts, chaired by ministry of economic and labour.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances **Yes** ☐ **No** ☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process? **Yes** ☐ **No** ☐

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used:

Yes	**No**
☐	☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

Yes	**No**
☐	☐

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes	**No**
X	☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

OELs from german sources namely DFG (german research society, deriving “MAK-Values”) or from AGS (committee hazardous substances) have been adopted in the past. Specific European Union legislation (carcinogens directive) has been implemented as well as other legislation on OELs (directives for indicative occupational limit values)

i) Are limit values indicative or constraining?

☐ indicative

X constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

-

B3) Revision of OEL for carcinogenic and mutagenic substances

	Yes	No
l) Is there a specific procedure for the revision of OELs?	☐	**X**

m) If yes, how often are limit values revised?
Please specify time period:

-

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	X

o) Is exposure monitoring mandatory?

Yes	No
X	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☐	X

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes	No
X	☐

If yes, please specify:

Methods to ensure consistent performance of health surveillance and biological monitoring are layed down in the Austrian regulation on health surveillance at the workplace, Annex 2.

In general, health surveillance has to be taken into account in the process of risk assessment at the workplace (Austrian workers safety and health act). Concretely the regulation on health surveillance at the workplace foresees that employers have to scrutinize existing risk assessment according to the results of health surveillance (including results of biological monitoring).

r) How is record keeping on the results of such measurements organised? (please describe)

Results of measurements are kept at authority level (in the labour inspectorate dealing with). Furthermore on enterprise level, documentation of measurements is obligatory in context of risk assessment at the workplace (safety and health documentation).

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

OELs are published in Austria as part of a regulation ("Grenzwerteverordnung"). They are therefore legally binding values.

The regulation and its Annexes containing OELs can be found at the webpage of the Austrian labour inspection: http://www.arbeitsinspektion.gv.at/AI/Arbeitsstoffe/Grenzwerte/default.htm

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**X**	
Methodology for developing measurement and analytical methods		**X**	
Methodology for the derivation of OELs		**X**	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances		**X**	
Measurement and analytical methods for individual substances		**X**	

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	X

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☐	X

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Belgium

17 October 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS-nr (1).	EINECS- nr. (2)	C/M/R	8 hour limit value mg/m^3 (3) (6)	8 hour limit value ppm (3) (5)	Short term limit value mg/m^3 (4) (6)	Short term limit value ppm (4) (5)	Biological limit value	Other	Skin Notation (7)	Remarks, comments (7)
Acrylamide	00079-06-1	201-173-7	C2	0,03				none	none	yes	Constraining
Acrylnitril	00107-13-1	203-466-5	C2	4,4	2			none	none	yes	Constraining
Arseen en anorganische verbindingen (als As)	07440-38-2	231-148-6	C1	0,1				none	none		Constraining
Benomyl	17804-35-2	241-775-7	M2	10	0,84			none	none		Constraining
Benzeen	00071-43-2	200-753-7	C1	3,25	1			none	none	yes	Constraining
Benzotrichloride	00098-07-7	202-634-5	C2			0,81	0,1	none	none	yes	Constraining M(Ceiling level)
Beryllium en -verbindingen (als Be)	07440-41-7	231-150-7	C2	0,002				none	none		Constraining
1,3-Butadieen	00106-99-0	203-450-8	C1	4,5	2			none	none		Constraining
Cadmium en verbindingen, als Cd (inadembare deeltjes)	07440-43-9	231-152-8	C2	0,002				none	none		Constraining
Cadmium en verbindingen, als Cd (inhaleerbare deeltjes)	07440-43-9	231-152-8	C2	0,01				none	none		Constraining
Calciumchromaat (als Cr)	13765-19-0	237-366-8	C2	0,001				none	none		Constraining
Captafol	02425-06-1	219-363-3	C2	0,1				none	none	yes	Constraining
bis-Chloormethylether	00542-88-1	208-832-8	C1	0,0048	0,001			none	none		Constraining

Substance name	CAS-nr (1).	EINECS- nr. (2)	C/M/R	8 hour limit value mg/m^3 (3) (6)	8 hour limit value ppm (3) (5)	Short term limit value mg/m^3 (4) (6)	Short term limit value ppm (4) (5)	Biological limit value	Other	Skin Notation (7)	Remarks, comments (7)
Chroom VI-wateronoplosbare verbindingen (als Cr) (elders niet ingedeeld)	--	--	C2	0,01				none	none		Constraining
Chroom VI-wateroplosbare verbindingen (als Cr) (elders niet ingedeeld)	--	--	C2	0,05				none	none		Constraining
Diazomethaan	00334-88-3	206-382-7	C2	0,34	0,2			none	none		Constraining
1,4-Dichloor-2-buteen	00764-41-0	212-121-8	C2	0,025	0,005			none	none	yes	Constraining
1,2-Dichloorethaan	00107-06-2	203-458-1	C2	41	10			none	none		Constraining
1,1-Dimethylhydrazine	00057-14-7	200-316-0	C2	0,025	0,01			none	none	yes	Constraining
Dimethylsulfaat	00077-78-1	201-058-1	C2	0,53	0,1			none	none	yes	Constraining
Epichloorhydrine	00106-89-8	203-439-8	C2	2	0,5			none	none	yes	Constraining
Ethyleenimine	00151-56-4	205-793-9	C2	0,89	0,5			none	none	yes	Constraining
Ethyleenoxide	00075-21-8	200-849-9	C2	1,8	1			none	none		Constraining
Hexachloorbenzeen	00118-74-1	204-273-9	C2	0,002				none	none	yes	Constraining
Houtstof van hard hout (inhaleerbare fractie)	--	--	C	3				none	none		Constraining
Hydrazine	00302-01-2	206-114-9	C2	0,013	0,01			none	none	yes	Constraining
Isobutylnitriet (damp en aërosol)	00542-56-3	208-819-7	C2			4,3	1	none	none		Constraining M (ceiling level)
Koolteer (uit koolteer afkomstige deeltjes extraheerbaar met cyclohexaan)	65996-93-2	232-361-7	C2	0,2				none	none		Constraining
4,4'-Methyleen bis(2-chlooraniline)	00101-14-4	202-918-9	C2	0,11	0,01			none	none	yes	Constraining

Substance name	CAS-nr (1).	EINECS- nr. (2)	C/M/R	8 hour limit value mg/m^3 (3) (6)	8 hour limit value ppm (3) (5)	Short term limit value mg/m^3 (4) (6)	Short term limit value ppm (4) (5)	Biological limit value	Other	Skin Notation (7)	Remarks, comments (7)
4,4'-Methyleendianiline	00101-77-9	202-974-4	C2	0,82	0,1			none	none	yes	Constraining
2-Nitropropaan	00079-46-9	201-209-1	C2	37	10			none	none		Constraining
1,3-Propiolacton	00057-57-8	200-340-1	C2	1,5	0,5			none	none		Constraining
Propyleenimine	00075-55-8	200-878-7	C2	4,8	2			none	none	yes	Constraining
Propyleenoxide	00075-56-9	200-878-7	C2	5	2			none	none		Constraining
Strontiumchromaat (als Cr)	07789-06-2	232-142-6	C2	0,0005				none	none		Constraining
o-Toluïdine	00095-53-4	202-429-0	C2	08,9	2			none	none	yes	Constraining
Triglycidylisocyanuraat	02451-62-9	219-514-3	M2	0,05				none	none		Constraining
Vezels (-asbest) (actinoliet, anthofylliet, crocidoliet, tremoliet, amosiet)	--	--	C1	100.000 v/m^3				none	none		Constraining F
Vezels (-asbest) (chrysotiel)	--	--	C1	100.000 v/m^3				none	none		Constraining F
Vinylchloride (monomeer van)	00075-01-4	200-831-0	C1	7,77	3			none	none		Constraining
Zinkchromaat (als Cr)	13530-65-9	236-878-9	C2	0,01				none	none		Constraining
Zinkkaliumchromaat (als Cr)	37300-23-5		C2	0,01				none	none		Constraining
Zinkkaliumchromaat-hydroxide (als Cr)	11103-86-9	234-329-8	C2	0,01				none	none		Constraining

(1) CAS-nr: Chemical Abstracts Service Registry Number.
EG-nr: identificatienummer in de “European Inventory of Existing Commercial Chemical Substances” (EINECS) of in de “European List of Notified Chemical Substances” (ELINCS).
(3) Gemeten of berekend voor een referentieperiode van acht uur, tijdgewogen gemiddelde
(4) Een grenswaarde voor blootstelling die niet mag worden overschreden en geldt voor een periode van 15 minuten tenzij anders vermeld
(5) ppm: deel per miljoen in luchtvolume (ml/m³)
(6) mg/m³ = milligram per kubieke meter lucht bij 20 °C en 101,3 kPa
(7) Bijkomende indeling:
- de vermelding “A” betekent dat dit agens gas of damp vrijgeeft dat of die op zich geen fysiologische werking heeft, maar het zuurstofgehalte in de lucht verlaagt. Wanneer het zuurstofgehalte daalt onder de 17-18 % (vol/vol), veroorzaakt het zuurstoftekort verstikking, die zich manifesteert zonder dat er een waarschuwing aan voorafgaat.
- de vermelding “C” betekent dat het betrokken agens valt onder het toepassingsgebied van het koninklijk besluit van 2 december 1993 betreffende de bescherming van de werknemers tegen de risico’s van blootstelling aan kankerverwekkende en mutagene agentia op het werk.
- de vermelding “D” betekent dat de opname van het agens via de huid, de slijmvliezen of de ogen een belangrijk deel van de totale blootstelling vormt. Deze opname kan het gevolg zijn van zowel direct contact als zijn aanwezigheid in de lucht.
- de vermelding “F” betekent dat de blootstelling aan het betrokken agens geschiedt in de vorm van vezels. Hiermee wordt elk deeltje bedoeld met een lengte groter dan 5 µm en een diameter kleiner dan 3 µm, waarvan de verhouding van de lengte over de diameter groter is dan 3. In afwijking van de vermelde concentratie-eenheid (mg/m³) wordt de vezelconcentratie uitgedrukt in aantal vezels per kubieke meter.
- de vermelding “M” duidt aan dat bij de blootstelling boven de grenswaarde irritatie optreedt of er gevaar bestaat voor acute vergiftiging. Het werkprocédé moet zo zijn ontworpen dat de blootstelling de grenswaarde nooit overschrijdt. Bij een controle geldt dat de bemonsterde periode zo kort mogelijk moet zijn om een betrouwbare meting te kunnen verrichten. het meetresultaat wordt dan gerelateerd aan de beschouwde periode.

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☒

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☐ Availability of data on exposure
- ☐ Availability of toxicological data
- ☐ Number of persons exposed
- ☐ Severity of effects
- ☐ Epidemiological evidence, including reported cases of ill-health in the workplace
- ☐ Availability of measurement methods
- ☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☒ Scientific experts
- ☒ Social partners – Employers
- ☒ Social partners – Workers
- ☐ Public authority - Ministry of Health
- ☒ Public authority - Ministry of Labour
- ☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	No
☐	☒

The scientific derivation of OELs for chemical agents is not performed on the national level: OELs , adopted from sources (often ACGIH) that provide a scientific evaluation are proposed to the High Council for Prevention and Protection at Work (employers' and workers' representatives, experts) and published on the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be).
Within 2 months after publication of the proposed OELs, parties concerned can lodge a notice of objection to these values; within 5 months after publication, an elaborate file has to presented for every contested OEL.
Based on the above mentioned files, the technical and socio-economic evaluation is performed within the High Council for Prevention and Protection at Work.

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☒ Short-term limit values

☒ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	No
☒	☐

see answer B2) d)

If yes, with which parties?

see answer B2) D) : employers' and workers' representatives, scientific experts

g) Where a national system exists does it contain criteria for the key components of the system, including: see answer B2) d)

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances **Yes** ☐ **No** ☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process? **Yes** ☐ **No** ☐

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☐

Information is provided by the social partners, scientific experts, and if possible tested against inspection data.

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health

described in terms other than monetary? **Yes** ☐ **No** ☐

If yes, please specify:

(iv) Other criteria: please describe them

Information is provided by the social partners, scientific experts.

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☒

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☒

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☒ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

- The American Conference of Industrial Hygienists (ACGIH)
- Other Member States

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☒ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

The agreement between the social partners on the eventual OELs.

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** ☒

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes ☒ No ☐

The following methods are used in order of preference:
- reference methods
- normalised methods
- methods published by institutes, specialised in occupational hygiene
- in house validated methods

If relevant for the analysis, the following standards are applied: EN 481, EN 13205, EN 482, EN 689, EN 838, EN 1076, EN 1231, EN 1232, EN 1540.
Furthermore standard EN 689 (Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) is applied.

o) Is exposure monitoring mandatory?

Yes ☐ No ☐

Whenever a carcinogen or mutagen is used, the employer shall use existing appropriate procedures for the measurement of these substances, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident.

p) Are there specific measurement methods laid down, or recommended?

Yes ☒ No ☐

If yes, please specify:

cfr. point C. n)
For the measurement of the concentration of asbestos fibres in air, the use of the standard NBN T96-102 is mandatory.

q) Is biological monitoring included in the monitoring methods?

Yes ☐ No ☒

If yes, please specify:

r) How is record keeping on the results of such measurements organised? (please describe)

All data on exposure to chemical agents are added to the individual medical records of the workers. These medical records are kept by the service, assigned to perform the medical surveillance. In case of exposure to carcinogens/mutagens, these medical records have to be kept for at least 40 years following the end of the exposure.

Furthermore, the employer has to keep a register with a list with the names of all workers who can be exposed to carcinogens/mutagens and the exposure to which they have been subjected.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered).

The OEL's for chemical agents (including the carcinogenic and mutagenic substances) are listed in Annex I of the Royal Decree of March 11th 2002, published in the "Belgisch Staatsblad" (http://www.juridat.be/cgi_loi/wetgeving.pl) .

They can also be found on the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be) with links to further explanation and legislation.

In which languages are these documents available? Dutch, French

Is it/are they linked to other texts (for example legal documents)?

On the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be) the list of OELs is linked to further explanation and legislation texts.

t) Which of the following types of information is publicly available?

General Information	Yes	No	Available from (contact point address or web site)
Methodology for identifying priority substances for OEL setting		x	
Methodology for developing measurement and analytical methods			EN482: Workplace atmospheres. General requirements for the performance of procedures for the measurement of chemical agents :copyrighted document: can be consulted at the library of the Belgian Federal Public Service Employment, Labour and Social Dialogue
Methodology for the derivation of OELs			The procedure, described in answer B2) d), is availasble on the website of the Belgian Federal Public Service Employment, Labour and Social Dialogue (http://www.werk.belgie.be or http://www.emploi.belgique.be)

Specific Information	Yes	No	Available from (contact point address or web site)
Evaluation documents for individual substances	x		copyrighted documents (e.g. ACGIH criteria documents): can be consulted at the library of the Belgian Federal Public Service Employment, Labour and Social Dialogue
Measurement and analytical methods for individual substances	x		copyrighted documents (standards): can be consulted at the library of the Belgian Federal Public Service Employment, Labour and Social Dialogue

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☒	☐

There are OELs defined for certain reprotoxic substances (Table E). Similar to the carcinogenic and mutagenic substances, they are listed in annex I of the Royal Decree of March 11th 2002, but their reprotoxic nature it is not specified in this list. For lead, a biological limit value is defined (70 µg Pb/100 ml blood)

If yes, how are these limit values applied in practice?

These limit values are constraining.

v) Are there any lists of reprotoxic substances?

Yes	No
☐	☒

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

See answer D.

Table E: reprotoxic substances (cat. 1 / 2) listed in the general table of OELs (Annex I of the Royal Decree of March 11th 2002)

EINECS	CAS	Name	OEL ppm	OEL mg/m^3	OEL short term ppm	OEL short term mg/m^3	skin notation	repro cat
203-839-2	111-15-9	2-Ethoxy-ethylacetaat	5	27			D	2
203-772-9	110-49-6	2-Methoxy-ethylacetaat	5	24			D	2
205-743-6	149-57-5	2-Ethylhexaanzuur (damp en aërosol)		5				2
203-772-9	110-49-6	2-Methoxy-ethylacetaat	5	24			D	2
203-445-0	106-94-5	1-Broompropaan	10	51				2
201-377-6	81-81-2	Warfarine		0,1				1
204-826-4	127-19-5	N,N-Dimethylacetamide	10	36	20	72	D	2
200-679-5	68-12-2	N,N-Dimethylformamide	10	30			D	2
203-804-1	110-80-5	2-Ethoxy-ethanol	5	18			D	2
200-842-0	75-12-7	Formamide	10	18			D	2
203-713-7	109-86-4	2-Methoxy-ethanol	5	16			D	2
211-128-3	630-08-0	Koolstofmonoxide	25	29				1
204-211-0	117-81-7	Di-sec-octylftalaat		5		10		2
201-557-4	84-74-2	Dibutylftalaat		5				2
231-846-0	7758-97-6	Lood(II)chromaat (als Pb)		0,05				1
231-100-4	7439-92-1	Lood, anorganisch, stof en rook, als Pb		0,15				1
201-075-4	78-00-2	Tetra-ethyllood (als lood)		0,1			D	1
200-897-0	75-74-1	Tetramethyllood (als lood)		0,15			D	1

Cyprus

12 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Benzene	71-43-2	200-753-7		3,25	1					Yes	Substantial contribution to the total body burden via dermal exposure possible
Viny Chloride Monomer	75-01-4	200-831		7,77	3						
Hard Wood Dusts	—	—		5	-						If hard word dusts are mixed with other wood dusts, the limit value shall apply to all dusts present in that mixture

[1] Please specify
[2] Please specify

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☑

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☐ Availability of data on exposure
- ☐ Availability of toxicological data
- ☐ Number of persons exposed
- ☐ Severity of effects
- ☐ Epidemiological evidence, including reported cases of ill-health in the workplace
- ☐ Availability of measurement methods
- ☑ Other (please explain)

EU Directives on the protection of workers from the risks related to exposure to carcinogens and mutagens at work (90/394/EC, 97/42/EC, 1999/38/EC).

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☐ Scientific experts
- ☐ Social partners – Employers
- ☐ Social partners – Workers
- ☐ Public authority - Ministry of Health
- ☑ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	☑

e) Which kind of limit values are adopted?

☐ 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☑	☐

If yes, with which parties?

Consultation with Social Partners for the adoption of the relevant EU legislation.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	No
☐	☑

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	No
☐	☑

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	No
☐	☑

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	No
☐	☑

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	No
☐	☑

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	No
☐	☑

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary?

Yes	No
☐	☑

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☑

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☑

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☐ **No** ☑

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

i) Are limit values indicative or constraining?

☐ indicative

☑ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☐ NA

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

NA

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** ☑

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	☑

o) Is exposure monitoring mandatory?

Yes	No
☑	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☐	☑

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes	No
☐	☑

If yes, please specify:

r) How is record keeping on the results of such measurements organised? (please describe)

In cases where health surveillance monitoring is established health records must be kept for at least 40 years.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

OELs, for carcinogenic and mutagenic substances are published in the Safety and Health at Work (Carcinogens and Mutagens Agents) Regulations of 2001 and 2004. These documents are available on the website (http://www.mlsi.gov.cy/dli) of the Department of Labour Inspection, in greek language.

t) Which of the following types of information is publicly available? NA

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting			
Methodology for developing measurement and analytical methods			
Methodology for the derivation of OELs			

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances			
Measurement and analytical methods for individual substances			

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	☑

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☐	☑

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Czech Republic

14 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

All OELs in the Czech Republic are constraining

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments[3] (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Arsenic compounds (as As) (Except Arsine)				0.1		0.4					following compounds are classified as C
Triethyl arsenate	15606-95-8	427-700-2	C1								
Arsenic acid and its salts											Index No: 033-005-00-1
Arsenic pentoxide	1303-28-2	215-116-9									
Arsenic trioxide	1327-53-3	215-481-4									
Asbestos	12001-29-5 12001-28-4 12172-73-5 77536-66-4 77536-68-6 77536-67-5 132207-32-0		C1	4							Index No: 650-013-00-6
Benzene	71-43-2	200-753-7	C 1 M 2	3		10		*S*-Phenylmercap-turic acid in urine, end of shift 0.024 μmol/mmol creatinine		D	P
Benzo(a)pyren	50-32-8	200-028-5	C 2 M 2 R 2	0.005		0.025				D	P
Beryllium and Beryllium	7440-41-7	231-150-7	C2	0.001		0.002					S, P

[1] C1 = Carcinogens: category 1, C2 = Carcinogens: category 2, M2 = Mutagens: category 2, R1 toxic to reproduction: category 1, R2 toxic to reproduction: category 2

[2] set in CR

[3] D= dermal = skin, S = sensibilisation, P = serious concern about delayed effects

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments[3] (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
compounds (as Be)											
Beryllium oxide	1304-56-9	215-133-1	C2								
1,3-Butadiene	106-99-0	203-450-8	C1 M2	10		20					P
Carbon Monoxide	630-08-0	211-128-3	R1	30		150				D	P
Cadmium and compounds (as Cd)	7440-43-9	231-152-8	C2	0.05		0.1		Cd, in urine Sampling Time Not critical 0.005 µmol/mmol creatinine Cd in blood, Sampling Time Not critical 0.045µmol/L		D	
Cadmium sulfate (as Cd)	10124-36-4	233-331-6	C2 M2 R2								
Cadmium sulfide (as Cd)	1306-23-6	215-147-8	C2								
Cadmium fluoride (as Cd)	7790-79-6	232-222-0	C2 M2 R2								
Cadmium chloride (as Cd)	10108-64-2	233-296-7	C2 M2 R2								
Cobalt and compounds (as Co)	7440-48-4	231-158-0	C2	0.05		0.1					
Cobalt (II) chloride (as Co)	7646-79-9	231-589-4	C2								
Cobalt (II) sulfate	10124-43-3	233-334-2	C2								
2-Chloro-1,3-Butadiene	126-99-8	204-818-0	C2	10		20				D	
1-Chloro-2,3-Epoxypropane	106-89-8	203-439-8	C2	1		2				D	S, P
Chloromethyl Methyl Ether	107-30-2	203-480-1	C1	0.003		0.006				D	P
α-Chloro-Toluene	100-44-7	202-853-6	C2	5		10					
Chromium(VI) compounds (as Cr)				0.05		0.1		total Cr, end of shift at end of workweek,			S, P following compounds are classified as CMR

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments[3] (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
								0.065 µmol/mmol creatinine			
Ammonium dichromate	7789-09-5	232-143-1	C2 M2 R2								
Sodium dichromate	10588-01-9	234-190-3	C2 M2								
Chromyl chloride	14977-61-8	239-056-8	C2 M2								
Potassium chromate	7789-00-6	232-140-5	C2								
Chromium (III) chromate	24613-89-6	246-356-2	C2								
Sodium chromate	7775-11-3	231-889-5	C2 M2 R2								
Strontium chromate	7789-06-2	232-142-6	C2								
Calcium chromate	13765-19-0	237-366-8	C2								
Chromium trioxide	1333-82-0	215-607-8	C1 M2								
Ammonium dichromate	7789-09-5	232-143-1	C2 M2 R2								
Potassium dichromate	7778-50-9	231-906-6	C2 M2								
C.I. Pigment Yellow 34	1344-37-2	215-693-7	R1								
Zinc chromates (as Cr) (including Potassium Zinc Chromate)	13530-65-9 11103-86-9 37300-23-5	236-878-9 234-329-8	C1								index no: 024-007-00-3
Chromyl dichloride	14977-61-8	239-056-8	C2 M2								
Diazomethane	334-88-3	206-382-7	C2	1		2					P
1,2-Dibromoethane	106-93-4	203-444-5	C2	1		2				D	P
Dibutyl Phtalate	84-74-2	201-557-4	C2	5		10					
1,2-Dichloroethane	107-06-2	203-458-1	C2	10		20				D	P

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments[3] (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Di-(2-ethylhexyl) Phtalate	117-81-7	204-211-0	R2	5		10					
N,N-Dimethylacetamide	127-19-5	204-826-4	R2	30		60				D	
N,N-Dimethylformamide	68-12-2	200-679-5	R2	30		60		N-Methyl formamide in urine, end of shift, 0.25 mmol/L creatinine		D	P
1,1-Dimethylhydrazine	57-14-7	200-316-0	C2	0.025		0.05				D	P
1,2-Dimethylhydrazine	540-73-8		C2							D	index no: 007-013-00-0, P
Dimethyl Sulfate	77-78-1	201-058-1	C2	0.1		0.5				D	P
Dinitrotoluene (all isomers)	25321-14-6	246-836-1	C2	0.75		1.5				D	P
2-Ethoxyethanol	110-80-5	203-804-1	R2	20		40				D	P
2-Ethoxyethyl Acetate	111-15-9	203-839-2	R2	25		50				D	P
Ethyleneimine	151-56-4	205-793-9	C2 M2	1		2				D	P
Ethylene Oxide	75-21-8	200-849-9	C2 M2	1		3				D	P
Hexachlorobenzene	118-74-1	204-273-9	C2	0.02		-				D	P
Hydrazine	302-01-2	206-114-9	C2	0.05		0.1				D	S, P

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments[3] (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Lead elemental	7439-92-1	231-100-4	R1	0.05		0.02		delta-aminolevulinic acid in urine Sampling Time Not critical 13 µmol/mmol creatinine or coproporphyrin in urine Sampling Time Not critical 0.035 µmol/mmol creatinine or plumbaemia 0.4 mg/L			P
Lead compounds (as Pb)				0.05		0.2					following compounds are classified as CR
Lead (II) methanesulfonate	17570-76-2		R1								Index No: 082-008-00-4
Lead azide	13424-46-9	236-542-1	R1								
Lead hexafluorosilicate	25808-74-6	247-278-1	R1								
Lead phosphate (as Pb)	7446-27-7	231-205-5	R1								
Lead acetate (as Pb)	301-04-2	206-104-4	R1								
Lead 2,4,6-trinitro-m-phenylene dioxide	15245-44-0	239-290-0	R1								
Lead arsenate [AsHO4Pb] (as AsHO4Pb)	7784-40-9	232-064-2	C1 R1								
Lead chromate (as Cr)	7758-97-6	231-846-0	R1								
C.I. Pigment Red 104 [Colour Index Constitution Number, C.I.77605.]	12656-85-8	235-759-9	R1								
4,4'-Methylenedianiline	101-77-9	202-974-4	C2	0.1		0.2				D	S, P

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments[3] (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Nickel carbonyl (as Ni)	13463-39-3	236-669-2	R2	0.01		0.02		Ni, in urine Sampling Time Not critical 0.077 µmol/mmol creatinine		D	P
Nickel - compounds (as Ni) (Excluding nickel carbonyl)				0.05		0.25					following compounds are classified as C
Nickel (II) sulfide	16812-54-7	240-841-2	C1								
Nickel subsulfide	12035-72-2	234-829-6	C1								
Nickelous oxide	1313-99-1	215-215-7	C1								
Nickel dioxide	12035-36-8	234-823-3	C1								
Dinickel trioxide	1314-06-3	215-217-8	C1								
Phenyl Hydrazine	100-63-0	202-873-5	C2	1		2				D	
2-Propennitrile	107-13-1	203-466-5	C2	2		6				D	P
β-Propiolactone	57-57-8	200-340-1	C2	1		2					P
Refractory Ceramic Fibres			C2	4							index No: 650-017-00-8
o-Toluidine	95-53-4	202-429-0	C2	5		10				D	P
Trichloroethene	79-01-6	201-167-4	C2	250		750		Trichloroacetic acid in urine, end of workweek, 70 µmol/mmol creatinine or trichloroethanol in urine, end of shift, 150 µmol/mmol creatinine		D	
Vinyl Chloride	75-01-4	200-831-0	C1	7.5		15					P
Hardwood dust			C2	2							

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☒ No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

Priority is granted to substances to which the workers are exposed predominantly by inhalation, without simultaneous exposure to other CM compounds. Biological availability (i.e., toxicokinetic) criteria are then applied in mutagens and in probably genotoxic carcinogens, while the availability of NOELs for organotoxic effects and their level is decisive in non-genotoxic carcinogens.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☒ 5 Availability of data on exposure
- ☒ 3 Availability of toxicological data
- ☒ 1 Number of persons exposed
- ☐ Severity of effects
- ☒ 2 Epidemiological evidence, including reported cases of ill-health in the workplace
- ☒ 6 Availability of measurement methods
- ☒ 4 Other (please explain)

  Read-across, Structural alerts, SAR prediction

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☒ Scientific experts
- ☐ Social partners – Employers
- ☐ Social partners – Workers
- ☒ Public authority - Ministry of Health
- ☐ Public authority - Ministry of Labour
- ☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☒	☐

General system for derivation of OELs of chemicals incl. CMR substances. Most information below hold for all chemical substances; the specificity of CMR substances is reflected in the phase of risk evaluation and in the mandatory protective measures related to the exposure of workers to carcinogens.

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☒ Short-term limit values

☐ Ceiling limit values

☒ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☐	☒

If yes, with which parties?

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) Do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
☒	☐

(ii) Other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	**No**
☒	☐

If yes, please provide the name, address and website details:

OEL commission at National Institute of Public Health in Prague; members of the commission are appointed also to assess health risk of chemicals and biocides.

www.szu.cz Website is now under reconstruction.

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

Information is extracted from:

1) The National Registry of Working Activities representing national system of mandatory work categorisation,
2) The National List of Priority Substances,
3) HEDSET (Harmonized Electronic Data SET)

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

General technical feasibility is one of criteria used in the process of OEL derivation; compliance in individual enterprises is evaluated by regional centers of public health.

(iii) compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	No
☒	☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	**No**
☐	☒

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	**No**
☐	☒

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	**No**
☐	☒

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary?

Yes	**No**
☒	☐

If yes, please specify:

Information extracted from 1) National Registry of Occupational Diseases, and 2) Registry of Subjects Occupationally Exposed to Carcinogens

In 1998 the Registry of Subjects Occupationally Exposed to Carcinogens (REGEX) has been established in the Czech Republic. The major objective of the REGEX is to collect, centralized, and analyzed data collected by the Hygienic Service for sake of supervision of risky works. The data such as length, intensity, route of exposures to known occupational carcinogens is collected at individuals' level and provided by the Regional Hygienic Stations and/or Public Health Institutes to the National Institute of Public Health at

Prague. The major objectives of the REGEX follow:

1) Analysis of trends in levels and types of occupational exposures to carcinogens in the Czech Republic
2) Evaluation of effects of past and current exposures to carcinogens on workers' health
3) Identification of factors associated with elevated exposures and/or elevated incidence of cancer.
4) Delivery of health care to subjects at risk of occupational cancer.

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used:

Yes	**No**
☐	☒

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

Yes	**No**
☒	☐

(iii) Other administrative or policy criteria (please describe)

Usually, an OEL value is set at first for an individual enterprise ("private OEL") through the Regional Public Health Authority, and feedback information (on feasibility, compliance and specified health issues) is required also through the medium of this regional center. If there is no feedback, the OEL is recommended as a value with national force.

h) Do you ever adopt OELs from other sources?

Yes	**No**
☒	☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

All available OEL values are used as one source of supportive data; in case of discrepancies, preference is given to:

1) values supported by available background documents;
2) more recently updated values;
3) values based on biological inference;
4) values recommended by EC,
5) technically-based limits (e.g., Germany TRKs) are used as tentative estimates of feasibility.

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☒ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☒ **No** ☐

The same general system for derivation of OELs of chemicals incl. CMR substances.

m) If yes, how often are limit values revised?
Please specify time period:

No time period specified. Re-evaluation is initiated by new epidemiological or experimental data. Official setting of OELs is bound to the amendment of the directive.

(Now we are preparing a new revision.)

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	☒

o) Is exposure monitoring mandatory?

Yes	No
☒	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☒	☐

If yes, please specify:

Recommended

q) Is biological monitoring included in the monitoring methods?

Yes	No
☒	☐

If yes, please specify:

Number of chromosomal aberrations is used as a group test either as a cross-section test or as a dynamic test, namely 1) in workers exposed to many potentially genotoxic substances or to a genotoxic substance through more than one route; 2) to verify the carcinogenic risk in dependence on the exposure level (airborne concentrations).

r) How is record keeping on the results of such measurements organised? (please describe)

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

OELs of all substances (CMR and hazardous substances) - IOELVs, BOELVs and national OELs - are in the same document:
Government Regulation No. 178/2001 Coll., determining conditions for occupational health protection as amended by Government Regulation No: 523/2002 Coll. and Government Regulation No: 41/2004 Coll.
(In Czech: Nařízení vlády č. 178/2001 Sb., kterým se stanoví podmínky ochrany zdraví zaměstnanců při práci, ve znění Nařízení vlády č. 523/2002 Sb. a Nařízení vlády č. 441/2004 Sb.)

They are available only in Czech.
http://www.mvcr.cz/sbirka/2001/sb068-01.pdf
http://www.mvcr.cz/sbirka/2002/sb180-02.pdf
http://www.mvcr.cz/sbirka/2004/sb145-04.pdf

A new Government Regulation is prepared and will come into force probably in April 2008.

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting	**x**		OEL commission at National Institute of Public Health (NIPH) in Prague
Methodology for developing measurement and analytical methods	**x**		OEL commission at National Institute of Public Health in Prague
Methodology for the derivation of OELs	**x**		OEL commission at National Institute of Public Health in Prague

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**x**		OEL commission at National Institute of Public Health in Prague
Measurement and analytical methods for individual substances	**x**		OEL commission at National Institute of Public Health in Prague, NRL for Biological Monitoring of Occupational Exposure to Chemical Compounds Centre of Occupational Health NIPH NRL for Analysis of Toxic Gases in Workplace Air Centre of Occupational Health NIPH NRL for Monitoring and Evaluation of Dust and Microclimate at Workplaces Centre of Occupational Health NIPH

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes ☒ **No** ☐

If yes, how are these limit values applied in practice?

See D s)

v) Are there any lists of reprotoxic substances?

Yes ☒ **No** ☐

REGULATION (EC) No.1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
Appendix 5 Point 30 — Toxic to reproduction: category1
Appendix 6 Point 30 — Toxic to reproduction: category 2

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Documentation of MAC in Czechoslovakia – Czechoslovak committee of MAC. Prague, 1969. 166 p. Editor: Institute of Industrial Hygiene and Occupational Diseases (in English)

The same documentation in Czech: "*Návrh nejvýše přípustných koncentrací chemických škodlivin v průmyslovém ovzduší*, Praha, 1969, 162 s."

From 1994 all documentations are as internal documents Centre of Occupational Health The National Institute of Public Health (NIPH)

Denmark

17 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Ceiling Limit	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Acrylamide	79-06-1	201-173-7	Carc2 Mut2	0,03	-						
Acrylonitrile	107-13-1	203-466-5	Carc2	4	2						
o-Anisidin	90-04-0	201-963-1	Carc2	0,5	0,1						
Asbestos	12172-67-7		Carc1	0,1 fibre/cm³							
Asbestos	12172-73-5										
Asbestos	77536-66-4										
Asbestos	77536-67-5										
Asbestos	77536-68-6										
Asbestos	132207-32-0										
Asbestos	132207-33-1										
Benomyle	17804-35-2	241-775-7	Mut2	5							
Benzene	71-43-2	200-753-7	Carc1	1,6	0,5					X	
Beryllium	7440-41-7	231-150-7	Carc2	0,001							
Benzylchlorid	100-44-7	202-853-6	Carc2	5	1				X		
Bis(chlormethyl)ether	542-88-1	208-832-8	Carc1	0,005	0,001						
1,3-Butadiene	106-99-0	203-450-8	Carc1 Mut2	22	10						
Cadmium	7440-43-9	231-152-8	Carc2	0,005							Powder, dust, smoke and inorganic compounds, calculated as Cd

[1] Please specify

[2] Please specify

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Ceiling Limit	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Captafol	2425-06-1	219-363-3	Carc2	0,1						X	
2-chlor-1,3-butadien	126-99-8	204-818-0	Carc2	3,6	1					X	
Diazomethan	334-88-3	206-382-7	Carc2	0,4	0,2						
1,2-Dibrom-3-chlorpropan	96-12-8	202-479-3	Carc2 Mut2	0,01	0,001						
1,2-Dibromethan	106-93-4	203-444-5	Carc2	1	0,1					X	
1,4-Dichlor-2-buten	764-41-0	212-121-8	Carc2	0,025	0,005					X	
1,2-Dichlorethan	107-06-2	203-458-1	Carc2	4	1					X	
1,1-dimethylhydrazin	57-14-7	200-316-0	Carc2	0,025	0,01					X	
Dimethylsulfat	77-78-1	201-058-1	Carc2	0,05	0,01					X	
2,4-Dinitrotoluen	121-14-2	204-450-0	Carc2	0,15	-					X	
2,6-Dinitrotoluen	606-20-2	210-106-0	Carc2	0,15	-					X	
Dinitrotoluen	610-39-9 25321-14-6	210-222-1 246-836-1	Carc2 Carc2	0,15	-					X	All isomers
Epichlorhydrin	106-89-8	203-439-8	Carc2	1,9	0,5					X	
2,3-epoxy-1-propanol	556-52-5	209-128-3	Carc2 Rep2	1	0,2						
Erionit - fibres	12510-42-8 66733-21-9		Carc1	0,5 fibres/cm³					X		
Ethylenimin	151-56-4	205-793-9	Carc2 Mut2	1	0,5					X	
Ethylenoxid	75-21-8	200-849-9	Carc2 Mut2	1,8	1						
Hexachlorbenzen	118-74-1	204-273-9	Carc2	0,025						X	
Hydrazine	302-01-2	206-114-9	Carc2	0,01	0,013					X	

Substance name	CAS number	EINECS number	C/M/R [3]	8 hour limit value		Short-term-limit value		Biological Limit Value[4]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Kulafledte stoffer, herunder creosot, creosotolie og anthrancenolie	65996-93-2	266-028-2	Carc2	0,2							
4,4'-Methylenbis(2-chloranilin)	101-14-4	202-918-9	Carc2	0,11	0,01					X	
4,4'-Methylendianilin	101-77-9	202-974-4	Carc2	0,8	0,1						
2-Nitropropan	79-46-9	201-209-1	Carc2	18	5						
Phenylglycidylether	122-60-1	204-557-2	Carc2	0,6	0,1					X	
Phenylhydrazin	100-63-0	202-873-5	Carc2	0,6	0,1					X	
β-Propiolacton	57-57-8	200-340-1	Carc2	1,5	0,1						
Propylenimin	75-55-8	200-878-7	Carc2	5	2					X	
1,2-Propylenoxid	75-56-9	200-879-2	Carc2 Mut2	12	5					X	
Stenkulstjærebeg	65996-93-2	266-028-2	Carc2	0,2	-						Volatile ingredients, benzene soluble part
Strontiumchromat	7789-06-2	232-142-6	Carc2	0,0005							Calculated as Cr
o-Toluidin	95-53-4	202-429-0	Carc2	9	2					X	
Trichlorethen	79-01-6	201-167-4	Carc2	55	10						
1,2,3-trichlorpropan	96-18-4	202-486-1	Carc2 Rep2	0,6	0,1					X	
Vinylbromid	593-60-2	209-800-6	Carc2	20	5						
Vinylchlorid	75-01-4	200-831-0	Carc1	3	1					X	

[3] Please specify
[4] Please specify

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☒

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

Earlier the OEL's were based on acute damages. Later research results showed the compound was also a carcinogenic/mutagenic.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

4☐ Availability of data on exposure

2☐ Availability of toxicological data

☐ Number of persons exposed

3☐ Severity of effects

1☐ Epidemiological evidence, including reported cases of ill-health in the workplace

☐ Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☒ Scientific experts

☐ Social partners – Employers

☐ Social partners – Workers

☐ Public authority - Ministry of Health

☒ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☒	☐

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☐ Short-term limit values

☒ Ceiling limit values

☐ Biological limit values

☐ No limit values

☒ Other (please explain) – **skin notation – cancer notation**

f) Is there a consultation?

Yes	**No**
☒	☐

If yes, with which parties?

A group called The Quality Group consisting of scientific experts from the following research institutes:
National Research Centre for Working Environment
Danish Working Environment Authority
Danish Veterinary and Food Administration
Department of Environmental Medicine – Odense University
Department of Working Medicine, Aarhus
Danish Environmental Protection Agency

The social partners of workers and employers are only involved when a protest is given.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	No
☐	☒

(ii) other approach, please describe them

Available material

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

	Yes	No
The Quality Group of scientific experts	☒	☐

If yes, please provide the name, address and website details:

The group consists of members from the research institutes mentioned below point 2b f. There is no address for the entire group.

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	No
☒	☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	No
☐	☒

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	No
☐	☒

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	No
☐	☒

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☒

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☒

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☒

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☒ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

EU (SCOEL), USA (ACGIH, NIOSH, OSHA, IARC), Germany (MAK), The Netherland's (DECOS), the Scandinavian countries, the Nordic Expert group (NEG) and Great Britain.

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☒ Longer time period ☒

Setting of an OEL for carcinogens and mutagens takes at least three years.

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☒ **No** ☐

m) If yes, how often are limit values revised?
Please specify time period:
Every second year.

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	☒

o) Is exposure monitoring mandatory?

Yes	No
☐	☒

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☐	☒

q) Is biological monitoring included in the monitoring methods?

Yes	No
☐	☒

r) How is record keeping on the results of such measurements organised? (please describe)

There is no request on making measurements, but if measurements are made the procedure of making the measurement must follow the guideline in Executive Order No. 908 of 27 September 2005 on Measures to Protect Workers from the Risks related to Exposure to Carcinogenic Substances and Materials at Work.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published?

In WEA-Guideline nr. C.0.1. Limit values for substances and materials

Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available?

The Guideline is published on www.at.dk in both Danish and English.

Is it/are they linked to other texts (for example legal documents)?

The guideline is linked to Consolidated Act No. 268 of 18 March 2005 Danish Working Environment Act

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting			
Methodology for developing measurement and analytical methods			
Methodology for the derivation of OELs			

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**X**		The documents are not available at www.at.dk but can be ordered by contacting the Danish Working Environment Authority.
Measurement and analytical methods for individual substances		**X**	It is possible that the National Research Centre for Working Environment can provide some information

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☒	☐

If yes, how are these limit values applied in practice?

Limits values are often applied because of other effects i.e. allergies or other acute effects. Only later it is discovered that the compounds are repro-toxic.

v) Are there any lists of reprotoxic substances?

Yes	No
☒	☐

The repro-toxic substances are included on the list of dangerous compounds and materials.

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Material can be provided by contacting the Danish Working Environment Authority

Estonia

13 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Arsenic and inorganic compounds except arsenic hydride (as As)	7440-38-2			0.03	-	-	-				Sulphur dioxide enhances the carcinogenic characteristics of arsenic. In the planning of new facilities or the alteration of old ones, an effort shall be made to ensure that exposure to arsenic and inorganic compounds in the course of working day is acceptable with reference to a time-weighted average concentration of 0.01 mg/m3.
Asbestos, except crocidolite (crysotile)	12001-29-5			-	0,1 Fibre/ ml	-	-				
Acetaldehyde (ethanal)	75-07-0			45	-	90	50				
Acetamide (Ethanamide)	60-35-5			25	10	60	25				
Benzene	71-43-2			1.5	0.5	9	3				
Benzo(a)pyrene (3,4 –benzopyrene)	50-32-8			0.002	-	0.02	-				
3,4-Benzopyrene	50-32-8			0.002	-	0.2	-				

[1] Please specify

[2] Please specify

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
(benzo(a)pyrene											
Benzyl chloride (Chlorophenylmethane)	100-44-7			5	1	11	2				
Beryllium and compounds (as Be)	7440-41-7			0.002	-	-	-				Metallic beryllium is not sensitising
1,3-butadiene (bivinyl)	106-99-0			1	0.5	10	5				
2,4-diisocyanato toluene (toluenediisocyanate, toluol-2,4-diisocyanate)	584-84-9			0.04	0.005	0.07*	0.01*				* Ceiling limit value The ceiling limit value is calculated on 5 minute period.
p-dichlorobenzene (1,4-dichlorobenzene)	106-46-7			450	75	700	110				
1,2-dichloroethane (Ethylene dichloride)	107-06-2			4	1	20	5				
Dichloromethane (Methylene chloride,MEK)	75-09-2			120	35	250	70				
Dimethylhydrazines	57-14-7, 540-73-8			0.2	0.1	0.5	0.2				
Dioxane	123-91-1			90	25	180	50				
Divinyl (1,3-butadiene)	106-99-0			1	0.5	10	5				
Epichlorohydrin (1-chloro-2,3-epoxypropane)	106-89-8			1.9	0.5	4	1				
Epoxyethane (ethylene oxide)	75-21-8			2	1	9	5				
1,2-epoxypropane (propylene oxide)	75-56-9			5	2	25	10				
Ethanamide (acetamide)	60-35-5			25	10	60	25				

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Ethane thiol (Ethyl mercaptan)	75-08-1			1	0.5	-	-				
Ethanal (Acetaldehyde)	75-07-0			45	25	90	50				
Ethylene dichloride (1,2-diochloroethane)	107-06-2			4	1	20	5				
Ethylene oxide (epoxy ethane)	75-21-8			2	1	9	5				
Hydrazine	302-01-2			0.1	0.1	0.4	0.3				
Cadmium and inorganic compounds (as Cd) total dust respirable dust	7440-43-9			 0.05 0.01	 - -	 - -	 - -				**Biological limit values exist for lead and cadmium only.**
1-chloro-2,3-epoxy propane (epiclorohydrin	106-89-8			1.9	0.5	4	1				
Chloriethene (Vinyl chlorife)	75-01-4			2.5	1	13	5				
Chloroform (trichloromethane)	67-66-3			10	2	-	-				
Chromates (as Cr)				0.02	-	-	-				
Chromic acid (as Cr)	1308-38-9			0.02	-	0.06	-				
Methanal (formaldehyde)	50-00-0			0.6	0.5	1.2*	1*				* Ceiling limit value
Methylene chloride (MEK, dichloromethane)	75-09-2			120	35	250	70				
Methyl iodides (Iodomethane)	74-88-4			6	1	30	5				
Nickel carbonyl	13463-39-3			0.007	0.001	-	-				
Nickel subsulphide, (as Ni)	12035-72-2										
Nickel compounds, oxide, carbonate and soluble compounds				0.1	-	-	-				

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
(as Ni)											
2-nitro-Propane	79-46-9			18	5	35*	10*				* Ceiling limit value
Perchloroethylene (tetrachloroethylene)	127-18-4			70	10	170	25				
Polychlorinated biphenyls				0.01	-	0.03	-				
Propenenitrile (Acrylonitrile)	107-13-1			4.5	2	13	6				
Propenal (Acrolein)	107-02-8			0.2	0.1	0.7	0.3				
Propylene oxide (1,2-epoxy propane)	75-56-9			5	2	25	10				
Wood dust				2	-	-	-				
Carbon tetrachloride (tetrachloromethane)	56-23-5			13	2	19	3				
Tetrachloroethylene (perchloroethylene	127-18-4			70	10	170	25				
Tetrachloromethane (carbon tetrachloride)	56-23-5			13	2	19	3				
Wood				2	-	-	-				
Toluene diisocyanate (toluool-2,4-diisocyanate, 2,4-diisocyanatotoluene)	584-84-9			0.04	0.005	0.07*	0.01*				* Ceiling limit value
Toluol-2,4-diisocyanate (toluene diisocyanate, 2,4-diisocyanatptoluene)	584-84-9			0.04	0.005	0.07*	0.001*				* Ceiling limit value
Trichloroethylene	79-01-6			50	10	140	25				
Trichlorophenol, salts				0.5	-	1.5	-				
Trichloromethane (chloroform)	67-66-3			10	2	-	-				
Trinickel disulphide	12035-72-2			0.01	-	-	-				
Vinyl chloride (chloroethene)	75-01-4			2.5	1	13	5				

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

There is not a specific procedure for OELS and we have not used any selection criteria. Our OELS have been taken over from the Swedish appropriate standards + the EU standards (the specific national legislation enclosed). There is not any specific scientific or other institution which has some kind of possibilities and abilities to deal with these things.

There is not anything to answer regarding the next questions

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No X☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☐ Availability of data on exposure
- ☐ Availability of toxicological data
- ☐ Number of persons exposed
- ☐ Severity of effects
- ☐ Epidemiological evidence, including reported cases of ill-health in the workplace
- ☐ Availability of measurement methods
- ☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☐ Scientific experts

☐ Social partners – Employers

☐ Social partners – Workers

☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

X☐ The EU OELs setting (if there will be some new OELs)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes **No X**

☐ ☐

e) Which kind of limit values are adopted?

X☐ 8-hour limit values

X☐ Short-term limit values

X☐ Ceiling limit values (for some substances)

X☐ Biological limit values (for cadmium and lead only)

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes X **No**

General matters only.

☐ ☐

If yes, with which parties?

Confederations of employers and trade unions.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
☐	X☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	**No**
☐	X☐

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

Via Chemical Notification Centre, National Labour Inspectorate, Estonian Technical Inspectorate.

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Via inspections visits.

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	**No**
☐	☐

Partly – yes.

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	**No**
☐	X☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes **No**
☐ X☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes **No**
☐ X☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary?

Yes **No**
☐ X☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used:

Yes **No**
☐ X☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

Yes **No**
☐ X☐

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes **No**
X☐ ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

As was mentioned, from the other national set of standards (Sweden).

i) Are limit values indicative or constraining?

☐ indicative

X☐ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

As was mentioned, OELs were taken over.

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** X☐

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	X☐

o) Is exposure monitoring mandatory?

Yes	No
X☐	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
X☐	☐

If yes, please specify:

The different specific measurement labs are using different applicable methods – no universal national methods.

q) Is biological monitoring included in the monitoring methods?

Yes	No
X☐	☐

If yes, please specify:

It depends on substance – it exists for some substances.

r) How is record keeping on the results of such measurements organised? (please describe)

Record keeping on the results of such measurement (as for all measurements in the context of OSH) is a task of employer.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

List of OELs for carcinogenic and mutagenic substances has been published in "Limit values for chemical hazards in the working environment" (Regulation N0 239 of the Government of Estonia of 18 September 2001 (enclosed). Availability of these documents is high (via web sites of the Ministry of Social Affairs and official governmental information bulletin (as a booklet too). Languages – Estonian, English. It is linked to Chemical Act.

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**X**	
Methodology for developing measurement and analytical methods	**X**		**Different measurement labs are using different applicable methods which are publicly available via these labs.**
Methodology for the derivation of OELs		**X**	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**X**		**Chemical Notification Centre (Gonsiori 29, Tallinn 1502) ; www.ktk.ee**
Measurement and analytical methods for individual substances			**Chemical Notification Centre**

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
X	☐

If yes, how are these limit values applied in practice?

These limit values applied in practice in same way as all limit values – levels of applications are quite different in different enterprises.

v) Are there any lists of reprotoxic substances?

Yes	No
X	☐

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Level of availability is relatively high, especially through the Internet.

Finland

19 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Acrylamide	79-06-1		C, M	0,3		0,9					
Acrylonitrile	107-13-1		C	4,4	2	8,8	4			X	
Arsenic acid and its salts	-		C	0,01							
Arsenic pentoxide	1303-28-2		C	0,01							
Arsenic trioxide	1327-53-3		C	0,01							
Asbestos			C	0,1							fibres/cm^3
Benomyl	17804-35-2		M, R	9,6	0,8	29	2,4				
Benzene	71-43-2		C	3,25	1					X	
Benzo(a)pyrene	50-32-8		C, M, R	0,01						X	
Benzyl chloride	100-44-7		C	2,6	0,5	1,5	7,9				ceiling
Bis(Chloromethyl)ether	542-88-1		C	0,005	0,001	0,014	0,003				
1-Bromopropane	106-94-5		R	150	30	310	60				
1,3-Butadiene	106-99-0		C, M	2,2	1						
Diazomethane	334-88-3		C	0,35	0,2	1	0,6				
Ethylene dibromide	106-93-4		C	0,78	0,1					X	
Ethylene dichloride	107-06-2		C	4	1	20	5			X	
Dimethylacetamide	127-19-5		R	36	10	72	20			X	

[1] Please specify

[2] Please specify

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Dimethylformamide	68-12-2		R	15	5	30	10			X	
1,1-Dimethylhydrazine	57-14-7		C			0,25	0,1			X	
Dimethyl sulfate	77-78-1		C			0,052	0,01			X	
Dinitrotoluene	25321-14-6		C	0,2						X	
Epichlorohydrin	106-89-8		C	1,9	0,5					X	
2-Ethoxyethanol	110-80-5		R	7,5	2					X	
2-Ethoxyethyl acetate	111-15-9		R	11	2					X	
Ethylenimine	151-56-4		C, M			0,89	0,5			X	
Ethylene oxide	75-21-8		C, M	1,8	1						
Ethylene thiourea	96-45-7		R	0,1		0,6					
Phenyl glycidyl ether	122-60-1		C	3,1	0,5					X	
Phenylhydrazine	100-63-0		C			22	5				
Formamide	75-12-7		R	19	10	37	20			X	
Glycidol	556-52-5		C, R	6,1	2					X	
Carbon monoxide	630-08-0		R	35	30	87	75				
Hydrazine	302-01-2		C	0,13	0,1	0,4	0,3			X	
Cadmium	7440-43-9		C	0,02						X	
Cadmium fluoride	7790-79-6		C, M, R	0,02						X	
Cadmium chloride	10108-64-2		C, M	0,02						X	
Cadmium oxide	1306-19-0		C	0,02						X	
Cadmium sulfate	10124-36-4		C, M, R	0,02						X	
Cadmium sulphide	1306-23-6		C	0,02						X	
Cadmium oxide, fume	1306-19-0		C	0,01						X	
Refractory ceramic fibres			C	0,2							fibres/cm^3
Chloroprene	126-99-8		C	3,7	1	18	5				

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Cobalt chloride	7646-79-9		C	0,05							
Cobalt sulphate	10124-43-4		C	0,05							
Ammonium dichromate	7789-09-5		C, M, R	0,05							
Potassium dichromate	7778-50-9		C, M, R	0,05							
Potassium chromate	7789-00-6		C, M	0,05							
Calcium chromate	13765-19-0		C	0,05							
Chromium (III) chromate	24613-89-6		C	0,05							
Chromium trioxide	1333-82-0		C, M	0,05							
Sodium dichromate	10588-01-9		C, M, R	0,05							
Sodium chromate	7775-11-3		C, M, R	0,05							
Zinc chromate	-			0,05							
Strontium chromate	7789-06-2		C	0,05							
Chromyl chloride	14977-61-8		C, M	0,5							
Lead acetate, basic	1335-32-6		R								
Lead azide	13424-46-9		R								
Lead diacetate	301-04-2		R								
Lead hexafluorosilicate	25808-74-6		R								
Lead chromate	7758-97-6		R								
Lead chromatemolybdate-sulphate red	12565-85-8		R								

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Lead tetraethyl	78-00-2		R	0,075		0,23				X	
Lead tetramethyl	75-74-1		R	0,075		0,23				X	
2-Methoxyethanol	109-86-4		R	1,6	0,5					X	
2-Methoxyethyl acetate	110-49-6		R	2,5	0,5					X	
4,4'-Methylene bis(2-chloroaniline) and its salts	101-14-1		C	0,22	0,02	0,67	0,06			X	
Nickel (II) oxide	1313-99-1		C	0,1							
Nickel subsulfide	12035-72-2		C	0,1							
Nickel carbonyl	13463-39-3		R	0,007	0,001	0,021	0,003				
2-Nitropropane	79-46-9		C	18	5	150	40				
2-Nitrotoluene	88-72-2		C, M	11	2	23	4				
Propylenimine	75-55-8		C			4,7	2			X	
Propylene oxide	75-56-9		C, M	12	5					X	
o-Toluidine	95-53-4		C		2		4			X	
Trichloroethylene	79-01-6		C	50	10					X	
1,2,3-Trichloropropane	96-18-4		C, R	18	3					X	
Vinyl bromide	593-60-2		C	4,4	1						
Vinyl chloride	75-01-4		C	7,7	3						
Warfarin	81-81-2		R	0,1		0,3					

Of course there is a binding limit value also for hard wood dust of 5 mg / cubic metre (according to the carcinogens directive)

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

* *Usually secretaries of the committee propose in case of new scientific knowledge - for carcinogens, mutagens and other substances as well*

* *Also EU SCOEL / EU directives may require national selection*

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

☐	6th	Availability of data on exposure
☐	2nd	Availability of toxicological data
☐	4th	Number of persons exposed
☐	3rd	Severity of effects
☐	1st	Epidemiological evidence, including reported cases of ill-health in the workplace
☐	5th	Availability of measurement methods
☐	7th	Other (please explain)
		National HPV; SCOEL document availability; Updates in other countries

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☐ Scientific experts

☐ Social partners – Employers

☐ Social partners – Workers

☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes ☐ **No** ☐

1)Health based OELs and 2)so called binding limit values

e) Which kind of limit values are adopted?

☐ 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes ☐ **No** ☐

If yes, with which parties?

- *Employers*
- *Employees*
- *Various ministries*
- *Various agencies*

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances **Yes** ☐ **No** ☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process? **Yes** ☐ **No** ☐

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

* *Contribution from employers' and employees' organizations, FIOH, common knowledge, national registry of chemical products etc.*

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

* *employer/employee consultation; national measurement registries; literature*

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☐

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☐ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

* e.g., European Union limit values. We don't necessarily adopt them as such, but we will produce national documents on them also for the discussion in the OEL committee

i) Are limit values indicative or constraining?

☐ *indicative*

☐ constraining

* *We have both types, see B2 d) above*

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☐

* *We usually produce OELs with a time span of 2 years*

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

- *Reaching consensus on proposals*
- *Lacking measurement methodology or national exposure data*

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** ☐

m) If yes, how often are limit values revised?
Please specify time period:

- *The target lately has been to revise the list of limit values every 2 years. The list of 2007 has 15 new substances with OEL, for 29 substances there was a change in OEL, and for another 19 substances the documentation was updated without the need to change the existing OEL.*

- *The list has been revised at least in 1962, 1972, 1981, 1987, 1993, 1996,1998, 2000, 2002, 2005, and 2007*

- *As for changes of OELs for specifically C/M/R substances, either due to this C/M/R property or some other undesired effect, a look at first 11 substances in table A above showed that for these substances between year 1962 and the present, a median value of 1 change and an*

arithmetic mean of ca. 1,5 changes was made. For one substance (asbestos) four changes had taken place, for another one three changes (benzene), for three substances two changes (arsenic, butadiene and ethylene dibromide). Some examples:

- *For butadiene the limit value of year 1962 was 1000 ppm and the present one 1 ppm*
- *For asbestos the limit value of 1972 was 5 fibres/ml and the present 0,1 fibres/ml*
- *For ethylene dibromide the limit value of 1962 was 25 ppm and the present 0,1 ppm.*

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes ☐ **No** ☐

European standards/norms

o) Is exposure monitoring mandatory?

* *If it is possible to assess the exposure otherwise, there need not be monitoring by measurements*

Yes ☐ **No** ☐

p) Are there specific measurement methods laid down, or recommended?

Yes ☐ **No** ☐

If yes, please specify:

* *The FIOH methods are recommended for other parties also*

q) Is biological monitoring included in the monitoring methods?

Yes ☐ **No** ☐

If yes, please specify:

* *FIOH methods are recommended*

r) How is record keeping on the results of such measurements organised? (please describe)

- *FIOH maintains a registry of air and biological monitoring measurement results which they have carried out*
- *Employers themselves*
- *Occupational health care services*
- *Labour inspectorate*

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

- *A biennial booklet is published on OELs ; also published legislation (especially for binding limit values)*
- *Both in Finnish and in Swedish*
- *Also in web*
- *They are linked to legal documents, yes*

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		***No***	
Methodology for developing measurement and analytical methods		***No***	
Methodology for the derivation of OELs		***No***	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	***Yes***		*Contact point address and web site exist (contact sender of this report)*
Measurement and analytical methods for individual substances	***Yes***		*FIOH*

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

	Yes	**No**
• *see table A for R substances*	☐	☐

If yes, how are these limit values applied in practice?

- *As the other OELs*
- *Also to achieve a so-called special maternity leave right, a risk assessment at workplace may be carried out. For chemical reprotoxicants, OELs are used. For some, exceeding OEL is the limit, for some a specified fraction of the OEL may be the action level to stop working during pregnancy depending on how reprotoxicity originally has been taken into account at the OEL setting of a specific substance*

v) Are there any lists of reprotoxic substances?

- *EU Classification for reprotoxicity*
- *Special maternity leave (social security) legislation*
- *OSH legislation from year 1991 contains lists of reprotoxicants*

Yes	**No**
☐	☐

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

- *For list of limit values see table A above for R substances*
- *Criteria documents available in a similar way as for other substances with OEL*
- *Guidebook for risk assessment for need of special maternity leave published by FIOH in co-operation with the ministry – recently updated*

Germany

30 October 2007

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☒

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☐ Availability of data on exposure
- ☐ Availability of toxicological data
- ☐ Number of persons exposed
- ☐ Severity of effects
- ☐ Epidemiological evidence, including reported cases of ill-health in the workplace
- ☐ Availability of measurement methods
- ☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☐ Scientific experts
- ☐ Social partners – Employers
- ☐ Social partners – Workers
- ☐ Public authority - Ministry of Health
- ☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	☒

Currently, no OEL for carcinogenic or mutagenic substances are derived in Germany. Nevertheless, a new concept for the derivation of OEL is under discussion. This concept is based on two threshold values; an "acceptable threshold" and a "tolerable threshold", which define three regions representing different risk levels.
Within this "traffic light" approach, exposures below an "acceptable threshold" are associated with risks that are regarded acceptable, besides basic measures such as standard hygiene or risk communication no further risk reduction measures are necessary. Risks are regarded as tolerable, that result from exposures between the "acceptable threshold" and the "tolerable threshold", predominantly measures are requested that reduce these exposures and therefore risks. In those cases, where the "tolerable threshold" is exceeded, risks are intolerable and risk reduction measures are necessary immediately.
The derivation of limit values within this concept will primarily be based on toxicological and epidemiological data and will take into account the severity of the effect(s). The adopted values will be defined as 8-hour values.

e) Which kind of limit values are adopted?

☐ 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☐	☐

If yes, with which parties?

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances **Yes** ☐ **No** ☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process? **Yes** ☐ **No** ☐

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☐

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☐ **No** ☒

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

i) Are limit values indicative or constraining?

☐ indicative

☐ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** ☒

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes ☐ **No** ☐

o) Is exposure monitoring mandatory?

Yes ☐ **No** ☐

p) Are there specific measurement methods laid down, or recommended?

Yes ☐ **No** ☐

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes ☐ **No** ☐

If yes, please specify:

r) How is record keeping on the results of such measurements organised? (please describe)

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting			
Methodology for developing measurement and analytical methods			
Methodology for the derivation of OELs			

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances			
Measurement and analytical methods for individual substances			

Actually there are neither OEL for carcinogenic/mutagenic substances in Germany nor is there a national system for the derivation of such OEL. Nevertheless, such a system is under development but not yet installed. A concept is discussed that is based on a scientific expertise and that takes into account basically e.g. epidemiological and toxicological data and severity of effects. In addition, social partners (workers and employers) as well as the ministry of labour will be able to comment on those scientific proposals.
Based on two separate risk levels regarded as “tolerable” or “acceptable”, a splitted OEL will be derived. Exposures below an “acceptable” level will only be related to basic measures such as hygienic measures. Exposures between the “acceptable” level and a “tolerable” level will temporarily be tolerated but need to be reduced. Exceeding the tolerable” level will mean, that these exposures are not tolerable and that risk reduction measures have to be taken immediately.

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	☒

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☐	☒

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Greece

21 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Benzene	71-43-2	200-753-7	C1,M2	3,19	1,00	-	-	-	-	S	Constraining
Vinyl chloride	75-01-4	200-831-0	C1	7,64	3,00	-	-	-	-	-	Constraining
Hardwood dust	-	-		4,92	-	-	-	-	-	-	Constraining

[1] Please specify
[2] Please specify

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☒ No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

Harmonization of Greek legislation with EU directives by introducing the recommended limit values of EU characterized carcinogenic substances as constraining limit values.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☐ Availability of data on exposure
- ☐ Availability of toxicological data
- ☐ Number of persons exposed
- ☐ Severity of effects
- ☐ Epidemiological evidence, including reported cases of ill-health in the workplace
- ☐ Availability of measurement methods
- ☒ Other (please explain)

EU directives

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☐ Scientific experts
- ☐ Social partners – Employers
- ☐ Social partners – Workers

☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☒ Other (please explain)

The General Directorate of Occupational Health and Safety of the Greek Ministry of Labour, other Ministries, the General Confederation of workers, the Trade Union, the Greek Medical Association, the Technical chamber of Greece, Union of Greek chemists, two experts in Occupational Health & Safety.

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	☒

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☒	☐

If yes, with which parties?

The General Directorate of Occupational Health and Safety of the Greek Ministry of Labour, other Ministries, the General Confederation of workers, the Trade Union, the Greek Medical Association, the Technical chamber of Greece, Union of Greek chemists, two experts in Occupational Health & Safety.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances **Yes** ☐ **No** ☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process? **Yes** ☐ **No** ☐

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☐

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☐ **No** ☒

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☒ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** ☒

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes ☐ **No** ☒

o) Is exposure monitoring mandatory?

Yes ☒ **No** ☐

p) Are there specific measurement methods laid down, or recommended?

Yes ☐ **No** ☒

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes ☐ **No** ☒

If yes, please specify:

r) How is record keeping on the results of such measurements organised? (please describe)

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

In the gazette f Government as presidential decrees.
In the ministry's webpage in Greek.

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**X**	
Methodology for developing measurement and analytical methods		**X**	
Methodology for the derivation of OELs		**X**	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances		**X**	
Measurement and analytical methods for individual substances		**X**	

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	☒

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☐	☒

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Italy

9 November 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Benzene	71-43-2	200-753-7		3,25	1					Skin	Annex VIII-bis Legislative Decree N.66/2000; constraining OEL
Vinyl chloride monomer	75-01-4	200-831		7,77	3						Annex VIII-bis Legislative Decree N.66/2000; constraining OEL
Wood dust	–	–		5,00							Annex VIII-bis Legislative Decree N.66/2000; constraining OEL
Asbestos	13330-21-4			0,1 f/cc							Legislative Decree N. 257/2006 and title VI bis of Legislative Decree 626/1994; constraining OEL
Asbestos actinolite	77536-66-4	650-013-00-6		0,1f/cc							Legislative Decree N. 257/2006 and title VI bis of Legislative Decree 626/1994, constraining OEL
Asbestos amosite	12172-73-5	"		0,1f/cc							Legislative Decree N. 257/2006 and title VI bis of Legislative Decree 626/1994; constraining OEL
Asbestos antofillite	77536-67-5	"		0,1f/cc							Legislative Decree N. 257/2006 and title VI bis of Legislative Decree 626/1994, constraining OEL
Asbesto crisotilos	12001-29-5	"		0,1f/cc							Legislative Decree N. 257/2006 and title VI bis of Legislative Decree 626/1994; constraining OEL
Asbestos crocidolite	12001-28-4	"		0,1f/cc							Legislative Decree N. 257/2006 and title VI bis of Legislative Decree 626/1994; constraining OEL
Asbestos tremolite	77536-68-6	"		0,1f/cc							Legislative Decree N. 257/2006 and title VI bis of Legislative Decree 626/1994; constraining OEL

[1] Please specify
[2] Please specify

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No X

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

5 Availability of data on exposure

3 Availability of toxicological data

4 Number of persons exposed

1 Severity of effects

2 Epidemiological evidence, including reported cases of ill-health in the workplace

6 Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

X Scientific experts

☐ Social partners – Employers

X Social partners – Workers

X Public authority - Ministry of Health

X Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
X	☐

e) Which kind of limit values are adopted?

X 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
X	☐

If yes, with which parties?

1. The "Commissione Consultiva permanente per la prevenzione degli Infortuni e l'igiene del lavoro" at the Ministry of Labour and Social Security, composed by scientific experts from different Institutions (Ministry of Labour and Social Security, ISPESL, ISS, INAIL, CNR, UNI, CEI, ANPA, Ministry of Health),
2. Delegates of the Standing Conference for the Relationships between State and Regions,
3. Experts nominated by workers' and employers' representatives.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
☐	X

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	**No**
X	☐

If yes, please provide the name, address and website details: ISPESL –Via Urbana 167, 00184 Roma, website www.ispesl.it; ISS –Viale Regina Margherita 299, 00161 Roma, website www.iss.it, AIDII- Via Morgagni Giovanni Battista 32, 20129 Milano, website www.aidii.it; SIMLII- website www.simlii.net

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	**No**
X	☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	**No**
☐	X

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	**No**
☐	X

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	**No**
☐	X

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health

described in terms other than monetary? **Yes** ☐ **No** X

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** X

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** X

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes X **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

ACGIH
CEN
WHO

i) Are limit values indicative or constraining?

☐ indicative

X constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period X

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

To combine the different requirements of interested parties

B3) Revision of OEL for carcinogenic and mutagenic substances

	Yes	No
l) Is there a specific procedure for the revision of OELs?	**X**	☐

m) If yes, how often are limit values revised?
Please specify time period:

Over 3 years

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
X	☐

o) Is exposure monitoring mandatory?

Yes	No
X	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
X	☐

If yes, please specify:

ISO UNI EN Harmonized Norms

q) Is biological monitoring included in the monitoring methods?

Yes	No
X	☐

If yes, please specify:

Biomarkers of dose and effect: Guidelines for medical surveillance of workers occupationally exposed to carcinogens, set up by the Italian Society (SIMLII) in the year 2003
Guidelines for biological monitoring of workers occupationally exposed to chemical agents, set up by the Italian Society (SIMLII) in the year 2005

r) How is record keeping on the results of such measurements organised? (please describe)

The results of such measurements are reported in the Document of risk assessment and in the Register of the exposed workers

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

Annual TLV book from AIDII (Italian version of ACGIH TLV): it can be purchased on website www.aidi.it.

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting			
Methodology for developing measurement and analytical methods			
Methodology for the derivation of OELs			

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances			
Measurement and analytical methods for individual substances			

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	X

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☐	X

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Latvia

30 October 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Chromium trioxide	1333-82-0	215-607-8	C – cat. 1; M – cat. 2.	0,01							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
Butane	106-97-8	203-448-7	C - cat. 1	300							Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers. In the dangerous chemical substance list a general designation of the following type is sometimes used. In this case the manufacturer or any other person who markets such a substance must state on the label whether the substance is a specific isomer (a) or a mixture of isomers (b).

[1] Please specify
[2] Please specify

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
											A label is not necessary for such chemical substances.
1,3-Butadiene; buta-1,3-diene	106-99-0	203-450-8	C - cat. 1	100							Certain substances, which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the manufacturer or any person who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".
Benzene	71-43-2	200-753-7	C – cat. 1; M – cat. 2	3,25	1			determine phenol in urine in the end of work (BER 25 µg/g creatinine)		X	Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
Vinyl chloride; chloroethylene	75-01-4	200-831-0	C - cat. 1	7,77	3						
Asbestos	132207-33-1 132207-32-0 12172-73-5 77536-66-4 77536-68-6 77536-67-5		C - cat. 1	0,1 fibre /cm^3 air							

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Beryllium	7440-41-7	231-150-7	C - cat. 2	0,001							
Hydrazine	302-01-2	206-114-9	C - cat. 2	0,1							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
Dimethyl sulphate	77-78-1	201-058-1	C - cat. 2	0,1							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
Chromium III chromate; chromic chromate	24613-89-6	246-356-2	C - cat. 2	0,01							
Isoprene	78-79-5	201-143-3	C - cat. 2	40							Certain substances, which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the manufacturer or any person who places such a substance on the market must state on the label the name of the substance followed

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
											by the words "non-stabilised".
Benzo[a]pyren; benzo[d,e,f]chrysene	50-32-8	200-028-5	C - cat. 2; M – cat. 2; R – cat. 2.	0,00015							
1,2-dichloroethane; ethylene dichloride	107-06-2	203-458-1	C - cat. 2	10							
Trichloroethylene; trichloroethene	79-01-6	201-167-4	C - cat. 2	10							
α-chlorotoluene; benzyl chloride	100-44-7	202-853-6	C - cat. 2	5							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
1,2,3-trichlorpropane	96-18-4	202-486-1	C - cat. 2; R – cat. 2.	2							Certain substances, which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the manufacturer or any person who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Hexachlorobenzene	118-74-1	204-273-9	C - cat. 2	0,9							
Ethylene oxide; oxirane	75-21-8	200-849-9	C - cat. 2; M – cat. 2.	1							
1-chloro-2,3-epoxypropane; epichlorhydrin	106-89-8	203-439-8	C - cat. 2	1							
Propylene oxide; 1,2-epoxypropane	75-56-9	200-879-2	C - cat. 2; M – cat. 2.	1							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
Furan	110-00-9	203-727-3	C - cat. 2	0,5							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
Acrylonitrile	107-13-1	203-466-5	C - cat. 2	0,5							D, Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
2,4-	121-14-2	204-450-0	C - cat. 2	1							Substances with specific effects on

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Dinitrotoluene											human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
2,6-Dinitrotoluene	606-20-2	210-106-0	C - cat. 2	1							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
3,4-dinitrotoluene	610-39-9	210-222-1	C - cat. 2	1							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
2-nitrotoluene	88-72-2	201-853-3	C - cat. 2; M – cat. 2.	3							Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).
o-toluidīns	95-53-4	202-429-0	C - cat. 2	0,5		1					
Ethyleneimine; aziridine	151-56-4	205-793-9	C - cat. 2; M – cat. 2.	0,02							

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Acrylamide	79-06-1	201-173-7	C - cat. 2; M – cat. 2.	0,2							
Gasoline, natural; Naphtha with a low boiling point	8006-61-9	232-349-1	C - cat. 2	100		300					A substance need not be classified as carcinogenic if it can be shown that the substance contains less than 0.1% w/w benzene [EINECS No.200-753-7]
Petrol (gas)	8030-30-6	232-443-2	C - cat. 2	100							A substance need not be classified as carcinogenic if it can be shown that the substance contains less than 0.1% w/w benzene [EINECS No.200-753-7]
Naphtha; Naphtha with a low boiling point	8030-30-6	232-443-2	C - cat. 2	10							A substance need not be classified as carcinogenic if it can be shown that the substance contains less than 0.1% w/w benzene [EINECS No.200-753-7]
Ligroine; Naphtha with a low boiling point	8032-32-4	232-453-7	C - cat. 2	300							A substance need not be classified as carcinogenic if it can be shown that the substance contains less than 0.1% w/w benzene [EINECS No.200-753-7]
Naphtha (petroleum), heavy, hydrodesulphurised; Hydrogen treated naphtha with a low boiling point	64742-82-1	265-185-4	C - cat. 2	200		300					A substance need not be classified as carcinogenic if it can be shown that the substance contains less than 0.1% w/w benzene [EINECS No.200-753-7]

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Carbon monoxide	630-08-0	211-128-3	R – cat. 1	20							
Warfarin; 4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin	81-81-2	201-377-6	R – cat. 1	0,001							
Nickel tetracarbonyl	13463-39-3	236-669-2	R – cat. 2	0,0005							
1,2-dimetoxyetethane	110-71-4	203-794-9	R – cat. 2	10							
2-ethoxyethanol; ethylene glycol monoethylether	110-80-5	203-804-1	R – cat. 2	10							
Dibutyl phthalate; DBP	84-74-2	201-557-4	R – cat. 2	0,5							
N,N-dimethylformamide; dimethyl formamide	68-12-2	200-679-5	R – cat. 2	30		45					
N, N-Dimethylacetamide	127-19-5	204-826-4	R – cat. 2	36	10	72	20			X	Substances with specific effects on human health that are classified as carcinogenic, mutagenic or toxic for reproductive system in Categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn).

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
o-toluidine	95-53-4	202-429-0	C - cat. 2	0,5		1					
Hardwood dust	-	-	C	5,0 inhale							

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☒

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

Chemical substances for OELs are selected joint without specific procedure for CMR substances.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

1☐ Availability of data on exposure

3☐ Availability of toxicological data

2☐ Number of persons exposed

4☐ Severity of effects

5☐ Epidemiological evidence, including reported cases of ill-health in the workplace

6☐ Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☒ Scientific experts

☒ Social partners – Employers (Employers' Confederation of Latvia)

☒ Social partners – Workers (Free Trade Union Confederation of Latvia)

☒ Public authority - Ministry of Health

☒ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☒	☐

OELs for CMR substances are set not separately but within OEL for all chemicals (last update - Cabinet Regulation No. 325 Adopted 15 May 2007 „Labour Protection Requirements when in Contact with Chemical Substances at Workplaces")

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☒ Short-term limit values

☐ Ceiling limit values

☒ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☒	☐

If yes, with which parties?
Governmental organizations (Ministry of Welfare, Ministry of Health, Ministry of Environment), Social partners (Employers' Confederation, Free Trade Union Confederation), NGOs

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
☐	☒

(ii) other approach, please describe them

Evaluation of existing toxicological data according to OECD guidelines, evaluation of OEL values in other countries, consultation within partners, agreement on indicative or constraining value

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes ☒ **No** ☐

If yes, please provide the name, address and website details:
Technical Committee No 19 "Work Environment" of National Standardisation body "Latvijas Standarts"; http:/www.lvs.lv/lv/tc/tc_EP.html

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

Information from State Labour Inspection and Department of Chemical Substances of Ministry of Environment State agency "Latvian Environment, geology and meteorology agency"

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

According to results of risk assessment made by Competent Organisations (at present accepted 31 CO in Latvia)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☒ **No** ☐

Compliance can be achieved in this manner partly sometimes

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☒

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☒

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☒

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☒

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** **No**

Data in Register of Occupational Diseases (CA cases, exposure);
Data in State Cancer Register (CA cases without analyse of data in connection with exposure and job) ☒ ☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☒

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☒ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:
- *Scientific Board of Nordic Countries (OEL setting in Sweden, Norway, Denmark and Finland);*
- *Russian Commission on Occupational Health and OEL setting;*
- *"MAK werte" setting in Germany.*

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☒

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

- *experimental evaluation of toxicity;*
- *epidemiological study of impact of chemicals on health (uncertainty within groups exposed and co-factors).*

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** **No**

☐ ☒

m) If yes, how often are limit values revised?
Please specify time period:

OELs are revised after receiving new imformation from EC (including information from prof. Maija Eglite, participant of EC Scientific Committee for Occupational Exposure Limits) without official l specific procedure for revision.

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes ☒ **No** ☐

Cabinet Regulation No. 325 Adopted 15 May 2007 „Labour Protection Requirements when in Contact with Chemical Substances at Workplaces"
Cabinet Regulation No. 539 Adopted 27 December 2001 „Regulations regarding Requirements for Labour Protection When in Contact with Carcinogenic Substances at Workplaces"

o) Is exposure monitoring mandatory?

Yes ☒ **No** ☐

p) Are there specific measurement methods laid down, or recommended?

Yes ☐ **No** ☒

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes ☒ **No** ☐

If yes, please specify:

According to Regulation of Cabinet of Ministers No 325/2007 are defined biological exposure indices (BER) for benzene, chromium, cadmium.

r) How is record keeping on the results of such measurements organised? (please describe)

According to Regulations of Cabinet of Ministers No 325/2007 and No 539/2001 is defined time of data keeping (40 years) and after arhivation in connection with law.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

Cabinet Regulation No. 325 Adopted 15 May 2007 „Labour Protection Requirements when in Contact with Chemical Substances at Workplaces"
http://osha.lv/legislation
Latvian version is available now, but translation is in process and will be is available soon.

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**x**	
Methodology for developing measurement and analytical methods		**x**	
Methodology for the derivation of OELs		**x**	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances		**x**	
Measurement and analytical methods for individual substances		**x**	

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☒	☐

If yes, how are these limit values applied in practice?

OELs are defined united for Chemical substances within Regulation of Cabinet of Ministers No 325/2007 and in this regulation are included reprotoxic substances too.

v) Are there any lists of reprotoxic substances?

Yes	No
☒	☐

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

- Directive 76/769 EEK and Regulations of Cabinet of Ministers within implementation (Cabinet Regulation No. 158 Adopted 25 April 2000 „Regulations regarding Restrictions and Prohibitions on Use and Marketing of Dangerous Chemical Substances and Dangerous Chemical Preparations")

- Materials of EC Scientific Committee for Occupational Exposure Limits;
- Criteria documents of Nordic Council;
- Scientific literature in different data basis (NIOSH, OSHA, IOM, EPA).

Lithuania

15 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Acetaldehyde	75-07-0	200-836-8	K	45	25	90	50	-	-		
Acetamide	60-35-5	200-473-5	K	25	10	60	25	-	-		
Acrylamide	79-06-1	201-173-7	K M	0,03	-	0,1	-	-	-		
Acrylonitrile	107-13-1	203-466-5	K	4,5	2	13	6	-	-		
Carbon disulphide	75-15-0	200-843-6	K	16	5	25	8		-		
Carbon tetrachloride	56-23-5	200-262-8	K	13	2	19	3	-	-		
Aniline	62-53-3	200-539-3	K	4	1	8	2	-	-		
Arsenic and it's inorganic compounds (as As)	7440-38-2 metalic	231-148-6	K	0,03	-	-	-	-	-		
Asbestos (all varieties)			K	0,1 f/cm^3	- -	- -	- -	- -			
Benzo[def]chrysene	50-32-8	200-028-5	K M	0,002	-	0,02	-	-	-		
Benzene	71-43-2	200-753-7	K	3,25	1	19	6	-	-		
α-chlorotoluene Benzilo chloridas	100-44-7	202-853-6	K	5	1	11	2	-	-		
Beryllium and its compounds	7440-41-7 metalinis	231-150-7	K	0,002	-	-	-	-	-		
Buta-1,3-diene	106-99-0	203-450-8	K	1	0,5	10	5	-	-		
Chloroform	67-66-3	200-663-8	K	10	2	25	5	-	-		
Chromium (VI) compounds (as Cr)			K	0,005	-	0,015	-	-	-		
Chromium trioxide Chromo rūgštis (kaip Cr)	1333-82-0	215-607-8	K	0,005	-	0,015	-	-	-		
1,2-dichloroethane	107-06-2	203-458-1	K	4	1	20	5	-	-		
1,4-dioxane	123-91-1	204-661-8	K	35	10	90	25	-	-		

[1] Please specify

[2] Please specify

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Hardwood dust Dulkės kietosios medienos			K	5	-	-	-	-	-		
1-chloro-2,3-epoxypropane Epichlorhidrinas	106-89-8	203-439-8	K	1,9	0,5	4	1	-	-		
1,2-dichloroethane	107-06-2	203-458-1	K	4	1	20	5	-	-		
Etileniminas Aziridine	151-56-4	205-793-9	M	-	-	-	-		ceiling value 0,02 mg/m3		
Ethylene oxide	75-21-8	200-849-9	K M	2	1	9	5	-	-		
Formaldehyde	50-00-0	200-001-8	K	0,6	0,5	-	-		ceiling value 1 mg/m3 , 1,2 ppm		
Phosphorus Fosforas geltonasis	7723-14-0	231-768-7	K	0,03	-	-	-	-	-		
Mercury, Gyvsidabris, garai	7439-97-6	231-106-7	K	0,03	-	-	-	-	-		
Cadmium and its inorganic compounds Kadmis ir jo neorganiniai junginiai (kaip Cd): Breathable fraction Alveolar fraction	7440-43-9 metalic	231-152-8	K	 0,05 0,01	 - -	 - -	 - -	 - -	 - -		
Dichloromethane Metileno chloridas	75-09-2	200-838-9	K	120	35	250	70	-	-		
Trinickel disulphide Nikelio subsulfidas (trinikelio disulfidas)	12035-72-2	234-829-6	K	0,01							
2-nitropropane 2-nitropropanas	79-46-9	201-209-1	K	7	2	-	-		ceiling value 20 mg/m3 and 6 ppm		
Ethylene oxide Oksiranas (etilenoksidas)	75-21-8	200-849-9	K	2	1	9	5	-	-		
Tetrachloroethylene Perchloretilenas	127-18-4	204-825-9	K	70	10	170	25	-	-		

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
(tetrachloretilenas)											
Polychlorinated biphenyls Polichloruoti bifenilai (PCB)			K	0,01	-	0,03	-	-			
Methyloxirane Propileno oksidas	75-56-9	200-879-2	K	5	2	25	10	-	-		
Radon in underground work and other work Radonas, požeminiuose darbuose; kituose darbuose			K	400 Bq/m3	- -	- -	- -	- -			
Tetrachloroethane Tetrachloretanas	25322-20-7	246-842-4	K	5	-	-	-	-	-		
Tetrachloroethylene Tetrachloretilenas (perchloretilenas)	127-18-4	204-825-9	K	70	10	170	25	-	-		
Trinickel disulphide Trinikelio disulfidas (nikelio subsulfidas) (kaip Ni)	12035-72-2	234-829-6	K	0,01	-	-	-	-	-		
Vinyl chloride Vinilo chloridas	75-01-4	200-831-0	K	7,77	3	-	-	-	-		

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes X No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.
All carcinogens and mutagenic substances are selected according their toxicity. They are included in the list of toxic (poisonous) substances (Order of Ministry of Health Care, 30 December 2004 on the approval of the list of toxic (poisonous) substances according to their toxicity. Official gazette (2005, No. 3–47)).

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

☐ Availability of data on exposure

☐ Availability of toxicological data

☐ Number of persons exposed

☐ Severity of effects

☐ Epidemiological evidence, including reported cases of ill-health in the workplace

☐ Availability of measurement methods

X Other (please explain)
OEL's are selected according requirements of EU directives and the criteria are based on the experience of other EU countries.

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☐ Scientific experts

☐ Social partners – Employers

☐ Social partners – Workers

☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

X Other (please explain)

Temporary joint working group of specialists. The specialists are delegated by Ministry of Health Care and Ministry of Social Security and Labour, State Labour Inspectorate.

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	X

e) Which kind of limit values are adopted?

X 8-hour limit values

X Short-term limit values

X Ceiling limit values

X Biological limit values (for lead (Pb))

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
X	☐

If yes, with which parties?
Ministry of Health Care, Social Security and Labour, State Labour Inspectorate.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation
(i) do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
☐	**X**

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	**No**
☐	**X**

If yes, please provide the name, address and website details:

Technical Feasibility criteria?
How do you identify which:
(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☐

Socio-Economic Feasibility criteria ?

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☐

(iii) Other administrative or policy criteria (please describe). The criteria on the accepatbility of occupational risk are set in normative document Order of Ministry of Social Security and Labour and Ministry of Health Care, 16 October 2003 on the approval of regulations on occupational risk. Official gazette (2003, No. 100–4504).

h) Do you ever adopt OELs from other sources?

Yes	No
X	☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:
OEL's are adopted on the legal basis of other EU countries. This procedure laid down in normative document Order of Ministry of Health Care and Ministry of Social Security and Labour, 13 December 2001 on the Hygiene Norm HN 23:2001 Concentration limit values of harmful chemical substances in the air of working environment. Official gazette (2001, Nr. 110–4008). Must be replaced to Hygiene Norm HN 23:2007 Concentration limit values of chemical substances in the air of working environment (Draft).Usually there are adopted quite strict values of OEL's. Majority OEL's values are adopted from Statute Book of the Swedish work Environment Authority (AFS 2005:17).

i) Are limit values indicative or constraining?

☐ indicative

X constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year X 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs?

Yes	No
X	☐

m) If yes, how often are limit values revised?
Please specify time period: 5 years

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
X	☐

o) Is exposure monitoring mandatory?

Yes	No
X	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
X	☐

If yes, please specify:

Order of Ministry of Health Care, 13 January 2006 on methodical recommendations of determination of concentration of asbestos fibres in workplace air. Official gazette (2006, No. 13–461).

Standard of Lithuania LST ISO 8672:2001 en. Air quality. Determination of the number concentration of airborne inorganic fibres by phase contrast optical microscopy. Membrane filter method (identical ISO 8672 :1993). Vilnius: Lithuanian Standardisation Service.

Order of Ministry of Health Care, 7 June 2000 on the approval of methods ((1) determination of the concentration of vinyl chloride monomer in the workplace air by the method of gas chromatography ; (2) Determination of concentration of lead and lead compounds in the workplace air by the method of electrothermal atomic absorption spectrometric method ; (3) Determination of concentration of lead in blood by the method of electrothermal atomic absorption spectrometric method. Official gazette (2000, No. 57–1692).

Standard of Lithuania LST ISO 9487 :2003 en. Workplace air. Determination of vaporous aromatic hydrocarbons. Charcoal tube/solvent desorption/gas chromatographic method (identical ISO 9487 :1991). Vilnius: Lithuanian Standardisation Service.

Standard of Lithuania LST ISO 9486 :2003 en. Workplace air. Determination of vaporous chlorinated hydrocarbons. Charcoal tube/solvent desorption/gas chromatographic method (identical ISO 9486 :1991). Vilnius: Lithuanian Standardisation Service.

Standard of Lithuania LST ISO 8518 :2003 en. Workplace air. Determination of particulate lead and lead compounds. Flame or electrothermal atomic absorption spectrometric method (identical ISO 8518 :2001). Vilnius: Lithuanian Standardisation Service.

Standard of Lithuania LST ISO 8762 :2003 en. Workplace air. Determination of vinyl chloride. Charcoal tube/gas chromatographic method (identical ISO 8672 :1988). Vilnius: Lithuanian Standardisation Service.

Is biological monitoring included in the monitoring methods?

Yes	No
☐	X

If yes, please specify:

q) How is record keeping on the results of such measurements organised? (please describe)

The records are keeping by the measurements' laboratories and the employer or customer.

Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

Order of Ministry of Health Care and Ministry of Social Security and Labour, 13 December 2001 on the Hygiene Norm HN 23:2001 Concentration limit values of harmful chemical substances in the air of working environment. Official gazette (2001, No. 110–4008). Must be replaced to Hygiene Norm HN 23:2007 Concentration limit values of chemical substances in the air of working environment (Draft).

Order of Ministry of Social Security and Labour, 16 July 2004 on the approval of regulations on work with asbestos. Official gazette (2004, No. 116–4342).

Order of Ministry of Health Care, 30 December 2004 on the approval of the list of toxic (poisonous) substances according to their toxicity. Official gazette (2005, No. 3–47).

Order of Ministry of Social Security and Labour and Ministry of Health Care, 16 October 2003 on the approval of regulations on occupational risk. Official gazette (2003, No. 100–4504).

Order of Ministry of Social Security and Labour and Ministry of Health Care, 24 July 2001 on the approval of regulation on the protection of workers from risks related to exposure to carcinogens or mutagens at work. Official gazette (2005, No. 55-1907).

r) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

Order of Ministry of Health Care and Ministry of Social Security and Labour, 13 December 2001 on the Hygiene Norm HN 23:2001 Concentration limit values of harmful chemical substances in the air of working environment. Official gazette (2001, No. 110–4008). Must be replaced to Hygiene Norm HN 23:2007 Concentration limit values of chemical substances in the air of working environment (Draft). Available from : http://www.lrs.lt/DPaieska.html [in Lithuanian]

Order of Ministry of Social Security and Labour and Ministry of Health Care, 24 July 2001 on the approval of regulation on the protection of workers from risks related to exposure to carcinogens or mutagens at work. Official gazette (2005, No. 55-1907). Available from : http://www.lrs.lt/DPaieska.html [in Lithuanian]

s) Which of the following types of information is publicly available?

General Information	Yes	No	Available from (contact point address or web site)
Methodology for identifying priority substances for OEL setting	**X**		**Ministry of Health Care www.sam.lt**
Methodology for developing measurement and analytical methods	**X**		**Institute of Hygiene of Ministry of Health Care www.hi.lt**
Methodology for the derivation of OELs	**X**		**Ministry of Health Care www.sam.lt**

Specific Information	Yes	No	Available from (contact point address or web site)
Evaluation documents for individual substances?			
Measurement and analytical methods for individual substances	**X**		**Institute of Hygiene of Ministry of Health Care www.hi.lt**

D. Reprotoxic substances

t) Are there any limit values defined for reprotoxic substances?

Yes	No
x	☐

If yes, how are these limit values applied in practice?

u) Are there any lists of reprotoxic substances?

Yes	No
x	☐

v) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Order of Ministry of Health Care and Ministry of Social Security and Labour, 13 December 2001 on the Hygiene Norm HN 23:2001 Concentration limit values of harmful chemical substances in the air of working environment. Official gazette (2001, No. 110–4008). Must be replaced to Hygiene Norm HN 23:2007 Concentration limit values of chemical substances in the air of working environment (Draft). Available from : http://www.lrs.lt/DPaieska.html [in Lithuanian]

Luxembourg

28 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Asbestos			C1						25 fiber years		Luxembourg Accident Assurance Association (AAA)
Asbestos			C1						0.1 f/cm^3		constraining
Benzene	71-43-2	200-753-7	C1, M2	3.25	1						constraining
Chlorethylene	75-01-4	200-831-0	C1	7.77	3						constraining
Wood dust (hard wood) (inhalable part)			C1	2							constraining

[1] Please specify
[2] Please specify

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No X

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

☐ Availability of data on exposure

X Availability of toxicological data

☐ Number of persons exposed

☐ Severity of effects

☐ Epidemiological evidence, including reported cases of ill-health in the workplace

☐ Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

X Scientific experts

☐ Social partners – Employers

X Social partners – Workers

☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	X

e) Which kind of limit values are adopted?

X 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☐	X

If yes, with which parties?

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	No
☐	X

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	No
☐	X

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	No
X	☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	No
☐	X

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	No
☐	☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	No
☐	☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary?

Yes	No
X	☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used:

Yes	No
☐	X

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

Yes	No
☐	X

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes	No
X	☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

Limits established in other countries (Germany, France)

i) Are limit values indicative or constraining?

☐ indicative

X constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period X

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

		Yes	No
l)	**Is there a specific procedure for the revision of OELs?**	☐	**X**

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	X

o) Is exposure monitoring mandatory?

Yes	No
X	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
X	☐

If yes, please specify:
Different sources are used, ex: BGIA (D) for chemicals, NBN and DIN for asbestos, documented in the quality procedures of the test laboratories

q) Is biological monitoring included in the monitoring methods?

Yes	No
X	☐

If yes, please specify:

BAT values

r) How is record keeping on the results of such measurements organised? (please describe)

Occupational health services recordings, Company files, Labour inspectorate archives

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

Legal documents

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**X**	
Methodology for developing measurement and analytical methods		**X**	
Methodology for the derivation of OELs		**X**	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**X**		**Occupqtional health services, AAA, risk analysis at work**
Measurement and analytical methods for individual substances	**X**		

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
X	☐

If yes, how are these limit values applied in practice?

Hg, antimitotics, CO, Pb no exposure percutanous penetration + cancerogenic substances

v) Are there any lists of reprotoxic substances?

Yes	No
X	☐

Loi du 1ier août 2001 concernant la protection des travailleuses enceintes, accouchées et allaitantes

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Netherlands

12 November 2007

A. List and table of OELs for carcinogenic and mutagenic substances

LIJST VAN WETTELIJKE GRENSWAARDEN VOOR KANKERVERWEKKENDE STOFFEN (Bijlage 13b Arbeidsomstandighedenregeling)

Inwerking getreden per 1 januari 2007

STOF		**GRENSWAARDE**			
Naam	**CAS.nr**	**TGG 8u mg/m3**	**C**	**TGG 15min mg/m3**	**H**
A					
Aflatoxines		0,005 µg/m3			
Arseenpentoxide (als As)	1303-28-2	0,025		0,05	
Arseentrioxide (als As)	1327-53-3	0,025		0,05	
Arseenzuur (als As)	7778-39-4	0,025		0,05	
in water oplosb. zouten van arseenzuur (als As)		0,025		0,05	
in water onoplosb. zouten van arseenzuur (als As)		0,05		0,1	
Asbest (zie artikel 4.46 Arbobesluit)		0,01 vezel/cm3			
Azathioprine	446-86-6	0,005			
B					
Bariumchromaat (als Cr)	10294-40-3			0,025	
Benzeen	71-43-2	3,25			H
Benzine		240		480	
1,3-Butadieen	106-99-0	46,2			
C					

STOF		GRENSWAARDE			
Naam	**CAS.nr**	**TGG 8u mg/m3**	**C**	**TGG 15min mg/m3**	**H**
Cadmiumchloride (als Cd)	10108-64-2	0,005			
Cadmiumoxide (rook) (als Cd)	1306-19-0	0,005			
Cadmiumsulfaat (als Cd)	10124-36-4	0,005			
Calciumchromaat (als Cr)	13765-19-0			0,01	
Carbadox	6804-07-5	0,003			
4-Chloor-o-fenyleendiamine	95-83-0	0,2			
Chroom(III)chromaat (als Cr)	24613-89-6			0,01	
Chroom(VI)-oplosb. Verbindingen		0,025		0,05	H
Chroomtrioxide (als Cr)	1333-82-0	0,025		0,05	
Cisplatin	15663-27-1	0,00005			
D					
Dacarbazine	4342-03-4	0,0009			
1,2-Dibroomethaan	106-93-4	0,002			
1,2-Dichloorethaan	107-06-2	7			
2,2'-Dichloor-4,4'-Methyleendianiline	101-14-4	0,02			H
E					
Epichloorhydrine	106-89-8	1,9			
1,2-Epoxypropaan	75-56-9	6			
Ethyleenoxide	75-21-8	0,84			
H					
Hardhoutstof		2			
Hexachloorbenzeen	118-74-1	0,03			
K					

STOF		**GRENSWAARDE**			
Naam	**CAS.nr**	**TGG 8u mg/m3**	**C**	**TGG 15min mg/m3**	**H**
Keramische vezels (resp.)		0,5 vezel/cm3			
L					
Loodchromaat (als Cr)	7758-97-6			0,025	
M					
2-Methylaziridine	75-55-8	0,6 µg/m3			
4,4'-Methyleendianiline	101-77-9	0,2			H
Metronidazol	443-48-1	0,0006			
N					
2-Nitropropaan	79-46-9	0,036			
N-Nitrosodimethylamine	62-75-9	0,2 µg/m3			
P					
Procarbazine hydrochloride	366-70-1	0,002			
S					
Silicium(di)oxide:					
– kwarts (resp.)	14808-60-7	0,075			
– cristoballiet (resp.)	14464-46-1	0,075			
– tridymiet (resp.)	15468-32-3	0,075			
Strontiumchromaat (als Cr)	7789-06-2			0,01	
T					
1,2,3-Trichloorpropaan	96-18-4	0,108			H
V					
Vinylbromide	593-60-2	0,012			
Vinylchloridemonomeer	75-01-4	7,77			
Z					

STOF		GRENSWAARDE			
Naam	**CAS.nr**	**TGG 8u mg/m3**	**C**	**TGG 15min mg/m3**	**H**
Zinkchromaat (als Cr)	13530-65-9			0,01	

List of legal Occupational Exposure Limits voor reprotoxic (CMR) substances (of enclosure 13A Working Conditions Regulation)

Into force since 1st January 2007

Substances		Occupational Exposure Limits			
Name	**CASnumber**	**TGG 8u mg/m3**	**C**	**TGG 15min mg/m3**	**H**
C					
Chloroform	67-66-3	5		25	
D					
N,N,-Dimethyl acetamide	127-19-5	36		72	H
H					
n-Hexane	110-54-3	72		144	
K					
Koolmonoxide	630-08-0	29			
Copper and inorganic Copperexpendicture (inhale) (Copper sulphate??)	7440-50-81	0,1			
L					
Lead	div				
M					
Methanol	67-56-1	260		520	H
2-(2-Methoxyethoxy)ethanol	111-77-3	45			H
N					
Nitrobenzeen	98-95-3	1			H
T					
Toluene	108-88-3	150		384	
V					
Vanadiumoxiden (as V)		0,01		0,03	
X					
Xylene, o-, m-, p-isomers	1330-20-7	210		442	

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes X No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

Report in preparation. Concept not yet available, and than possibly first advise from the Ministry of Social Affairs.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

X Availability of data on exposure

X Availability of toxicological data

X Number of persons exposed

X Severity of effects

☐ Epidemiological evidence, including reported cases of ill-health in the workplace

☐ Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☐ Scientific experts

☐ Social partners – Employers

☐ Social partners – Workers

☐ Public authority - Ministry of Health

X Public authority - Ministry of Labor

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
X	☐

e) Which kind of limit values is adopted?

X 8-hour limit values

X Short-term limit values

X Ceiling limit values

X Biological limit values (lead)

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
X	☐

If yes, with which parties?

For the value as advised by experts.
For the value advised by the SER: employers and employees, branch organizations.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	No
X	☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	No
X	☐

If yes, please provide the name, address and website details: Health Council http://www.gr.nl/

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Via advise of the tripartite SER.

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	No
X	☐

Only if these good work practices are validated for this purpose.

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Depends on the measure of importance of the substance.

Yes	No
☐	X

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	No
☐	X

Depends on the measure of importance of the substance.

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	No
☐	X

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary?

Yes	No
☐	X

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used:

Yes	No
☐	☐

OEL are set on a level of excess cancer death of 10^{-6}, but this value must be underscored when technically possible

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

Yes	No
☐	X

(iii) Other administrative or policy criteria (please describe)

OEL are set on a level of excess cancer death of 10^{-6}, but this value must be underscored when possible

h) Do you ever adopt OELs from other sources?

Yes	No
☐	X

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

i) Are limit values indicative or constraining?

☐ indicative

X constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years X (depends on the substance)
Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

- Actual exposure information.
- Trends in exposure and use.

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** **No**
X ☐

m) If yes, how often are limit values revised?
Please specify time period:

- Every four years when OEL is set above the risk value of 10^{-6}.
- Otherwise when need arises (see also part B1).

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	X

However, the requirements of the Directives on chemical agents and Carcinogenic and mutagenic substances do of course apply.

o) Is exposure monitoring mandatory?

Yes	No
☐	X

However, the requirements of the Directives on chemical agents and Carcinogenic and mutagenic substances do of course apply.

p) Are there specific measurement methods laid down, or recommended?

Yes	No
X	☐

If yes, please specify:

Non-binding methods as elaborated by the tripartite body of the SER. Moreover, CEN methods are recommended (non-binding).

q) Is biological monitoring included in the monitoring methods?

Yes	No
X	☐

If yes, please specify:

Only in special cases, as above.

r) How is record keeping on the results of such measurements organised? (please describe)

Not specified.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

Annex XIII B Arbeidsomstandighedenregeling
Web page SER
http://www.ser.nl/sitecore/content/Internet/en/OEL%20database.aspx. Only available in Dutch language.

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting	**X**		**Report in preparation**
Methodology for developing measurement and analytical methods	**X**		**SER www.ser.nl**
Methodology for the derivation of OELs	**X**		**Health Council www.gr.nl**

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**X**		**Health Council www.gr.nl** **SER** http://www.ser.nl/sitecore/content/Internet/en/OEL%20database.aspx
Measurement and analytical methods for individual substances	**X**		**SER www.ser.nl**

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
X	☐

If yes, how are these limit values applied in practice?

In the same way as non-carcinogenic substances.

v) Are there any lists of reprotoxic substances?

Yes	No
X	☐

This list is up dated regularly, and not limitative. Every half year.

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Annex XIII A Arbeidsomstandighedenregeling
Health Council www.gr.nl
SER:
http://www.ser.nl/sitecore/content/Internet/en/OEL%20database.aspx

Poland

31 October 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level: The Regulation of the Minister of Labour and Social Policy on the maximum admissible concentrations and intensities of harmful to health agents in the working environment (*Dziennik Ustaw* 2002, No. 217, item 1833, changes *Dziennik Ustaw* 2005, No. 212, item 1769, *Dziennik Ustaw* 2007, No. 161, item. 1142).
"Guidelines for assessing health risk from carcinogens. Carcinogenic and mutagenic agents in the working envirnments – new regulation". IMP, Łódź, 2005.

Substance name	CAS number	EINECS number	C/M/R[1]	**8 hour limit value**		**Short-term-limit value**		**Biological Limit Value[2]**	**Other**	**Skin notation**	**Remarks, comments** (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Acrylamide	79-06-1	201-173-7	Carc. Cat. 2; R45; Muta. Cat. 2; R46 Repr. Cat. 3; R62	0.1		–		–	Ft	Sk	Analytical methods of measurement: PiMOŚP* 1997, z. 17
Acrylonitryle	107-13-1	203-466-5	Carc. Cat. 2; R45	2	–	10			Ft, I	Sk	Analytical methods of measurement: PN-Z-04113-12:2005; PiMOŚP 2000, nr 3(25)
Arsenic and inorganic compounds – as As	7440-38-2	231-148-6	Carc. Cat. 1; R45	0.01		–		arsenic and monomethylarsonic acid + dimethylarsinic acid BLV: 35 µg/l in count out to medium urine	Ft	–	Analytical methods of measurement: PN-75/Z-04011/02; PN-Z-04011-8:2004 - arsenic(III) oxide - arsenic(V) oxide - arsenic(V) acid and its salts - lead hydrogen arsenate

[1] Please specify
[2] Please specify

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
								density			
Benzene	71-43-2	200-753-7	Carc. Cat. 1; R45 Muta. Cat. 2; R46	1.6		–		S-Pheny-lomerca-pturic acid in urine, BLV: 25 µg/g creatinine T,t-Muconic acid in urine BLV: 0,5 mg/g creatinine		Sk	Analytical methods of measurement: PN-Z-04016-10:2005; PiMOŚP 2000, nr 3(25)
Benz[a]anthracene	56-55-3	200-280-6	Carc. Cat. 2; R45	0.002*		–		–	–	–	Analytical methods of measurement: PN-Z-04240-5:2006, PiMOŚP 2000, nr 3(25)
Benzo[a]pyrene	50-32-8	200-028-5	Carc. Cat. 2; R45 Muta. Cat. 2; R46	0.002 0.002*		–		–	Ft	–	Analytical methods of measurement: PN-Z-04240-2:1999, PN-Z-04240-5:2006 PN-Z-04240-5:2006, PiMOŚP 2000, nr 3(25)
Benzo[*b*]fluoranten	205-99-2	205-911-9	Carc. Cat. 2; R45	0.002*		–		–	–	–	Analytical methods of measurement: PN-Z-04240-5:2006, PiMOŚP 2000, nr 3(25)
Benz[e]acephenanthrylene	207-08-9	205-916-6	Carc. Cat. 2; R45	0.002*		–		–	–	–	Analytical methods of measurement: PN-Z-04240-5:2006, PiMOŚP 2000, nr 3(25)
Benzidine	92-87-5	202-199-1	Carc. Cat. 1; R45	0		0	–	–	Ft	Sk	Analytical methods of measurement: PN-85/Z-04145.02, PN-85/Z-04145.03
Petroleum: a) naphta	8030-30-6	232-443-2	Carc. Cat. 2; R45	500		1,500		–	–	–	Analytical methods of measurement: PN-81/Z-04134.01, PN-81/Z-04134.02
b) stoddard solvent Naphtha petroleum), hydrodesulfurized heavy; Naphtha;	8052-41-3 64742-82-1	232-489-3 265-185-4	Carc. Cat. 2; R45 Carc. Cat. 2;	300		900		–	–	–	Analytical methods of measurement: PN-81/Z-04134.01, PN-81/Z-04134.03

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Naphtha (petroleum), hydrotreated heavy	64741-92-0 64742-48-9	265-095-5 265-150-3	R45 Carc. Cat. 2; R45								
Beryllium and inorganic compounds – as Be	7440-41-7	231-150-7	Carc. Cat. 2; R49	0.0002		–		–	–	–	Analytical methods of measurement: PN-84/Z-04013.02, PN-Z-04013-3:2003, PiMOŚP 1999, z. 22
Biphenyl-4-ylamine	92-67-1	202-177-1	Carc. Cat. 1; R45	0.001		–		–	–	–	The method recommended by research institutes
Buta-1,3-diene	106-99-0	203-450-8	Carc. Cat. 1; R45 Muta. Cat. 2; R46	10		40		–	Ft	–	Analytical methods of measurement: PN-84/Z-04014.02
Chromyl dichloride	14977-61-8	239-056-8	Carc. Cat. 2; R49 Muta. Cat. 2; R46	0.15		–		–	–	–	The method recommended by research institutes
4-Chloroaniline	106-47-8	203-401-0	Carc. Cat. 2; R45	3		10		–	–	Sk	Analytical methods of measurement: PN-Z-04315:2003, PN-81/Z-04031.03 PiMOŚP 1998, z. 19
2-Chlorobuta-1,3-diene	126-99-8	204-818-0	Carc. Cat. 2; R45	2		16		–	Ft, I	Sk	Analytical methods of measurement: PiMOŚP 2004, nr 4(42)
1-Chloro-2,3-epoxypropane	106-89-8	203-439-8	Carc. Cat. 2;	1		–		–	A, C, Ft	Sk	Analytical methods of measurement: PN-81/Z-04029.01

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
			R45								
Chloroethylene	75-01-4	200-831-0	Carc. Cat. 1; R45	5		30		–	Ft	–	Analytical methods of measurement: PN-78/Z-04112.02; PN-93/Z-04231.02 PiMOŚP 2000, nr 3(25)
Benzyl chloride	100-44-7	202-853-6	Carc. Cat. 2; R45	3		– 5 (ceiling)		–	Ft, I	–	Analytical methods of measurement: PN-Z-04249:1998
Chromate(VI) and dichromiate(VI) – as Cr(VI)	–	–	Carc. Cat. 1; R45 Muta. Cat. 2; R46 all without **	0.1		0.3		Chro-mium(VI) BLV: 10 µg/g creatinine Water-soluble fume BLV: 30 µg/g creatinine	–	–	- zinc chromates including zinc potassium chromate Carc. Cat. 2; R45 - potassium dichromate(VI) - ammonium dichromate(VI) - sodium dichromate(VI) - sodium dichromate(VI) sodu - dihydrate - calcium chromate(VI)** - strontium chromate(VI) ** - chromium(III)chromate(VI)** - sodium chromate(VI) - disodium chromate(VI) Carc. Cat. 2; R49 - Chromium (VI) compounds, with the exception of barium chromate and of compounds specified elsewhere in this Annex** - potassium chromate(VI) Analytical methods of measurement: PN-87/Z-04126.02 ; PN-87/Z-04126.03
Chrysene	218-01-9	205-923-4	Carc. Cat. 2; R45	0.002*		–		–	–	–	Analytical methods of measurement: PN-Z-04240-5:2006, PiMOŚP 2000, nr 3(25)
Dibenz[a,h]anthra-cene	53-70-3	53-70-3	Carc. Cat. 2; R45	0.004		–		–	–	–	Analytical methods of measurement: PN-Z-04240-5:2006; PN-Z-04240-4:1999 PiMOŚP 1997, z. 16
1,2-Dibromoethane	106-93-4	203-444-5	Carc. Cat. 2; R45	0.5		–		–	Ft, I	Sk	Analytical methods of measurement: PN-93/Z-04144.02
1,2-Dichloroethane	107-06-2	203-458-1	Carc. Cat. 2;	50		–		–	–	Sk	Analytical methods of measurement: PN-79/Z-04120.01; PiMOŚP 2000, nr

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
			R45								3(25)
4,4'-Methylenebis [2-chloroaniline] MOCA	101-14-4	202-918-9	Carc. Cat. 2; R45	0.02		–		–	–	Sk	Analytical methods of measurement: PN-Z-04295:2003 ; PiMOŚP 1998, z. 19
N,N-Dimethylhydrazine	57-14-7	200-316-0	Carc. Cat. 2; R45	0.1		–		–	A	Sk	Analytical methods of measurement: PN-87/Z-04148.03
Dinitrotoluene – mixed isomers	25321-14-6	246-836-1	Carc. Cat. 2; R45	0.33		–		–	–	Sk	Analytical methods of measurement: PN-82/Z-04128.03; PN-Z-04128-4:1996
Ethylene oxide	75-21-8	200-849-9	Carc. Cat. 2; R45 Muta. Cat. 2; R46	1		3		–	A, Ft, I	–	Analytical methods of measurement: PN-Z-04300:2002; PiMOŚP 1998, z. 19
2,3-Epoxypropyl-phenyl-ether	122-60-1	204-557-2	Carc. Cat. 2; R45	0.6		3		–	A	Sk	Analytical methods of measurement: PN-Z-04243-2:1996
2,3-Epoxypropan-1-ol	556-52-5	209-128-3	Carc. Cat. 2; R45	6		–		–	–	–	Analytical methods of measurement: PN-Z-04306:2002; PiMOŚP 1998, z. 19
Phenylhydrazine	100-63-0	202-873-5	Carc. Cat. 2; R45	20		–		–	A, Ft, I	Sk	Analytical methods of measurement: IMP, Łódź 1994
Hexachlorobenze-ne	118-74-1	204-273-9	Carc. Cat. 2; R45	0.5		–		–	Ft	Sk	Analytical methods of measurement: PN-Z-04236-2:1994
Hexamethylphosphoric triamide	680-31-9	211-653-8	Carc. Cat. 2; R45 Muta. Cat. 2; R46	0.05		–		–	–	–	Analytical methods of measurement: PN-Z 04353:2005, PiMOŚP 2001, nr 4(30)
Hydrazine	302-01-2	206-114-9	Carc. Cat. 2; R45	0.05		0.1		–	A, C	Sk	Analytical methods of measurement: PiMOŚP 2007, z. x(xx)

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Isoprene	78-79-5	201-143-3	Carc. Cat. 2; R45	100		300		–	–	–	Analytical methods of measurement: PN-Z-04271:2000; PiMOŚP 1997, z. 16
Cadmium and its inorganic compounds - as Cd – dusts and fume	7440-43-9	231-152-8	Carc. Cat. 2; R45 Muta. Cat. 2; R46	0.01		–		Cadmium inorganic compounds In urine BLV: 5 µg Cd/g creatinine In blood BLV: 5 µg Cd/L	C, Ft	–	- cadmium (non-pyrophoric) - cadmium(II) (non-pyrophoric) - cadmium(II) fluoride - cadmium(II) chloride - cadmium(II) sulphate - cadmium(II) sulphide - cadmium (pyrophoric) Muta. Cat. 2; R46 - cadmium(II) fluoride - cadmium(II) chloride - cadmium(II) sulphate Analytical methods of measurement: PN-85/Z-04102.03 ; PiMOŚP 2003, nr 4(38)
Carbendazim	10605-21-7	234-232-0	Muta. Cat. 2; R46 Repr. Cat. 2; R 60-61	10		–		–	Ft	–	The method recommended by research institutes
o-Anisidine	90-04-0	201-963-1	Carc. Cat. 2; R45	0.5		1		–	–	Sk	IMP, Łódź 1994
2-Naphthylamine	91-59-8	202-080-4	Carc. Cat. 1; R45	0		0					
4,4’ -Methylene dianiline	101-77-9	202-974-4	Carc. Cat. 2; R45	0.08		–		–	–	–	Analytical methods of measurement: PiMOŚP 2005, nr 1(43)
Nickel and its compounds except nickel tetracarbonyl – as Ni	7440-02-0	231-111-4	Carc. Cat. 1; R49	0.25		–		–	A, C, Ft, I	–	- nickel(II) oxide - nickel(IV) oxide - dinickel trioxide - nickel(II) sulfate

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
											- trinickel disulphide Analytical methods of measurement: PN-85/Z-04124.03; PN-Z-04124-5:2006
2-Nitrotoluene	88-72-2	201-853-3	Carc. Cat. 2 R45	11		–		–		Sk	Analytical methods of measurement: PN-79/Z-04128.01 PN-Z-04128-6:2002
Propiolactone	57-57-8	200-340-1	Carc. Cat. 2; R45	1		–		–	I	Sk	Analytical methods of measurement: PN-Z-04288:2001; PiMOŚP 1997, z. 16
Dimethyl sulphate	77-78-1	201-058-1	Carc. Cat. 2; R45	0.5		1		–	C, Ft	Sk	Analytical methods of measurement: PN-85/Z-04068.03; PN-Z-04273-1:2001 PiMOŚP 1997, z. 16
o-Toluidine	95-53-4	202-429-0	Carc. Cat. 2; R45	3		–		–	I	Sk	Analytical methods of measurement: PiMOŚP 2007,
4-Methyl-m-phenylenediamine	95-80-7	202-453-1	Carc. Cat. 2; R45	0.04		0.1		–	I	–	Analytical methods of measurement: PN-Z-04310:2002; PiMOŚP 1998, z. 19
Trichloroethylene	79-01-6	201-167-4	Carc. Cat. 2; R45	50		400			Ft	–	Analytical methods of measurement: PN-74/Z-04047.01; PN-78/Z-04047.02 ; PN-83/Z-04047.03 ; PiMOŚP 2000, nr 3(25)
Propylene oxide	75-56-9	200-879-2	Carc. Cat. 2; R45 Muta. Cat. 2; R46	9		–		–	–	–	Analytical methods of measurement: PN-Z-04286:2003; PiMOŚP 1998, z. 19
1,2,3-Trichloropropane	96-18-4	202-486-1	Carc. Cat. 2; R45	7		–		–	Ft	Sk	Analytical methods of measurement: PN-Z04287:2005 ; PiMOŚP, 1998, z. 19
PAH	–	–	Carc. Cat. 2; R45	0.002**		–		–	–	–	Analytical methods of measurement: PN-Z-04240-5:2006, PiMOŚP 2000, nr 3(25)
Dusts containing asbestos (one or more the asbestos			Carc. Cat. 1;			–		–	–	–	Analytical methods of measurement: Dusts : PN-89/Z-04202/02, PN-91/Z-

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
dusts name under): - Actinolite - Gruenerite (amosite) - Anthophyllite - Chrysotile - Crocidolite, - Tremolite	77536-66-4 12172-73-5 77536-67-5 12001-29-5 12001-28-4 77536-68-6	IDX : 650-013-00-6	R45	totally inhalable dust – 0.5 respirable fibres - 0.1 fibre/cm^3							04030/05,
Artificial mineral fibre dust : a) artificial mineral fibre dusts except ceramic fibres - totally inhalable dust - respirable fibres	–	–	Carc. Cat. 2; R49	2 1 fibre/cm^3		–		–	–	–	Refractory Ceramic Fibres; Special Purpose Fibres, with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na2O + K2O + CaO + MgO + BaO) content less or equal to 18% by weight] Analytical methods of measurement: Dust : PN-89/Z-04202/02, PN-91/Z-04030/05
Artificial mineral fibre dust : b) ceramic fibre dust - totally inhalable dust - respirable fibres	–		Carc. Cat. 2; R49	1 0.5 fibre/cm^3		–		–	–	–	Refractory Ceramic Fibres; Special Purpose Fibres, with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na2O + K2O + CaO + MgO + BaO) content less or equal to 18% by weight] Analytical methods of measurement: Dust : PN-89/Z-04202/02, PN-91/Z-04030/05

Substance name	CAS number	EINECS number	C/M/R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Artificial mineral fibre dust : c) mixture of ceramic fibre dust with other artificial mineral fibres (MMMF) - totally inhalable dust - respirable fibres	–		Carc. Cat. 2; R49	 1 0.5 fibre/cm^3		–		–	–	–	Refractory Ceramic Fibres; Special Purpose Fibres, with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na2O + K2O + CaO + MgO + BaO) content less or equal to 18% by weight] Analytical methods of measurement: Dust: PN-89/Z-04202/02, PN-91/Z-04030/05
Hardwood dusts as beech and oak - totally inhalable dust				 2		–		–	–	–	Technology processes in which are released carcinogen or mutagenic substances; work involving exposure to hardwood dusts. Analytical methods of measurement: Dust: PN-91/Z-04030/05
Mixture wood dusts containing hardwood dusts - beech and oak - totally inhalable dust				 2		–		–	–	–	Technology processes in which are released carcinogen or mutagenic substances; work involving exposure to hardwood dusts. Analytical methods of measurement: Dust: PN-91/Z-04030/05

* PiMOŚP – Principles and Methods for Assessing the Working Environment, editor CIOP-PIB www.ciop.pl

** MAC value refer to **Polyaromatic hydrocarbons (PAH)** – as sum of multiply the concentration and carcinogenic coefficients for 9 carcinogenic substances

Carc. Cat. 1 Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Carc. Cat. 2 Substances, which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:
1) appropriate long-term animal studies,
2) other relevant information.

Muta. Cat. 2 Substances, which should be regarded as if they are mutagenic to man. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:
- appropriate animal studies,
- other relevant information.

Totally inhalable dust – all particles surrounded by air in a given volume of air
Respirable dust – the mass fraction of inhaled particles penetrating to the unciliated airways
Respirable fibres – fibres more than 5 μm long with the maximum diameter below 3 μm, the proportion length to diameter is above 3:1

R45 May cause cancer.
R46 May cause heritable genetic damage.
R49 May cause cancer by inhalation.

C – corrosive, **I** – irritation, **A** – sensitive
Ft – fetotoxicity
The basis of notation:
- Registry of Toxic Effects of Chemical Substances, RTCES.
- The documentations prepare of the Group of Experts for Chemical Agents.
- The Ordinance of Cabinet on jobs prohibition to women (Journal of Law 1996, No 114, item 542 with changes).
- The Act of the chemical substances and preparations (Journal of Law 2001, No 11, item 84 with changes).

The substance notation as **Ft** – fetotoxicity, there are the substances which in case of inhalation, intake or contact with skin cause the toxic effects in offspring's in prenatal stadium of development – from the end of embryo stadium to birth.
Sk – the substance absorb through the skin
The basis of notation:
- The LD_{50S} value from acute animal toxicity data < 1000 mg/kg
- Where repeated dermal application studies have shown significant systemic effects.
- The chemical and physical data (solubility, octanol-water partition coefficients, molecular weight) according to the method's of Fiserova-Bergerova et al. (Fiserova-Bergerova V., Thomas P.J., Droz P.O.: *Dermal absorption potential of industrial chemicals: criteria for skin notation.* Am. J. Ind. Med., 1990, 17, 617-635).

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes X No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

The carcinogenic or mutagenic substances for OELs are selecting for the following criteria:

- application form industry,
- classification as carcinogenic or mutagenic according to national or UE law

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

3 Availability of data on exposure

4 Availability of toxicological data

2 Number of persons exposed

5 Severity of effects

1 Epidemiological evidence, including reported cases of ill-health in the workplace

6 Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

X Scientific experts

X Social partners – Employers

X Social partners – Workers

X Public authority - Ministry of Health

X Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
X	☐

e) Which kind of limit values are adopted?

X 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

X Biological limit values, if existing data are available

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
X	☐

If yes, with which parties?

It is a consultation for representatives of health and labour administration, various sectors of industry, trade unions and research institutes in the fields of occupational safety and medicine on the forum of the Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment. The main responsibility of the Commission is to consider, evaluate and adopt exposure limits for chemical and physical agents in the working environment and submits them to the Minister of Labour and Social Policy, who is responsible for introducing those values into legislation. The secretariat of the Commission is based at the Central Institute for Labour Protection – National Research Institute.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
X	☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	**No**
X	☐

If yes, please provide the name, address and website details:

Group of Experts for Chemical and Dust Agents Interdepartmental Commission for MAC and MAI, Central Institute for Labour Protection – National Research Institute www.ciop.pl
Group of Expert for Risk Assessment of Carcinogenic Compounds, Nofer Institute of Occupational Medicine www.imp.lodz.pl

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

1. According to the Regulation of Minister of Health of 20 April 2005 on substances, preparations and agents or processes that are carcinogenic or mutagenic in the working environment (*Dziennik Ustaw* 2004, No 280, item 2771 with changes), each entrepreneur is obliged at the start of the activity to send information concerning the manufacturing process to the State Sanitary Inspection and the National Labor Inspectorate. The central register of exposure to carcinogenic and/or mutagenic substances, preparations or technological processes has been compiled at the Nofer Institute of Occupational Medicine in Łódź, Poland.
2. The basis for the publication create registers on working conditions introduced regulation of the Council of Ministers of the 13 June 2005 concerning of statistical surveys of the public statistic for the year 2005 (Dz. U. Nr 195, item 2004). The Central Statistical Office collects information of working conditions using the form Z-10 “Work conditions”. Registers on working conditions cover employed by entities in the sections and the additional criterion describing a subject obliged to the report transmission was the number of employees 9 persons and over. Work conditions include the group of factors appearing in the working environment deriving from the process of work and factors connected with performing work. Work environment consists of: physical factors (e.g. lighting, noise, micro-climate), chemical (e.g. toxic substances) and biological (e.g. bacteria), occurring within the space of the work place (e.g. factory room, work position) as well as the space surrounding establishment. Hazard related to work environment comprises influence on employees of the harmful factors arising in the process of work, which concentration or intensity exceed obligatory MAC (maximum admissible concentration) and MAI (maximum admissible intensity), Polish standards or other hygienic standards.
3. The occupational diseases are reported on a special form. The form contains detailed data including diagnosis, job description, causal agent of the disease, exposure level and duration, patient’s name, date of birth, home address, name of enterprise with its code number and postal address, industrial branch, name of health service unit that diagnosed the disease, date of issue of medical certification. The models of forms (wzory formularzy) are given in the Regulation of the Minister of Health of 1 August 2002 on documentation of occupational diseases and the effects of these diseases (OJ of 2002 No 132, item 1121). For biological and allergic agents not the exposure levels are required, but the

type of agent, the kind of contact and its duration [regulation of the Council of Ministers of 30 July 2002 on occupational diseases index, specific procedures concerning reporting doubts, identification and recognition of occupational diseases and subjects that are appropriate for these cases (OJ of 2002 No 132, item 1115)]. This information should be sent to the Nofer Institute of Occupational Medicine in Łódź and to the State Sanitary Inspection. The same applies to farmers, but they send information about occupational diseases to the Agricultural Social Insurance Fund (KRUS).

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** X **No** ☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** X

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** X

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** X

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** X

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** X **No** ☐

For carcinogenic agents, the Commission has adopted the socially accepted risk at the level of 10^{-3} to 10^{-5}. The experts propose the MAC for carcinogenic for those two levels and the Commission decides for one of them. When preparing draft MAC values for carcinogenic substances, health risk assessment

resulting from human exposure to the carcinogens can be also used. The following considerations have been valid when performing the assessment based on the results of animal studies:

- The relationship between the dose (expressed in suitable units) and tumor frequency in animals is determined from the results of biological research on animals;
- The dose-response relationship is the same in humans and in the animals;
- Both mg/kg body weight and mg/m^2 body surface area *per diem* may by used as the suitable units of the equivalent dose;
- The carcinogenic activity after received small doses is linear.

The risk assessment from animal experiments or human data is estimated by the Group of Expert for Risk Assessment of Carcinogenic Compounds. It is included in documentation, which prepares experts. Uniform documentation for each compound includes:

1. Contents
2. Summary
3. Substance characterisation, uses and occupational exposure
4. Toxic effects on human
5. Toxic effects on laboratory animals
6. Carcinogenicity, mutagenicity, teratogenicity, embriotoxicity, and effects on reproduction
7. Toxicokinetics
8. Mechanism of toxicity
9. Combined effects
10. Dose-effect and dose-response relationships
11. Bases for existing MAC or MAI values and biological tolerance limits
12. Bases for proposed MAC or MAI values and biological tolerance limits
13. Methods of determining the agents harmful to health in the air and in biological material
14. Pre-employment and periodical medical examinations
15. References

Documentations of MAC values are published quarterly in a publication of the Interdepartmental Commission "Principles and Methods of Assessing the Working Environment".

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

Yes	**No**
X	☐

(iii) Other administrative or policy criteria (please describe)

The representatives of employers and employees can report these difficulties on the meeting of the Interdepartmental Commission.

h) Do you ever adopt OELs from other sources?

Yes	**No**
☐	X

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

i) Are limit values indicative or constraining?

☐ indicative

X constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years X Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs?

Yes	**No**
☐	**X**

m) If yes, how often are limit values revised?
Please specify time period:

The limits for carcinogens or mutagens are revised as other chemicals for 2-3 years.

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
X	☐

In Poland the employers are obliged to carry out measurements of chemical substances at the workplace area and to make the results available to the workers (Regulation of the Minister of Health of 20 April 2005 on the detection and measurement of harmful agents in working environment *Dziennik Ustaw* 2005, No. 73, item 645).
In the case of carcinogens or mutagens the measurements should be done:
1) every 3 months if in the last measurements the concentrations of them was below 0.5 of MAC;
2) every 6 months if in the last measurements the concentrations of them was above 0.1 to 0.5 of MAC;
3) in every case if there is any change in the use of those agents.
The employer does not have to determine carcinogenic agent in the workplace air in case when its concentration was below 0.1 of MAC in two round of measurement.

o) Is exposure monitoring mandatory?

Yes	No
X	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
X	☐

If yes, please specify:

According to Regulation of the Minister of Health of 20 April 2005 on the detection and measurement of harmful agents in working environment (*Dziennik Ustaw* 2005, No. 73, item 645) the measurement methods definite Polish Standards and international standards or others equivalent. There are recommended.

q) Is biological monitoring included in the monitoring methods?

Yes	No
X	☐

The Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment in Poland also propose BEI values, but they

are only as recommendation values. They are published in a Commission booklet "Harmful agents in the working environment – limit values". The Commission established BEIs for 26 chemical substances. In Poland only workers exposed to lead in the working environment must have blood tests to determine how much lead there is in their blood – this is so in accordance with regulation of the Minister of Health and Social Welfare of May 30, 1996 on medical examinations of workers, the scope of preventive health care and on expert medical opinions for purposes provided for in the Labour Code.
Biological monitoring entails the measurement of substances and/or metabolites in biological media, and the measurement of biological effects induced by the substance.

If yes, please specify:
For the following carcinogens the Commission is established BEI:

Chemical *Determinant*	Normal value	Sampling time	BEI value
Arsenic and inorganic compound Arsenic + MMA + DMA in urine	< 10 μg/L	End of workweek	35 μg/L count out to density of urine 1.024
Benzene S-Phenylmercapturic in urine t,t-Muconic acid in urine	< 2 μg/g creatinine* < 0.15 μg/g creatinine*	End of shift End of shift	25 μg/g creatinine 0.5 mg/g creatinine * for non-smokers
Chromium(VI) Chromium(VI) in urine Water-soluble fume in urine	About 1 μg/g creatinine –	Before shift and in the end of shift End of shift and end of workweek	10 μg/g creatinine 30 μg/g creatinine
Cadmium and inorganic compounds Cadmium in urine Cadmium in blood	About 0.5-1 μg/g creatinine About 0.5 μg/L	No earlier than mount No earlier than mount	5 μg/g creatinine 5 μg/L
Trichloroethylene Trichloroacetic acid in urine	–	End of shift	20 mg/L

r) How is record keeping on the results of such measurements organised? (please describe)

The employer is obliged to approach the State Sanitary Inspection and the National Labour Inspectorate in each case of recognized or suspected occupational disease. The obligation also applies to the physician, who recognizes such a disease. The employer is obliged to:

- Establish the cause of the occupational disease, its nature and extent together with the State Sanitary Inspection.
- Immediately eliminate the agents responsible for the occupational disease and apply necessary preventive means.
- Guarantee the realization of the physician's recommendations.
- Keep a list of occupational diseases.
- Analyze the causes of occupational diseases and apply necessary preventive means.

Employers cover costs of hygienic measurements and prophylactic examinations. The results of BEI measurements are keeping by physician specialized in occupational health or industrial medicine

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

Documentations of MAC values are published quarterly in a publication of the Interdepartmental Commission "Principles and Methods of Assessing the Working Environment" (in Polish language, short summary is in English, Central Institute for Labour Protection – National Research Institute www.ciop.pl - publication - Principles and Method of Assessing the Working Environment).
Risk assessment for carcinogens and/or mutagens are published by IMP, Lodz in a publication "Guidelines for assessing health risk from carcinogens" (in Polish language, short summary is in English). The list of substances for which the guidelines were published in annex 1.
In the basic Legal Act – the Regulatory of the Minister of Labour and Social Policy – there is no information about the action of chemical substances. So, the Interdepartmental Commission decided to put these notations in a booklet "**Harmful agents in the working environment – limit values**" (only in Polish language, Central Institute for Labour Protection – National Research Institute www.ciop.pl) to make them more easily accessible for the industry, hygienists and occupational inspectors (only in Polish). The following notations are used in the booklet:
C – corrosive, ***I** *– irritation, ***A** *– sensitive, **Carcinogenic categories 1 and 2,** ***Ft** *– fetotoxicity, ***Sk*** – the substance absorb through the skin

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting	**X**		The Interdepartmental Commission for MAC and MAI, Central Institute for Labour Protection – National Research Institute, Warsaw www.ciop.pl The secretary of the Commmission Jolanta Skowroń Ph. D. josko@ciop.pl
Methodology for developing measurement and analytical methods	**X**		Central Institute for Labour Protection – National Research Institute www.ciop.pl CIOP-PIB, Warsaw Ewa Gawęda Ph.D. ewgaw@ciop.pl Nofer Institute of Occupational Medicine IMP, Łódź www.imp.lodz.pl

			Jan. P Gromiec Ph.D. jpgrom@imp.lodz.pl
Methodology for the derivation of OELs	**X**		The Interdepartmental Commission for MAC and MAI, Central Institute for Labour Protection – National Research Institute, Warsaw www.ciop.pl The secretary of Commmission Jolanta Skowroń Ph. D. josko@ciop.pl

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**X**		The Interdepartmental Commission for MAC and MAI Central Institute for Labour Protection – National Research Institute, Warsaw www.ciop.pl The secretary of Commmission Jolanta Skowroń Ph. D. josko@ciop.pl
Measurement and analytical methods for individual substances			The member of the Commission Central Institute for Labour Protection – National Research Institute, Warsaw www.ciop.pl Małgorzata Pośniak Ph.D., mapos@ciop.pl Nofer Institute of Occupational Medicine, IMP Łódź www.imp.lodz.pl Jan. P Gromiec Ph.D. jpgrom@imp.lodz.pl

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
X	☐

If yes, how are these limit values applied in practice?

This limit are applied in the same way as MAC for other chemicals by Group of Experts for Chemical and Dust Agents Interdepartmental Commission for MAC and MAI www.ciop.pl

v) Are there any lists of reprotoxic substances?

Yes	No
X	☐

In a booklet "**Harmful agents in the working environment – limit values**" there are signed ***Ft** *– fetotoxicity.

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Documentations of MAC values for reprtotoxic substances are published in a publication of the Interdepartmental Commission "Principles and Methods of Assessing the Working Environment". The list of substances with singed "Ft" are published in booklet "**Harmful agents in the working environment – limit values**" (only in Polish language).

Annex 1

The list of existing guidelines:

Czynnik rakotwórczy	Carcinogen	CAS	Numer No.
Aflatoksyny	Aflatoxins	1162-65-8 7220-81-7 1165-39-5 7241-98-7	1
Akrylami	Acrylamide	79-06-1	3
Akrylonitryl	Acrylonitrile	107-13-1	4
5-Allilo-1,3-benzodioksol	5-Allyl-1,3-benzodioxole	94-59-7	2(19)
Arsen i nieorganiczne związki arsenu	Arsenic and inorganic arsenic compounds	------	17
Antygoryt włóknisty	Antigorite fibrous	------	1
Azbest	Asbestos	1332-21-4	5
Azirydyna	Aziridine	151-56-4	16
Barwniki benzydynowe: czerń bezpośrednia 38 błękit bezpośredni 6 brąz bezpośredni 95	Benzidine dyes: Direct Black 38 Direct Blue 6 Direct Brown 95	 1937-37-7 2602-46-2 16071-86-6	9
Benzen	Benzene	71-43-2	12
Benzo[*a*]antracen	Benz[*a*]anthracene	56-55-3	8
Benzydyna	Benzidine	92-87-5	4
Beryl i jego związki	Beryllium and its compounds	------	3
Bifenylo-4-amina	4-Biphenylamine	92-67-1	1(18)
Błękit zawiesinowy 1	Disperse Blue 1	2475-45-8	17
Bromian(V) potasu	Potassium bromate	7758-01-2	17
Bromoeten	Bromoethene	593-60-2	15
1,3-Butadien	1,3-Butadiene	106-99-0	1
Chlorek dimetylokarbamoilu	Dimethylcarbamoyl chloride	79-44-7	15
Chlorek winylu	Vinyl chloride	75-01-4	5
4-Chloroanilina	4-Chloroaniline	106-47-8	13
Chloro(metoksy)metan	Chloro(methoxy)methane	107-30-2	15
α-Chlorowane tolueny i chlorek benzoilu: chlorek benzoilu chloro(fenylo)metan dichloro(fenylo)metan trichloro(fenylo)metan	α-Chlorinated toluenes and benzoyl chloride: benzoyl chloride chloro(phenyl)methane dichloro(phenyl)methane trichloro(phenyl)methane	 98-88-4 100-44-7 98-87-3 98-07-7	14
p-Chloro-*o*-toluidyna	*p*-Chloro-*o*-toluidine	95-69-2	1
Czerwień zasadowa 9	Basic Red 9	569-61-9	13
Czynniki rakotwórcze lub mutagenne w środowisku pracy – nowe ustawodawstwo	Carcinogenic and/or mutagenic agents in working environment – the new regulations	------	2(21)
1,2-Dibromo-3-chloropropan	1,2-Dibromo-3-chloropropane	96-12-8	13
2,3-Dibromopropan-1-ol	2,3-Dibromopropan-1-ol	96-13-9	2(19)
1,2-Dibromoetan	1,2-Dibromoethane	106-93-4	6
1,2-Dichloroetan	1,2-Dichloroethane	107-06-2	14
2,2’-Dichloro-4,4’-metylenodianilina	2,2’-Dichloro-4,4’-methylenedianiline	101-14-4	16
3,3’-Dichlorobenzydyna i jej sole	3,3’-Dichlorobenzidine and its salts	91-94-1	1(22)
3,3’-Dimetoksybenzydyna i jej sole	3,3’-Dimethoxybenzidine and its salts	119-90-4	1(22)
3,3’-Dimetylobenzydyna i jej sole	3,3’-Dimethylbenzidine and its salts	119-93-7	1(22)
1,1-Dimetylohydrazyna	1,1-Dimethylhydrazine	57-14-7	17
1,2-Dimetylohydrazyna	1,2-Dimethylhydrazine	540-73-8	13

Czynnik rakotwórczy	Carcinogen	CAS	Numer No.
2,4-Dinitrotoluen	2,4-Dinitrotoluene	121-14-2	1(18)
2,6-Dinitrotoluen	2,6-Dinitrotoluene	606-20-2	13
Epichlorohydryna	Epichlorohydrin	106-89-8	4
1,2-Epoksy-3-fenoksypropan	1,2-Epoxy-3-phenoxypropane	122-60-1	1(18)
2,3-Epoksypropan-1-ol	2,3-Epoxypropan-1-ol	556-52-5	14
Eter bis(chlorometylowy)	Bis(chloromethyl)ether	542-88-1	4
N-Etylo-*N*-nitrozomocznik	*N*-Ethyl-*N*-nitrosourea	759-73-9	2
Fluorek winylu	Vinyl fluoride	75-02-5	8
Formaldehyd	Formaldehyde	50-00-0	4
Frakcje destylacyjne smoły węglowej i mieszaniny frakcji	Coal-tar distillate fractions and their mixtures	------	11
Furan	Furan	110-00-9	2(19)
Gazyfikacja węgla	Coal gasification	------	11
Heksachlorobenzen	Hexachlorobenzene	118-74-1	15
Hydrazyna	Hydrazine	302-01-2	9
Kadm i jego związki	Cadmium and its compounds	------	3
Kaptafol	Captafol	2425-06-1	1
2-Metoksyanilina	2-Methoxyaniline	90-04-0	16
6-Metoksy-*m*-toluidyna	6-Methoxy-*m*-toluidyne	120-71-8	1(22)
N-Metylo-*N'*-nitro-*N*-nitrozoguanidyna	*N*-Methyl-*N'*-nitro-*N*-nitrosoguanidine	70-25-7	2
N-Metylo-*N*-nitrozomocznik	*N*-Methyl-*N*-nitrosourea	684-93-5	2
2-Naftyloamina	2-Naphtylamine	91-59-8	7
Nikiel i jego związki	Nickel and its compounds	------	10
4-Nitrobifenyl	4-Nitrobiphenyl	92-93-3	7
Nitrofen	Nitrofen	1836-75-5	1(20)
2-Nitropropan	2-Nitropropane	79-46-9	15
2-Nitroanizol	2-Nitroanisole	91-23-6	17
N-Nitrozodietyloamina	*N*-Nitrosodiethylamine	55-18-5	2
N-Nitrozodimetyloamina	*N*-Nitrosodimethylamine	62-75-9	2
2,2'-(Nitrozoimino)dietanol	2,2'-(Nitrosoimino)diethanol	1116-54-7	2(19)
Odlewnictwo żelaza i stali	Iron and steel founding	------	11
Oleje łupkowe	Shale-oils	68308-34-9	8
Oleje mineralne nierafinowane lub słabo rafinowane	Mineral oils untreated or mildly-treated	8002-05-9	5
Paki węglowe	Coal-tar pitches	65996-93-2	6
Pochodne chlorowane bifenylu	Polychlorinated biphenyls	53469-21-9 11097-69-1	9
Produkcja aluminium	Aluminium production	------	11
Produkcja koksu	Coke production	------	11
Produkcja i naprawa obuwia	Boot and shoe manufacture and repair	------	12
Propano-3-lakton	Propane-3-lactone	57-57-8	16
Propano-1,3-sulton	1,3-Propanesultone	1120-71-4	16
Przemysł gumowy	Rubber industry	------	9
Przemysł meblarski i stolarstwo meblowe	Furniture and cabinet-making	------	12
Pyły drewna	Wood dusts	------	10
Pyły włókien ceramicznych	Refractory ceramic fibres	------	2(19)
Rafinacja ropy naftowej	Petroleum refining	------	11
Sadze kominowe	Soots	------	7
Siarczan dietylowy	Diethyl sulfate	64-67-5	5
Siarczan(VI) dimetylu	Dimethyl sulfate	77-78-1	14
Siarczan(VI) kobaltu	Cobalt(II) sulfate	10124-43-3	1(20)

Czynnik rakotwórczy	Carcinogen	CAS	Numer No.
Smoły węglowe	Coal tars	8007-45-2	5
Spaliny silnika Diesla	Diesel engine exhausts	------	6
Sulfalat	Sulfallate	95-06-7	1(20)
Talk	Talc	14807-96-6	3
Tetrachloroeten	Tetrachloroethene	127-18-4	6
N,N,N'N'-Tetrametylo-4,4'-metylenodianilina	4,4'-Methylenebis(*n,n*-dimethyl)benzenamine	101-61-1	1(22)
Tioacetamid	Thioacetamide	62-55-5	1(18)
Tlenek etylenu	Ethylene oxide	75-21-8	3
Tlenek propylenu	Propylene oxide	75-56-9	8
Tlenek styrenu	Styrene-7,8-oxide	96-09-3	1(18)
Tolueno-2,4-diamina	Toluene-2,4-diamine	95-80-7	1(20)
o-Toluidyna	*o*-Toluidine	95-53-4	14
Trichloroeten	Trichloroethene	79-01-6	6
1,2,3-Trichloropropan	1,2,3-Trichloropropane	96-18-4	7
Tris(2,3-dibromopropylo)fosforan	Tris(2,3-dibromopropyl)phosphate	126-72-7	8
Wielopierścieniowe węglowodory aromatyczne:	Polycyclic aromatic hydrocarbons:		1(20)
Benzo[*a*]piren	Benzo[*a*]pyrene	50-32-8	
Benzo[*e*]piren	Benzo[*e*]pyrene	192-97-2	
Benzo[*b*]fluoranten	Benzo[*b*]fluoranthene	205-99-2	
Benzo[*j*]fluoranten	Benzo[*j*]fluoranthene	205-82-3	
Benzo[*k*]fluoranten	Benzo[*k*]fluoranthene	207-08-9	
Dibenzo[*a,h*]antracen	Dibenzo[*a,h*]anthracene	53-70-3	
Benzo[*a*]antracen	Benzo[*a*]anthracene	56-55-3	
Chryzen	Chrysene	218-01-9	
Wolna krzemionka krystaliczna	Crystalline silica	------	7
Związki chromu(VI)	Chromium(VI) compounds	------	10

Portugal

7 November 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M /R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Benzeno	71-43-2	200-753-7	C1	3,25	1	-	-			cutaneous absorption	National legislation: Decret-law 301/2000, 18/11
Cloreto de vinilo	75-01-4	200-831-0	C1	7,77	3						National legislation: Decret-law 301/2000, 18/11
Éter bis(clorometilo)	542-88-1	208-832-8	C1		0,001						
Amianto: Acnitolite Grunerite (Amusite) Antofilite Crisótilo Crocidolite Tremolite	 77536-66-4 12172-73-5 77536-67-5 12001-29-5 12001-28-4 77536-68-6	-	C1	0,1 fibras/cm^3							National legislation: Decret-law 266/2007, 24/07
Butano	106-97-8	203-448-7	C1		1000						
1,3 Butadieno	106-99-0	203-450-8	C1		2						
Berílio e compostos	7440-41-7	231-150-7	C2	0,002		0,01					
Diazometano	334-88-3	206-382-7	C2		0,2						
Hidrazina	302-01-2	206-114-9	C2		0,01					cutaneous absorption	
N,N dimetilhidrazina	57-14-7	200-316-0	C2		0,01					cutaneous absorption	
Sulfato de dimetilo	77-78-1	201-058-1	C2		0,1					cutaneous absorption	
Cromato de calico	13765-19-0	237-399-8	C2	0,001							
Cromato de estrôncio	7789-06-2	232-142-6	C2	0,0005							
Butano	106-97-8	203-448-7	C2		1000						

[1] Please specify

[2] Please specify

Substance name	CAS number	EINECS number	C/M /R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
1,3 butadieno	106-99-0	203-450-8	C2		2						
1,2 Dicloroetano	107-06-2	203-458-1	C2		10						
Triclorotolueno	98-07-7	202-634-5	C2				0,1			cutaneous absorption	
Hexaclorobenzeno	118-74-1	204-273-9	C2	0,002						cutaneous absorption	
1,4 Dicloro-2-buteno	764-41-0	212-121-8	C2		0,005					cutaneous absorption	
Óxido de etileno	75-21-8	200-849-9	C2		1						
Óxido de propileno	75-56-9	200-879-2	C2		2						
3-Propanolida (or ß-Propiolactona)	57-57-8	200-340-1	C2		0,5						
Acrilonitrilo	107-13-1	203-466-5	C2		2					cutaneous absorption	
2-Nitropropano	79-46-9	201-209-1	C2		10						
2-Metoxianilina (o-Anisidina)	90-04-0	201-963-1	C2	0,5						cutaneous absorption	
2,2 – Dicloro -4,4-metileno dianilina	101-14-4	202-918-9	C2		0,01					cutaneous absorption	
o-Toluidina	95-53-4	202-429-0	C2		2					cutaneous absorption	
Etilenoimina	151-56-4	205793-9	C2		0,5					cutaneous absorption	
2-Metilaziridina	75-55-8	200-878-7	C2		2					cutaneous absorption	
Captafol	2425-06-1	219-363-3	C2	0,1						cutaneous absorption	
Acrilamida	79-06-1	201-173-7	C2	0,03						cutaneous absorption	
Gases de petróleo liquefeito (GPL)	68476-85-7	270-704-2	C2		1000						
Gasolina	8006-61-9	232-349-1	C2		300		500				
Compostos de crómio (composed of crómio) Soluble in water Insoluble in water	-	-	C2	 0,05 0,01							
Tricloroetileno	79-01-6	201-167-4	C2		50		100				
α Clorotolueno (or Cloreto de Benzilo)	100-44-7	202-853-6	C2		1						
Óxido de propileno	75-56-9	200-879-2	C2		2						
2,3 Epoxipropano-1-ol (or Glicidol)	556-52-5	209-128-3	C2		2						
Éter fenilglicídico	122-60-1	204-557-2	C2		0,1					cutaneous absorption	
Fenilhidrazina	100-63-0	202-873-5	C2		0,1					cutaneous absorption	

Substance name	CAS number	EINECS number	C/M /R[1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m^3]	ppm	[mg/m^3]	ppm				
Acrilamida	79-06-1	201-173-7	M	0,03						cutaneous absorption	
Etilenoimina	151-56-4	205-793-9	M		0,5					cutaneous absorption	
Óxido de etileno	75-21-8	200-849-9	M		1						
Butano	106-97-8	203-448-7	M		1000						
1,3 Butadieno	106-99-0	203-450-8	M		2						
Óxido de propileno	75-56-9	200-879-2	M		2						
2-Etóxietanol	110-80-5	203-804-1	R		5						
Mónoxido de carbono	630-08-0	211-128-3	R		25						
Cromato de chumbo	7758-97-6	231-846-0	R	0,05 (express in lead) 0,012 (express in cromio)							
Warfina	81-81-2	201-377-6	R	0,1							
Tetracarbonilniquel (or Níquel carbonilo)	13463-39-3	236-669-2	R		0,05						
Acetato de 2 metoxietilo	110-49-6	203-772-9	R		0,1					cutaneous absorption	
2 Metozietanol (or 2-Metoxietanol)	109-86-4	203-713-7	R		0,1						
Acetato de 2 etoxietilo	111-15-9	203-839-2	R		5					cutaneous absorption	
N,N – Dimetioformamida (or Dimetilformamida)	68-12-2	200-679-5	R		10					cutaneous absorption	

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☒

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☐ Availability of data on exposure
- ☐ Availability of toxicological data
- ☐ Number of persons exposed
- ☐ Severity of effects
- ☐ Epidemiological evidence, including reported cases of ill-health in the workplace
- ☐ Availability of measurement methods
- ☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☐ Scientific experts
- ☐ Social partners – Employers
- ☐ Social partners – Workers
- ☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

there is a technical Portuguese committee that regularly meets in order to review the Portuguese standard about the OEL

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	X

e) Which kind of limit values are adopted?

☐ 8-hour limit values

☐ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☐	☐

If yes, with which parties?

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
☐	☒

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	**No**
☐	☒

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	**No**
☐	☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	**No**
☐	☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	**No**
☐	☐

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	**No**
☐	☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary?

Yes	**No**
☐	☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☐

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☐

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☒ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

Our OEL's are based on the ACGIH (American Conference of Governmental Industrial Hygienists) values (2006), except for those that have specific European legislation

i) Are limit values indicative or constraining?

☐ indicative

☐ constraining

We have indicative limit values for non carcinogenic, and non mutagenic substances and we have constraining limit values for three substances that are carcinogenic (Benzeno, cloreto de vinilo, amianto). We also have recommended limit values for other carcinogenic, mutagenic and toxic for reproduction substances that are established on a Portuguese standard (based on ACGIH values)

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** [X] **No** [ ]

The revision of OEL's is based on the latest version of the ACGIH values

m) If yes, how often are limit values revised?
Please specify time period:

annually

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes ☐ **No** ☐

o) Is exposure monitoring mandatory?

Yes ☐ **No** ☐

p) Are there specific measurement methods laid down, or recommended?

Yes ☐ **No** ☐

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes ☐ **No** ☐

If yes, please specify:

r) How is record keeping on the results of such measurements organised? (please describe)

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

The OELs for carcinogenic and mutagenic substances are published on the Portuguese Standard NP1796 of 2007, available on the Portuguese Standardization Body – Portuguese Institute for Quality – www.ipq.pt (available only in Portuguese)

The OEL's for Benzeno (Benzol – CAS 71-43-2), cloreto de vinilo (cloride of vinilo – CAS 75-01-4) and amianto (asbestos) are published on national Decret-laws – DL 301/2000, of 18th November and DL 266/2007, of 24th Jully, available on http://www.dgert.msst.gov.pt/Arquivo/seguranca/Indice%20das%20directivas%20comunitarias.htm only in Portuguese

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting			
Methodology for developing measurement and analytical methods			
Methodology for the derivation of OELs			

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances			
Measurement and analytical methods for individual substances			

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	☐

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☒	☐

On legislation published by the Ministry of Environment

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Slovakia

2 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Acrylamide	79-06-1	201-173-7	C/M	0,03	-					+	
Acrylonitrile (2-propenenitrile)	107-13-1	203-466-5	C	7	3			cyanoethyl valine 420 µg/l blood (erythrocyte)		+	[3]Exposure equivalent for carcinogenic substances (abr. EKA)
arsenic – compounds (III, V as a As) arsenictrioxid, arsenicpentoxide, arsenic acid and arsenous acid and their salts, lead hydrogen arsenate except the hydrogen arsenide)	1303-28-2 7778-39-4 7784-40-9	215-116-9 232-064-2	C	0,1 (I)	-			arsenic 130 µg/ l urine		-	[3]EKA
auramine and its compounds 4,4'-carbonimidoylbis[N,N-dimethylaniline]	492-80-8	207-762-5	C	0,08(I)	-					+	
asbestos (fibres)	-	-	C	0,1 fibr.cm^{-3} 6)	-					-	
Benzene	71-43-2	200-753-7	C	3,25	1,0			benzene 5µg/ l		+	[3]EKA

[1] Please specify
[2] Please specify

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
								blood S-Pheny-lmercaptu-ric acid 0,045 mg/g creatinine (urine) t,t-Muconic acid 2 mg/l urine			
benzidine and its compounds	92-87-5	202-199-1	C	8	-					+	
benzo(a)pyrene - coke industrry - others	50-32-8	200-028-5	C	 0,005 0,002	 - -					 - -	
beryllium and its compounds (except aluminum beryllium silicates) as a metal - metal and alloys working - others	7440-41-7	231-150-7	C	 0,005(I) 0,002(I)	 - -					 - -	
bis(chloromethyl) ether	542-88-1	208-832-8	C	0,005	0,001					+	
1,3-butadiene	106-99-0	203-450-8	C/M	11	5					-	
butane with content ≥ 0,1% of butadiene (n-butane) (isobutane)	 106-97-8 75-28-5	 203-448-7 200-857-2	C/M	2400	1000					-	
1,2-dibromethane	106-93-4	203-444-5	C	0,8	0,1					+	
diethyl sulfate	64-67-5	200-589-6	C/M	0,2	0,03					-	
1,2-dichlorethane (ethylene dichloride)	107-06-2	203-458-1	C	20	5					+	
2,2'-dichloro-4,4'-methylendianiline (3,3'-dichloro-4,4'-	101-14-4	202-918-9	C	0,02	-					+	

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
diaminodiphenylmethane)											
1,2-dimethylhydrazine	540-73-8		C	0,1	-					+	
dimethyl sulfate	77-78-1	201-058-1	C/M	0,1	0,02					+	
2,6-dinitrotoluene	606-20-2	210-106-0	C/M	0,05	0,007					+	
Epichlorhydrin	106-89-8	203-439-8	C	12	3					+	
Etylenimine (aziridine)	151-56-4	205-793-9	C/M	0,9	0,5					+	
etylene oxide	75-21-8	200-849-9	C/M	2	1			hydroxy-ethylvaline 90 µg/ l blood		+	[3]EKA
hydrazine	302-01-2	206-114-9	C	0,13	0,1			hydrazine 380 µg/g creatinine (urine) 340 µg/ l blood		+	[3]EKA
chloromethoxymethane	107-30-2	203-480-1	C	0,003	-					+	
chromium (VI) compounds, including lead chromate (dust/aerosol) except barium chromate			C/M					chromium 35 µg/l erythrocyte whole blood			[3]EKA
- manual coated electrode arc welding				0,1 (I)	-			40 µg/l urine		-	
- manufacturing of water-soluble chrome compounds(VI)				0,1 (I)	-					-	
- others				0,05 (I)	-					-	
cadmium and its coumpounds as adust and aerosole (cadmium oxide,	1306-19-0	215-146-2	C/M							-	

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
cadmium dichloride, cadmium sulfate, cadmium fluoride) -battery production, heat extraction of zinc, lead and mercury, cadmium alloys welding -ostatné	10108-64-2 10124-36-4 7790-79-06	233-296-7 233-331-6 232-222-0		0,03 (I) 0,015(I)	- -					- - -	
4,4'-diaminodiphenyl-methane	101-77-9	202-974-4	C/M	0,1	-					+	
nickel as a metal (nickel monoxide, nickel peroxide, nickel(III) trioxide, nickel sulfide, nickel tetracarbonyl) - others	 1313-99-1 12035-36-8 1314-06-3 16812-54-7 13463-39-3	 215-215-7 234-823-3 215-217-8 240-841-2 236-669-2	C	 0,5 (I) 0,05 (I)	-			nickel 45 µg/l urine		-	[3]EKA
2-nitropropane	79-46-9	201-209-1	C	18	5					-	
silica, crystalline	14808-60-7	-	C	0,1 (R)	-					-	
hard wood dust (oak, beech)[12)]	-	-	C	5,0	-					-	
propylene oxide	75-56-9	200-879-2	C/M	6	2,5					+	
o-toluidine (2-methylaniline)	95-53-4	202-429-0	C	0,5	-					+	
Trichlorethylene	79-01-6	201-167-4	C	275	50			trichlorace-tic acid 100 mg/l urine		-	[3]EKA
Vinylchloride monomer (chloroethene)	75-01-4	200-831-0	C	7,77	3			thiodiclico-lic acid 4 mg/24 h. urine		-	[3]EKA

Note: (I) inhalable fraction
(R) respirable fraction

B. Questions Specific to OELs for Carcinogens and Mutagens

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☒ No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

Note: In the Slovak republic OEL are set down as Technical Exposure Limits (TSH) and they were in the past adapted from TRK of Germany. Present limits valid in the Slovak Republic reflects status and changes from years 2003 – 2004 and current limits proposals according to Directive 2004/37/EC. They are stated in Governmental Order of the Slovak Republic No. 356/2006 Coll. of Laws on health protection of workers to the risks arising from exposure to carcinogenic and mutagenic factors at work. The Slovak Republic has neither a commission for the setting up of limits nor a scientific and research basis for establishing of limits. Therefore we adapt limits of any other EU states.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

☐ 5 Availability of data on exposure

☐ 2 Availability of toxicological data

☐ 6 Number of persons exposed

☐ 3 Severity of effects

☐ 1 Epidemiological evidence, including reported cases of ill-health in the workplace

☐ 4 Availability of measurement methods

☐ 7 Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☐ Scientific experts

☐ Social partners – Employers

☐ Social partners – Workers

☒ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	☒

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☒ Short-term limit values

☐ Ceiling limit values

☐ Biological limit values

☐ No limit values

☒ Other (please explain) - as an "exposure equivalent for carcinogenic substances" EKA

f) Is there a consultation?

Yes	**No**
☒	☐

If yes, with which parties?
Ministry of Labour, Employers

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	**No**
☐	☒

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	**No**
☐	☒

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☒

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☒

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☒

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☒

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☒

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☒ **No** ☐

At assessment and prediction of risks in a process of decision making dealing with risk control measures which is responsibility of employers, local authorities etc.

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☒

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☒ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

Most of limits have been adapted from MAK (Federal Republic of Germany), UK or Czech Republic.

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☒ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

Approval procedure.
We see a problem therein that there is not established any specific expert committee or commission for adoption of an OEL.

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☒ **No** ☐

m) If yes, how often are limit values revised?
Please specify time period:

3 – 5 years according to new toxicologic-epidemiological informations or legislative requirements.

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes ☐ **No** ☒

o) Is exposure monitoring mandatory?

Yes ☒ **No** ☐

Employers are obliged to make a risks assessment in compliance with Governmental Order of the Slovak Republic No. 356/2006 Coll. of Laws (this Governmental Order adapts requirements of relevant Directive 2004/37/EC.

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☐	☒

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes	No
☒	☐

If yes, please specify:

As for carcinogens with established biological limit value there are available methods for biological monitoring.

r) How is record keeping on the results of such measurements organised? (please describe)

Results are kept by employers and occupational health services. Since measurements in the Slovak Republic are performed and organised also by Regional Authorities of Public Health, copies of all records and documentation are kept and archived by these authorities.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

Law No. 355/2007 Coll. of Laws on protection, promotion and development of public helath (in force from 1. sept. 2007)
Governmental Order of the Slovak Republic No. 356 Coll. of Laws on the health protection of workers from the risks related to exposure to carcinogens or mutagens at work as amended

These legislative documents are published in printed version of Collection of Laws and also published at www.zbierka.sk (in Slovak language).

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**X**	
Methodology for developing measurement and analytical methods		**X**	
Methodology for the derivation of OELs		**X**	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**X**		Selected Regional Public Health Authorities with laboratories at the Slovak Republic.
Measurement and analytical methods for individual substances	**X**		Selected Regional Public Health Authorities with laboratories at the Slovak Republic.

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	☒

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☒	☐

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Informations and documents are available, e.g. from SCOEL reports (Scientific Committee on Occupational Exposure Limits); Advisory Committee on Safety and Health at Work; Working Group on Chemicals at Work of EC.

Slovenia

7 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
1	Acrylamide (Prop-2-enamide) - solid acrylamide – use - other	201-173-7 79-06-1	2	2	3		2_a	 0,06 0,03		4	K, TDK
2	Acrylonitrile	203-466-5 107-13-1	2				2_a	7	3	4	K, TDK
3	4-Allyl-1,2-methylenedioxybenzene (Safrole)	202-345-4 94-59-7	2	3							
4	4-Aminoazobenzene (4-Phenylazoaniline)	200-453-6 60-09-3	2				2_b				
5	4-Aminobiphenyl [92-67-1] and salts of 4-Aminobiphenyl	202-177-1 92-67-1	1				1				
6	4-Amino-3-fluorophenol	402-230-0 399-95-1	2								
7	Ammonium dichromate	232-143-1 7789-09-5	2	2			3				
8	Aromatic hydrocarbons C_{26-55}	307-753-7 97722-04-8	2								
9	Aromatic hydrocarbons C_{8-10}	292-695-4 90989-39-2	2								
10	Arsenic acid [7778-39-4] (As_2O_5) and salts of Arsenic acid	231-901-9 7778-39-4	1				1	0,1 (I)		4	TDK

[1] KTV: lists coefficient to be applied to the 8h-limit value. The exposure to the short-term limit may last a maximum of 15 minutes and may not be repeated more than 4 times within the working hours, and at least 60 minutes must pass between two exposures to this concentration.

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
11	Asbestos	12001-28-4 132207-32-0 12172-73-5 77536-66-4 77536-68-6 77536-67-5 12001-29-5	1				1				
12	Benzidine based azo dyes; 4,4'-diarylazobiphenyl dyes, with the exception of those specified elsewhere in this Annex		2								
13	o-Dianisidine based azo dyes; 4,4'-diarylazo-3,3'-dimethoxybiphenyl dyes with the exception of those mentioned elsewhere in this Annex		2								
14	Azobenzene	203-102-5 103-33-3	2	3							
15	o-Tolidine based dyes; 4,4'-diarylazo-3,3'-dimethylbiphenyl dyes, with the exception of those mentioned elsewhere in this Annex		2								
16	Benzene	200-753-7 71-43-2	1				1	3,25	1	4	K, TDK, EKA, BAT, EU
17	Benzidine (4,4`-Diaminobiphenyl)	202-199-1 92-87-5	1				1				
18	Salts of Benzidine (Salts of 4,4`-Diaminobiphenyl)	208-519-6 531-85-1 208-520-1 531-86-2 244-236-4 21136-70-9 252-984-8 36341-27-2	1				1				
19	Benzo(a)anthracene	200-280-6 56-55-3	2				2_a				
20	Benzo(j)fluoranthene	205-910-3 205-82-3	2				2_b				
21	Benzo(k)fluoranthene	205-916-6 207-08-9	2				2_b				

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
22	Benzo[b]fluoranthene; benzo[e]acephenanthrylene	205-911-9 205-99-2	2				2_b				
23	Benzo(a)pyrene - Coking pitch residue - preparation and handling; coke oven surroundings; - other	200-028-5 50-32-8	2	2	2	2	2_a	 0,005 0,002		4	TDK
24	Benzo(e)pyrene	205-892-7 192-97-2	2								
25	Beryllium [7440-41-7] compounds with the exception of aluminium beryllium silicates and with the exception of those mentioned elsewhere in this Annex - grinding - other	231-150-7 7440-41-7	2				1	 0,005 (I) 0,002 (I)		4	TDK
26	Beryllium oxide	215-133-1 1304-56-9	2								
27	Bis (chloromethyl) ether (Oxibis(chloromethan))	208-832-8 542-88-1	1				1				
28	Bromoethylene (Vinyl bromide)	209-800-6 593-60-2	2								
29	1,3-Butadiene - treatment after polymerization - other	203-450-8 106-99-0	1	2			2_a	 34 11	 15 5	4	TDK
30	Butane containing ≥ 0,1 % Butadiene [203-450-8]	203-448-7 106-97-8	1	2				2400	1000	4	
31	Zinc chromates including zinc potassium chromate		1				1				
32	4,4′-Diaminodiphenylmethane	202-974-4 101-77-9	2	3				0,1		4	K, TDK
33	Diaminotoluene	246-910-3 25376-45-8	2								
34	Arsenic pentoxide	215-116-9 1303-28-2	1				1	0,1 (I)		4	TDK
35	Diarsenic trioxide (Arsenic (III) oxide)	215-481-4 1327-53-3	1				1	0,1 (I)		4	TDK, EKA
36	Diazomethane	206-382-7 334-88-3	2				3				

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
37	Dibenz(a, h)anthracene	200-181-8 53-70-3	2				2_a				
38	1,2-Dibromoethane (Ethylene dibromide)	203-444-5 106-93-4	2				2_a	0,8	0,1	4	K, TDK
39	1,2-Dibromo-3-chloropropane	202-479-3 96-12-8	2	2	*1*						
40	2,3-Dibromopropan-1-ol (2,3-Dibromo-1-propanol)	202-480-9 96-13-9	2	3							
41	1,2,3,4-Diepoxybutane (2,2'-Bioxirane)	215-979-1 1464-53-5	2	2							
42	Diethyl sulphate	200-589-6 64-67-5	2	2			2_a	0,2	0,03	4	K, TDK
43	3,3'-Dichlorobenzidine	202-109-0 91-94-1	2				2_b	0,03 (I)	0,003	4	K, TDK
44	Salts of 3,3′-Dichlorobenzidine	210-323-0 612-83-9 265-293-1 64969-34-2 277-822-3 74332-73-3	2				2_b	0,03 (I)	0,003	4	K, TDK
45	1,4-Dichlorobut-2-ene	212-121-8 764-41-0	2					0,05	0,01	4	K, TDK
46	1,2-Dichloroethane (Ethylene chloride)	203-458-1 107-06-2	2				2_b	20	5	4	TDK
47	2,2′-Dichloro-4,4′-methylenedianiline [101-14-4] and Salts of 2,2′-Dichloro-4,4′-methylenedianiline (4,4′-Methylene bis(2-chloroaniline) and Salts of 4,4′-Methylene bis(2-chloroaniline))	202-918-9 101-14-4	2				2_a	0,02		4	K, TDK
48	1,3-Dichloro-2-propanol	202-491-9 96-23-1	2								
49	3,3′-Dimethylbenzidine (o-Tolidine)	204-358-0 119-93-7	2				2_b	0,03 (I)	0,003	4	K, TDK
50	Salts of 3,3′-dimethylbenzidine (Salts of o-Tolidine)	210-322-5 612-82-8 265-294-7 64969-36-4 277-985-0 74753-18-7	2				2_b	0,03 (I)	0,003	4	K, TDK

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
51	1,2-Dimethylhydrazine	540-73-8	2				2_b				
52	N,N-Dimethylhydrazine	200-316-0 57-14-7	2				2_b				
53	Dimethylcarbamoyl chloride	201-208-6 79-44-7	2				2_a				
54	Dimethylnitrosamine (N-Nitrosodimethylamine) - vulcanization, finishing, including storage of rubber technical products; pneumatic tyres storages built before 1992 - manufacturing of Polyacrylonitrile (dry procedure) using dimethylformaldehyde -filling of containers and reactors with amines -other	200-549-8 62-75-9	2				2_a	 0,0025 0,0025 0,0025 0,001		4	TDK
55	N,N-Dimethylsulfamoylchloride	236-412-4 13360-57-1	2					0,1		4	K, TDK
56	Dimethyl sulphate - production - use	201-058-1 77-78-1	2	3			2_a	 0,1 0,2	 0,02 0,04	4	K, TDK
57	3,3′-Dimethoxybenzidine and Salts of 3,3′-Dimethoxybenzidine (o-Dianisidine and Salts of o-Dianisidine)	204-355-4 119-90-4	2				2_b	0,03 (I)	0,003	4	K, TDK
58	Disodium 4-amino 3-[[4′-[(2,4-diaminophenyl)azo][1,1′-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphtalene-2,7-disulphonate (C.I. Direct Black 38)	217-710-3 1937-37-7	2			3					
59	Disodium 3,3′-[[1,1′-bifenyl]-4,4′dylbis(azo)]bis[4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	209-358-4 573-58-0	2			3					

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
60	Disodium {5-[(4′-((2,6-hydroxy-3-((2-hydroxy-5-sulphophenyl)azo) phenyl)azo) (1,1′-biphenyl)-4-yl)azo]salicylato(4-)} cuprate(2-) (C.I. Direct Brown 95)	240-221-1 16071-86-6	2								
61	Dinickel trioxide	215-217-8 1314-06-3	1				1				
62	Dinitrotoluene	246-836-1 25321-14-6	2	3	*3*						
63	2,3-Dinitrotoluene	210-013-5 602-01-7	2	3	*3*						
64	2,4-Dinitrotoluene	204-450-0 121-14-2	2	3	*3*						
65	2,5-Dinitrotoluene	210-581-4 619-15-8	2	3	*3*						
66	2,6-Dinitrotoluene	210-106-0 606-20-2	2	3	*3*		2_b	0,05	0,007	4	K, TDK
67	3,4-Dinitrotoluene	210-222-1 610-39-9	2	3	*3*			1,5			K, TDK
68	3,5-Dinitrotoluene	210-566-2 618-85-9	2	3	*3*						
69	1,2-Epoxy-3-phenoxypropane (Phenyl glycidyl ether) (2,3-Epoxypropyl phenyl ether)	204-557-2 122-60-1	2	3							
70	2,3-Epoxypropan-1-ol (Glycidol)	209-128-3 556-52-5	2	3	*2*			150	50	1	K
71	R-2,3-Epoxy-1-propanol	404-660-4 57044-25-4	2	3	*2*						
72	Erionite	12510-42-8	1				1				
73	Ethyleneimine (Aziridine)	205-793-9 151-56-4	2	2			3	0,9	0,5	4	K, TDK
74	Ethylene oxide (Oxirane)	200-849-9 75-21-8	2	2			1	2	1	4	K, TDK, EKA
75	Phenylhydrazine	202-873-5 100-63-0	2	3				22	5		K
76	Phenylhydrazine hydrochloride	248-259-0 27140-08-5	2	3							

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
77	Phenylhydrazinium chloride	200-444-7 59-88-1	2	3							
78	Phenylhydrazinium sulphate (2:1)	257-622-2 52033-74-6	2	3							
79	Furan	203-727-3 110-00-9	2	3							
80	Hexachlorobenzene	204-273-9 118-74-1	2								
81	Hydrazine and Salts of Hydrazine	206-114-9 302-01-2	2					0,13	0,1	4	K, TDK
82	Hydrazine bis(3-carboxy-4-hydroxybenzensulfonate)	405-030-1	2								
83	Hydrazine-tri-nitromethane	414-850-9	2								
84	Hydrazobenzene	204-563-5 122-66-7	2								
85	6-Hydroxy-1-(3-isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo) phenylazo]-1,2-dihydro-3-pyridinecarbonitrile	400-340-3 85136-74-9	2								
86	4,4'-((4-Iminocycloheksa-2,5-dienylidene)methylene)dianiline hydrochloride (C.I.Basic Red 9)	209-321-2 569-61-9	2								
87	Isobutane containing ≥ 0,1 % Butadiene [203-450-8]	200-857-2 75-28-5	1	2							
88	Cadmium fluoride	232-220-0 7790-79-6	2	2	*2*	2					
89	Cadmium chloride	233-296-7 10108-64-2	2	2	*2*	2	1				
90	Cadmium oxide	215-146-2 1306-19-0	2				1				
91	Cadmium sulphate	233-331-6 10124-36-4	2				1				
92	Calcium chromate	237-366-8 13765-19-0	2				1				
93	Potassium bromate	231-829-8 7758-01-2	2				2_b				
94	Potassium dichromate	231-906-6 7778-50-9	2	2							K, EKA

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
95	Potassium chromate	232-140-5 7789-00-6	2	2							EKA
96	Captafol (ISO) (1,2,3,6-Tetrahydro-N-(1,1,2,2-tetrachloroethylthio) phthalimide)	219-363-3 2425-06-1	2				2_a				
97	Carbadox (INN) (Methyl 3-(quinoxalin-2-ylmethylene)carbazate 1,4-Dioxide)	229-879-0 6804-07-5	2								
98	4-Chloroaniline	203-401-0 106-47-8	2				2_b	0,2	0,04	4	K, TDK
99	1-Chloro-2,3-epoxypropane (Epichlorhydrin)	203-439-8 106-89-8	2				2_a	12	3	4	K, TDK
100	(R)-1-Chloro-2,3-epoxypropane	424-280-2 51594-55-9	2								
101	Chloromethyl methyl ether (Chlorodimethyl ether)	203-480-1 107-30-2	1								
102	α-Chlorotoluene (Benzyl chloride)	202-853-6 100-44-7	2					0,2		4	TDK
103	Cobalt dichloride	231-589-4 7646-79-9	2								
104	Cobalt sulphate	233-334-2 10124-43-3	2								
105	Chrysene	205-923-4 218-01-9	2	3							
106	Chromium (VI) compounds, with the exception of Barium chromate and of compounds specified elsewhere in this Annex - manual arc-welding - preparation of soluble Chromium (VI) compounds - other		2				1	 0,1 (I) 0,1 (I) 0,05 (I)		4	TDK, EKA, BAT
107	Chromium III chromate (Chromic chromate)	246-356-2 24613-89-6	2				1				

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
108	Chromic oxychloride (Chromyl dichloride)	239-056-8 14977-61-8	2	2							
109	Chromium (VI) trioxide	215-607-8 1333-82-0	1				1				
110	Methyl acrylamidoglycolate (containing ≥ 0,1 % Acrylamide)	403-230-3 77402-05-2	2	2							
111	Methyl acrylamidomethoxyacetate (containing ≥ 0,1 % Acrylamide)	401-890-7 77402-03-0	2	2							
112	2-Methylaziridine (Propyleneimine)	200-878-7 75-55-8	2				2_b				
113	Methyl-ONN-azoxymethyl acetate (Methyl azoxy methyl acetate)	209-765-7 592-62-1	2			2	2_b				
114	4,4'-Methylenedi-o-toluidine	212-658-8 838-88-0	2				2_b	0,05		4	K, TDK
115	4-Methyl-m-phenylenediamine (2,4-Toluenediamine)	202-453-1 95-80-7	2					0,1		4	K, TDK
116	1-Methyl-3-nitro-1-nitrosoguanidine	200-730-1 70-25-7	2				2_a				
117	2-Methoxyaniline (o-Anisidine)	201-963-1 90-04-0	2	3				0,5	0,1	4	K, TDK
118	2-Naphthylamine	202-080-4 91-59-8	1				1				
119	Salts of 2-Naphthylamine	209-030-0 553-00-4 210-313-6 612-52-2	1								
120	Sodium dichromate anhydrate	234-190-3 10588-01-9	2	2							
121	Sodium dichromate, dihydrate	234-190-3 7789-12-0	2	2							
122	Sodium chromate	231-889-5 7775-11-3	2	2							
123	Nickel dioxide	234-823-3 12035-36-8	1				1				
124	Nickel monoxide	215-215-7 1313-99-1	1				1				

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
125	Nickel sulphide	240-841-2 16812-54-7	1				1				
126	5-Nitroacenaphthene	210-025-0 602-87-9	2				2_b				
127	2-Nitroanisole	202-052-1 91-23-6	2				2_b				
128	4-Nitrobiphenyl	202-204-7 92-93-3	2				3				
129	Nitrofen (ISO) (2,4-Dichlorophenyl-4-nitrophenyl ether)	217-406-0 1836-75-5	2			2	2_b				
130	2-Nitronaphthalene	209-474-5 581-89-5	2				3	0,25	0,035	4	TDK
131	2-Nitropropane	201-209-1 79-46-9	2					18	5	4	TDK
132	Nitrosodipropylamine	210-698-0 621-64-7	2				2_b				
133	2,2′-(Nitrosoimino)bisethanol	214-237-4 1116-54-7	2				2_b				
134	Wood dust		1	1			1	5 (I*[2])		4	TDK, EU
135	3-Propanolide (1,3-propiolactone)	200-340-1 57-57-8	2				2_b				
136	1,3-Propanesultone	214-317-9 1120-71-4	2				2_b				
137	Propylene oxide (1,2-epoxypropane) (Methyloxirane)	200-879-2 75-56-9	2	2				6	2,5	4	K, TDK
138	Refractory ceramic fibres; Special Purpose Fibres, with the exception of those specified elsewhere in this Annex (Manmade vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na2O + K2O + CaO + MgO + BaO) content less or equal to 18 % by weight.)		2								

[2] I* : inhalable fraction of wood dust – when hard wood is mixed with other kinds of wood dust, the limit value should be used for wood dust mixture

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
139	Styrene oxide ((Epoxyethyl)benzene)	202-476-7 96-09-3	2								
140	Strontium chromate	232-142-6 7789-06-2	2				1				
141	Sulfallate (ISO) (2-Chlorallyl diethyldithiocarbamate)	202-388-9 95-06-7	2				2_b				
142	Lead hydrogen arsenate	232-064-2 7784-40-9	1		*3*	1					
143	1,4,5,8-Tetraaminoanthraquinone (C.I. Disperse Blue 1)	219-603-7 2475-45-8	2								
144	Tetrasodium 3,3′-[[1,1′-biphenyl]-4,4′-dylbis(azo)]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonate] (C.I. Direct Blue 6)	220-012-1 2602-46-2	2			3					
145	Thioacetamide	200-541-4 62-55-5	2				2_b				
146	4-o-Tolylazo-o-toluidine (4-Amino-2',3-dimethylazobenzene) (o-Aminoazotoluene)	202-591-2 97-56-3	2				2_b				
147	Toluene-2,4-diammonium sulphate	265-697-8 65321-67-7	2								K
148	o-Toluidine	202-429-0 95-53-4	2				2_b	0,5		4	K,TDK
149	Hexamethylphosphoric triamide (Hexamethylphosphoramide)	211-653-8 680-31-9	2	2			2_b				
150	Trichloroethylene (Trichloroethene)	201-167-4 79-01-6	2	3				270	50	4	Y, BAT
151	α,α,α-Trichlorotoluene (Benzotrichloride)	202-634-5 98-07-7	2				2_b	0,1	0,012	4	TDK

No.	Substance name	EINECS No. CAS No.	Classification					Limit value (8 hour)		Short-term limit value[1]	Notations
			C	M	R_F	R_E	IARC	mg/m^3	ml/m^3 (ppm)		
1	2	3	4					5	6	7	8
152	Trisodium-[4'-(8-acetylamino-3,6-disulfonato-2-naphthylazo)-4''-(6-benzoylamino-3-sulfonato-2-naphthylazo)biphenyl-1,3',3'',1'''-tetraolato-O, O', O'', O''']copper(II)		2								
153	Nickel subsulphide	234-829-6 12035-72-2	1				1				
154	1,3,5-Tris-[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione	59653-74-6		2							
155	1,3,5,-Tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione (TGIC)	219-514-3 2451-62-9		2							
156	Urethane(INN) (Ethyl carbamate)	200-123-1 51-79-6	2				2_b				
157	Vinyl chloride (Chloro-1-ethylene)	200-831-0 75-01-4	1				1	7,77	3	4	TDK, EKA, EU
158	A mixture of: N-[3-hydroxy-2-(2-methylacryloylamino-methoxy) propoxymethyl]-2-methylacrylamide; N-[2,3-Bis-(2-methylacryloylamino-methoxy)propoxymethyl]-2-methylacrylamide; methacrylamide; 2-methyl-N-(2-methyl-acryloylaminomethoxymethyl)-acrylamide; N-2,3-dihydroxypropoxymethyl)-2-methylacrylamide	412-790-8	2	3							

The meaning of notations:

Notation	
K	Skin notation
Y	Embrio notation - there is no danger for embrio when the limit value and biological limit value are respected

EU	European Union – limit value adpted on EU level
TDK	Technically reachable concentration
BAT	Biological limit value
EKA	EKA value

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☒

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

1 Availability of data on exposure

2 Availability of toxicological data

4 Number of persons exposed

5 Severity of effects

3 Epidemiological evidence, including reported cases of ill-health in the workplace

6 Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☐ Scientific experts

☐ Social partners – Employers

☐ Social partners – Workers

☐ Public authority - Ministry of Health

☒ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☐	☒

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☒ Short-term limit values

☐ Ceiling limit values

☒ Biological limit values

☐ No limit values

☒ Other (please explain)

TDK – technically reachable concentratios

f) Is there a consultation?

Yes	**No**
☒	☐

If yes, with which parties?

There is a consultation with all social partners.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes ☐ **No** ☒

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes ☐ **No** ☒

If yes, please provide the name, address and website details:

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☐ **No** ☒

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☒

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☒

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☒

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☒

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☒

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☒

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☒ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

TRGS 905 – German technical standard

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** ☒

m) If yes, how often are limit values revised?
Please specify time period:

B. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	☒

o) Is exposure monitoring mandatory?

Yes	No
☒	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☐	☒

If yes, please specify:

q) Is biological monitoring included in the monitoring methods?

Yes	No
☐	☒

If yes, please specify:

r) How is record keeping on the results of such measurements organised? (please describe)

The employer must keep the list of all workers exposed together with the factors of exposure (name of the substance, duration of exposure, concentration of the substance) at least 40 years after the end of exposure

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

OELs for carcinogens and mutagens are listed in the Rules on the protection of the workers from the risks related to exposure to carcinogens and/or mutagens (Official Gazzette of the Republic of Slovenia, No. 101/2005).

Rules are available on the Webpage of the Government Office for Legislation and on the Webpage of the Ministry of Labour, Family and Social Affairs:

http://zakonodaja.gov.si/rpsi/r09/predpis_PRAV6839.html
http://www.mddsz.gov.si/si/zakonodaja_in_dokumenti/veljavni_predpisi

The document is available only in Slovene language.

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**X**	
Methodology for developing measurement and analytical methods		**X**	
Methodology for the derivation of OELs		**X**	

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances		**X**	
Measurement and analytical methods for individual substances		**X**	

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☐	☒

If yes, how are these limit values applied in practice?

v) Are there any lists of reprotoxic substances?

Yes	No
☐	☒

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Spain

7 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

The following tables are taken from the publication Occupational Exposure Limit for Chemical Agents in Spain 2007. Available at http://empleo.mtas.es/insht/practice/vlas.htm

OCCUPATIONAL EXPOSURE LIMIT FOR CHEMICAL AGENTS IN SPAIN 2007

LIST FOR CARCINOGENIC AND MUTAGENIC SUBSTANCES WITH LIMIT VALUE ADOPTED

EINECS	CAS	SUBSTANCE	ADOPTED LIMITS VLA-ED ppm	ADOPTED LIMITS VLA-ED mg/m³	C	M	NOTES	PHRASES R
201-173-7	79-06-1	Acrylamide		0,03	C2	M2	Skin, Sen, r	45-46-20/21-25-36/38-43-48/23/24/25-62
232-143-1	7789-09-5	Ammonium dichromate, as Cr		0,05	C1	M2	Sen, r	45-46-60-61-2-8-21-25-26-34-42/43-48/23-50/53
201-963-1	90-04-0	o-Anisidine	0,1	0,5	C2		Skint, r, VLBm	45-23/24/25
		Arsenic acid and salts, as As		00,1	C1		VLB, r, z	45-23/25-50/53
	132207-33-1	Asbestos					t, r	
	132207-32-0	Asbestos :					t, r	45-48/23
	12001-29-5	Chrysotile	0,1 fib/cc		C1		t, r	45-48/23
	77536-66-4	Actinolite	0,1 fib/cc		C1		t, r	45-48/23
	12172-73-5	Amosite	0,1 fib/cc		C1		t, r	45-48/23
	77536-67-5	Antophylite	0,1 fib/cc		C1		t, r	45-48/23
	12001-28-4	Crocidolite	0,1 fib/cc		C1		t, r	45-48/23
	77536-68-6	Tremolite	0,1 fib/cc		C1		t, r	45-48/23
241-775-7	17804-35-2	Benomyl	0.83	10		M2		46-60-61-37/38-43-50/53
200-753-7	71-43-2	Benzene	1	3,25	C1		Skin, VLB, (v)	45-11-48/23/24/25
202-853-6	100-44-7	Benzyl chloride	1	5.3	C2		r	45-22-23-37/38-41-48/22
231-150-7	7440-41-7	Berillium and compounds, as Be		0.0002	C2		Sen, r	49-25-26-36/37/38-43-48/23

EINECS	CAS	SUBSTANCE	ADOPTED LIMITS		C	M	NOTES	PHRASES R
			VLA-ED					
			ppm	mg/m^3				
		Berillium compounds, as Be, except doubles silicates Al+Be and anothers compounds listed in this table		0.0002	C2		Sen, r	49-25-26-36/37/38-43-48/23-51/53
215-133-1	1304-56-9	Berillium oxide		0.0002	C2		Sen, r	49-25-26-36/37/38-43-48/23
208-832-8	542-88-1	Bis(chloromethyl) ether	0,001	0,005	C1		r	45-10-22-24-26
209-800-6	593-60-2	Bromoethylene	0,5	2,2	C2		r	45-12
203-450-8	106-99-0	1,3-Butadiene	2	4,5	C2	M2	r	45-46-12
231-152-8	7440-43-9	Cadmium (stabilized)					VLB, r	45-26-48/23/25-62-63-68-50/53
		Inhalable fraction		0,01			d	
		Respirable fraction		0,002			d	
231-152-8	7440-43-9	Cadmium chloride, as Cd			C2	M2	VLB, r, TR2	45-46-60-61-25-26-48/23/25-50/53
		Inhalable fraction		0,01			d	
		Respirable fraction		0,002			d	
232-220-0	7790-79-6	Cadmium fluoride, as Cd			C2	M2	VLB, r, TR2	45-46-60-61-25-26-48/23/25-50/53
		Inhalable fraction		0,01			d	
		Respirable fraction		0,002			d	
215-146-2	1306-19-0	Cadmium oxide, as Cd			C2	M2	VLB, r	45-26-48/23/25-62-63-68-50/53
		Inhalable fraction		0,01			d	
		Respirable fraction		0,002			d	

EINECS	CAS	SUBSTANCE	ADOPTED LIMITS		C	M	NOTES	PHRASES R
			VLA-ED					
			ppm	mg/m^3				
233-331-6	10124-36-4	Cadmium sulfate			C2	M2	VLB, r, TR2	45-46-60-61-25-26-48/23/25-50/53
		Inhalable fraction		0,01			d,	
		Respirable fraction		0,002			d	
215-147-8	1306-23-6	Cadmium sulfide					VLB, r	45-22-48/23/25-62-63-68-50/53
		Inhalable fraction		0,01	C2		d,	
		Respirable fraction		0,002			d	
237-266-8	13765-19-0	Calcium chromate, as Cr		0,001	C2		r	45-22-50/53
219-363-3	2425-06-1	Captafol		0,1	C2		Skin, s, Sen, r	45-43-50/53
204-818-0	126-99-8	1-Chloro-1,3-butadiene	10	37	C2		Skin, r	45-11-20/22-36/37/38-48/20
203-439-8	106-89-8	1-Chloro-2,3-epoxypropane	0,5	1,9	C2		Skin, Sen, r	45-10-23/24/25-34-43
246-356-2	24613-89-6	Chromium (III) chromate, as Cr		0,05	C2		Sen, r	45-8-35-43-50/53
		Chromium (VI) , inorganics compounds, except lead and barium chromate and listed,			C2		VLB, (c), Sen, r	49-43-50/53
		Solubles compounds, as Cr		0,01				
		Insolubles compounds, as Cr		0,05				
215-607-8	1333-82-0	Chromium trioxide		0,05	C1		VLB, Sen, r	49-8-25-35-43-50/53
239-056-8	14977-61-8	Chromyl chloride	0,025	0,16	C2	M2	Sen, r	49-46-8-35-43-50/53
215-116-9	1303-28-2	Diarsenium pentaoxide, as As		00,1	C1		VLB, r, z	45-23/25-50/53
215-481-4	1327-53-3	Diarsenium trioxide, as As		00,1	C1		VLB, r, z	45-28-34-50/53
206-382-7	334-88-3	Diazomethane	0,2	0,34	C2		r	45

EINECS	CAS	SUBSTANCE	ADOPTED LIMITS VLA-ED		C	M	NOTES	PHRASES R
			ppm	mg/m^3				
203-444-5	106-93-4	1,2-Dibromoethane	0,5	3,9	C2		Skin, s, r	45-23/24/25-36/37/38-51/53
212-121-8	764-41-0	1,4-Dichlorobutadiene	0,005	0,025	C2		Skin, r	45-24/25-26-34-50/53
203-458-1	107-06-2	1,2-Dichloroethane	5	20	C2		s, r	45-11-22-36/37/38
201-058-1	77-78-1	Dimethyl sulfate	0,05	0,26	C2		Skin, Sen, r	45-25-26-34-43
200-316-0	57-14-7	N,N-Dimethylhydrazine	0,01	0,025	C2	M2	Skin, r	45-11-23/25-34-51/53
204-450-0	121-14-2	2,4-Dinitrotoluene		0,15	C2		Skin, VLBm, r	45-23/24/25-48/22-51/53-62-68
210-106-0	606-20-2	2,6-Dinitrotoluene		0,15	C2		Skin, VLBm, r	45-23/24/25-48/22-51/53-62-68
246-836-1	25321-14-6	Dinitrotoluene technique		0,15	C2		Skin, VLBm, r, See Part 8	45-23/24/25-48/22-51/53-62-68
209-128-3	556-52-5	2,3-Epoxy-1-propanol	2	6,2	C2		Sen, TR2, r	45-60-21/22-23-36/37/38-68
200-849-9	75-21-8	Ethylene oxide	1	1,8	C2	M2	s, r	45-46-12-23-36/37/38
205-793-9	151-56-4	Ethyleneimine	0,5	0,9	C2	M2	Skin, r	45-46-11-26/27/28-34-51/53
204-273-9	118-74-1	Hexachlorobenzene		0,002	C2		Skin, ae, r, s, z	45-48/25-50/53
206-114-9	302-01-2	Hydrazine	0,01	0,013	C2		Skin, Sen, r	45-10-23/24/25-34-43-50/53
232-064-2	7784-40-9	Lead arsenate, as $PbHAsO_4$		0,15	C1		TR1, VLB, r, z	45-61-23/25-33-50/53-62
202-918-9	101-14-4	4,4´-Methylene bis(2-chloroaniline) (MBOCA)	0,01	0,1	C2		Skin, r	45-22-50/53
202-974-4	101-77-9	4,4'-Methylene dianiline	0,1	0,82	C2		Skin, Sen, r	45-39/23/24/25-43-48/20/21/22-51/53-68
234-823-3	12035-36-8	Nickel dioxide, as Ni		0,1	C1		Sen, r	49-43-53
234-829-6	12035-72-2	(tri)Nickel disulfide, as Ni		0,1	C1		Sen, r	49-43-51/53
231-111-4	7440-02-0	Nickel monoxide		0,1	C1		Sen, r	49-43-53

EINECS	CAS	SUBSTANCE	ADOPTED LIMITS		C	M	NOTES	PHRASES R
			VLA-ED					
			ppm	mg/m³				
240-841-2	16812-54-7	Nickel sulfide, as Ni		0,1	C1		Sen, r	49-43-50/53
215-217-8	1314-06-3	(di)Nickel trioxide, as Ni		0,1	C1		Sen, r	49-43-53
201-209-1	79-46-9	2-Nitropropane	5	19	C2		r	45-10-20/22
201-853-3	88-72-2	2-Nitrotoluene	5	29	C2	M2	Skin, VLBm, See Part 8	45-46-22-62-51/53
202-429-0	95-53-4	o-Toluidine	0,2	0,89	C2		Skin, VLBm, r	45-23/25-36-50
289-220-8	86290-81-5	Petrol	300		C2		r	45-65
204-557-2	122-60-1	Phenil glycidyl ether (PGE)	0.1	0.62	C2		Skin, Sen, r	45-20-37/38-43-52/53-68
202-873-5	100-63-0	Phenilhidrazine	0.1	0.45	C2		Skin, Sen, r	45-23/24/25-36/38-43-48/23/24/25-68-50
266-028-2	65996-93-2	Pitch, coal tar, high-temp, as benzene solubles		0,2	C2		r	45
232-140-5	7789-00-6	Potassium chromate, as Cr		0,05	C2	M2	Sen, r	49-46-36/37/38-43-50/53
231-906-6	7778-50-9	Potassium dichromate, as Cr		0,05	C2	M2	Sen, r	45-46-60-61-8-21-25-26-34-42/43-48/23-50/53
200-879-2	75-56-9	Propilene oxide	5	12	C2	M2	r, See Part 8	45-46-12-20/21/22-36/37/38

EINECS	CAS	SUBSTANCE	ADOPTED LIMITS		C	M	NOTES	PHRASES R
			VLA-ED					
			ppm	mg/m^3				
200-878-7	75-55-8	Propileneimine	2	4,7	C2		Skin, r	45-11-26/27/28-41-51/53
200-340-1	57-57-8	β-Propiolactone	0,5	1,5	C2		r	45-26-36/38
		Refractory ceramic fibres; special purpose fibres	0,5 fib/cc		C2		h, x, r	49-38
81-889-5	7772-11-3	Sodium chromate, as Cr		0,05	C2	M2	Sen, r	45-46-60-61-21-25-26-34-42/43-48/23-50/53
234-190-3	10588-01-9	Sodium dichromate, as Cr		0,05	C2	M2	Sen, r	45-46-60-61-8-21-25-26-34-42/43-48/23-50/53
	7789-12-0	Sodium dichromate, dihidrated, as Cr		0,05	C2	M2	Sen, r	49-46-21-25-26-37/38-41-43-50/53
232-142-6	7789-06-2	Strontium chromate, as Cr		0,0005	C2		r	45-22-50/53
201-167-4	79-01-6	Trichloroethylene	50	273	C2		VLB, r	45-36/38-52/53-67-68
219-514-3	2451-62-9	1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione		0,05		M2	Sen, r	46-23/25-41-43-48/22-52/53
200-831-0	75-01-4	Vinyl chloride	3	7,8	C1		(w), r	45-12
203-466-5	107-13-1	Vinyl cyanide	2	4,4	C2		Skin, Sen, r	45-11-23/24/25-37/38-41-43-51/53
		Woods hard, dust		5			w, md, fi	
		Zinc chromates, included Zn+K chromate, as Cr		0,01	C1		Sen, r	45-22-43-50/53

List of Biological limit values

OCCUPATIONAL LIMIT EXPOSURE FOR CHEMICAL AGENTS IN SPAIN 2007							
EINECS	**CAS**	**SUBSTANCE**	**BIOLOGICAL INDICATOR**	**VLB**	**Sampling Time**	**Notes**	**Phrases R**
232-066-3	7784-42-1	Arsenic elemental and and soluble inorganic compounds	Arsenic inorganic and methylmetabolites in urine	35 µg As/l	End of workweek (1)	F	23/25-50/53
200-753-7	71-43-2	Benzene	S-Phenylmercapturic acid in urine	120 µg/g creatinine	End of shift (2)	F	45-46-11-36/38-48/23/24/25-65
			t,t-Muconic acid in urine	4.5 mg/g creatinine	End of shift (2)	F	
231-152-8	7440-43-9	Cadmium and inorganic compounds	Cadmium in urine	5 µg/g creatinine	Not critical (3)	F	49-22-49/23/25
			Cadmium in blood	5µg/l	Not critical (3)	F	
			Total p-chlorophenol in urine	25 mg/g creatinine	End of shift (2)	I	
		Chromium (VI), water soluble fume	Total Chromium in urine	10 µg/g creatinine	Increased during shift (4)	F	
				30 µg/ g creatinine	End of workweek (1)	F	
231-100-4	7439-92-1	Lead and ionic derivateds	Lead in blood	70 µg/dl	Not critical (3)	k	
			Hippuric acid in urine	1.6 g/g creatinine	End of shift (2)	F, I	
			Toluene in blood	0.05 mg/l	Prior to last shift of workweek (5)		
201-167-4	79-01-6	Trichloroethylene	Trichloroacetic acid in urine	100 mg/g creatinine	End of workweek (1)		45-36/38-52/53-67
			Trichloroacetic acid plus trichloroethanol in urine, as trichloroacetic acid	300 mg/g creatinine	End of workweek (1)	I	
			Free trichloroethanol in blood	4 mg/l	End of workweek (1)	I	

Key :

Update
VLB under review

Notes to the Tables

(1) It means after four or five consecutive days working under exposure, as soon as possible after the end of the last day, because the biological indicators are removed after five hours. These indicators are accumulated in the body along the work week, and therefore the sampling time is critical in relation to previous exposures.

(2) As soon as possible after the exposure stop.

(3) Biological indicators with a non-critical sampling time have very long elimination half lives and are accumulated in the body over a period of years, sometimes throughout the whole life. Once the stationary state, which varies with each biological indicator, has been achieved (weeks, months), sampling can be carried out at any time. **It is essential to consult the specific documentation on the subject.**

(4) The value refers to the difference in the results of the samples taken at the beginning and at the end of the working day.

(5) Means before commencing the fifth consecutive day of exposure.

(6) Means after two consecutive days without exposure.

(7) The sampling time is not critical due to the fact that the inhibition of the cholinesterase's activity is fairly rapid whereas recuperation is a very slow process.

(8) It means free 2,5-hexanodione, this is, without any combination. This metabolite also is specific in the n-hexane.

(a) Except castor, cashew nut or similar irritant oils.

(ae) Endocrine disturber. It is suspected that a series of substances used in industry, agriculture and consumer goods interferes with the endocrine system in human and animals and causes health damages as cancer, behavior disturbances and reproduction anomalies. Such a substances are named "endocrine disturbers". [Implementation of the communitary strategy for endocrine disturbers - substances suspected of interfering with the hormonal systems in human and animals - COM(1999) 706. European Community Commission, COM(2001) 262 final, Brussels 14-06-2001].

In humans, some potential exposure ways to endocrine disturbers are a direct exposure in the workplace or by consumer goods as food, some plastics, paints, detergents and cosmetics, or an indirect exposure by environment (air, water and soil). [Communitary strategy for endocrine disturbers (substances suspected of interfering with the hormonal systems in human and animals). European Community Commission, COM (1999) 706 final, Brussels, 17-12-1999].

These agents have not any limit value assigned to prevent the potential effects of endocrine disturbance, which should be considered for purposes of vigilance of workers health.

(am) This value is applied to the refined mineral oil and it is not applied to the potential additives in its formulation.

(b) Simple asphyxiant. From the physiological point of view, the only limiting concentration factor is given by the available air oxygen, which must be at least 18%.

(c) The terms soluble and insoluble are understood to refer to the water.

C1 First category carcinogenic substance. "Substances that are known to be carcinogenic for humans. Sufficient elements are available to establish the existence of a cause and effect between human exposure to such substances and the appearance of cancer". Royal Decree 665/1997 is applicable.

C2 Second category carcinogenic substance. "Substances that can be considered as carcinogenic for humans. Sufficient elements are available for it to be assumed that human exposure to such substances can cause cancer. This assumption is normally founded on:

- Appropriate long-term studies on animals

- Other types of pertinent information."

Royal Decree 665/1997 is applicable.

(d) Please refer to UNE EN 481: Workplaces atmospheres. Size fraction definitions for measurement of airborne particles.

(e) This value is for the particulated matter that is free from asbestos and contains less than 1% of crystalline silica.

(F) Background. The biological indicator is normally present in detectable quantities in people who are not occupationally exposed. These background levels are taken into account in the VLB.

(f) Reacts with nitrogenous agents that may give rise to the formation of carcinogenic N-Nitrosamines.

(fi) Inhalable fraction. If the powders from hard woods are mixed with other powders, the limit value will be applicated to all the powders being in the mix (RD 349/2003, March 21th).

(g) Fibres with a random orientation, with a content in alkaline and alkali-earth oxides ($Na_2O+K_2O+CaO+MgO+BaO$) in excess of 18% in weight. Ministerial Order of 11/9/1998 (Official State Gazette No. 223, dated 17th September, 1998), by virtue of which Annexes I and VI to the Regulations for the Notification of New Substances and the Classification, Packing and Labelling of Dangerous Substances, approved by Royal Decree 363/1995, were amended.

(h) Fibres $l>5\mu m$ $d<3\mu m$, $l/d\geq 3$ determined by phase contrast optic microscopy.

(I) Indicates that the biological indicator is non-specific because it can be found after exposure to other chemical agents.

(i) Please refer to notes Q and R of Ministerial Order of 11/9/1998 (Official State Gazette No. 223 dated 17th September, 1998), by virtue of which Annexes I and VI to the Regulations for the Notification of New Substances and the Classification, Packing and Labelling of Dangerous Substances, approved by Royal Decree 363/1995, were amended

(j) According to the available information, the white spirit marketable in Spain contains less than 0,1% of benzene, and it is not classified as carcinogenic.

(k) Royal Decree 374/2001, of 6th April (Official State Gazette No. 104 dated 1st May, 2001) on the protection of the health and safety of workers from the risks related to chemical agents at work

(l) The thermal decomposition in the atmosphere of polytetrafluoroethylene* gives rise to the formation of markedly toxic products, for which at present no VLA has been established but in respect of which it is recommended that their concentration in the atmosphere is kept as low as possible; it is also recommended that smoking in the presence of polytetrafluoroethylene aerosols should be avoided. (* Algoflon, Fluon, Teflon, and Tetran are registered trademarks of polytetrafluoroethylene.

(m) The products of the thermal decomposition in the atmosphere of the welding rosin nucleus, colophony, are known sensitizers, which makes it advisable to keep exposure to them to the minimum.

(md) There are two kinds of woods: soft and hard woods. This is a botanical distinction: gymnospermae give soft woods and angiospermae give hard woods, and the density and hardness of the wood have not any correspondence one-to-one with this classification.

As an example, because this is not an exhaustive list, we can quote among the soft woods: fir, cedar, cypress, larch, spruce, pine, Douglas fir, Oregon pine, secoya, thuya and hemlock. They are hard woods: maple, alder, birch, hickory, carpe, chestnut, beech, ash, walnut, plane, sycamore, poplar, cherry tree, oak, ilez, willow, lime tree, elm and tropical species as Kauri pine, iroko or kambala, rimu or red pine, palisander, Brazilian rosewood, ebony, african mahogany, bete, balsa, nyatoh, afrormosia, meranti, teak, afara, obeche and samba. This relation is taken out the Guía técnica para la evaluación y prevención de los riesgos relacionados con la exposición durante el trabajo a Agentes Cancerígenos o Mutágenos (Technical guide to the risks evaluation and prevention related to the work exposure to Carcinogenic or Mutagenic Agents).

M1 Mutagenic substance to human being. "There are enough elements to set a cause and effect relationship between the human exposure to such substances and the appearance of hereditary genetic alterations". Here it is applicable the RD 665/1997.

M2 This substance can be considered as mutagenic to human being. "There are enough elements to suppose that the human exposure to such substances can produce hereditary genetic alterations. This supposition is based generally on:

- studies appropriate with animals,
- other kind of information relevant."

Here it is applicable the RD 665/1997.

(n) IIn mining work, please refer to Ministerial Order of 16/10/1991 (Official State Gazette No. 260 dated 30th October, 1991), which Complementary Technical Instruction 07.1.04 of Chapter VII of the Basic Mining Safety Standards General Regulation was approved.

(ñ) The composition and quantity of smoke, and the total number of particles, depend on the alloy that is welded and the electrodes that are used. Evaluations based on inhalable smoke concentrations are generally adequate provided that the rod for welding metals or the metal's coating does not contain toxic elements and that conditions do not contribute to the formation of toxic gases. Otherwise, an evaluation must be carried out to establish whether or not the specific Occupational Exposure Limits are exceeded.

(o) Particled matter without toxicological data for preparing a VLA. However, it is recommended to maintain any exposures below generic limit value indicated. Such a limit value only can be applied to particled pollutant matters which meet the following requirements:

- They have not a specific VLA.
- They are insoluble or not much soluble in water (or, preferably, in the watery pulmonary fluid, if this information there is).
- They have a low toxicity, that is, they are not cytotoxic, or genotoxic, or react chemically, or in other way, with the pulmonary tissue, or emit ionizant radiations, or produce sensitization, or any other toxic effect different from the effect which could derive from the mere accumulation in the lung.

(p) However, 2mg/m^3 of respirable particles must not be exceeded.

(q) A generally prohibited chemical agent in accordance with the terms established in Article 8 of Royal Decree 374/2001, of 6th April (Official State Gazette No. 104, dated 1st May, 2001) on the protection of workers' health and safety against the hazards associated with chemical agents in the workplaces.

(r) The commercialization and use of this substance is limited in the Real Decreto 1406/1989 (BOE nº278 20-November), 10-November-1989, and modifications and complementary orders: They impose Limitations to the Commercialization and Use of Dangerous Substances and Preparations.

(s) The commercialization and use of this substance is limited in the Orden from 7-09-1989 (BOE nº219 13-September-1989) modificated by the OM from 1-February-1991 (BOE nº37 12-February-1991), on prohibition of commercialization and use of some phytosanitary products.

S Means that the biological indicator is an indicator of exposure to the chemical agent in question, but that the quantitative interpretation of its measurement is ambiguous (semi-quantitative).

Sen Sensitizer agent. See Section 7.

sr The phytosanitary products which contain this active substance have been withdrawn from the market because they had been excluded from the community list of the Annex I in the RD 2163/1994, as a consequence of the community program for review the active substances in the phytosanitary products, according to the Resolución of 30/6/2003 by the Dirección General de Agricultura (Official State Gazette nº 164, July 10th,2003).

sr(a) These active substances had been included in the Annex I of the RD 2163/1994, November 4th. This Royal Decree implements the community harmonized system of authorization for marketing and using phytosanitary products, and its subsequent changes.

(t) Ministerial Order of 31/10/1984 (Official State Gazette Nº. 267, dated 7th November, 1984) and Ministerial Order of 26/7/1993 (Official State Gazette No. 186, dated 5th August,

1993) and complementary amendments and orders.

TR1 Substance that is harmful for the fertility of human beings or is toxic for their development.

TR2 Substance that can and must be considered harmful for the fertility of human beings and toxic for their development.

For information on reproduction-related toxicity, please refer to: Royal Decree 363/1995, of 10th March (Official State Gazette No. 133 dated 5th June, 1995) on the Notification of New Substances and the Classification, Packing and Labelling of Dangerous Substances; Ministerial Order of 21/2/1997 (Official State Gazette No. 59 dated 10th March, 1997), by which Annex I to the Regulations for the Notification of New Substances and the Classification, Packing and Labelling of Dangerous Substances, approved by Royal Decree 262/1995, of 10th March, was amended; Ministerial Order of 15/12/98 (Official State Gazette No. 305, dated 22nd December, 1998), by which Annex I to Royal Decree 1406/1989, of 10th November, for imposing limitations on the commercialisation and use of certain dangerous substances and preparations, was approved; and Order of 6th July, 2000 (Official State Gazette No.165, dated 11th July, 2000), by which Annex I to Royal Decree 1406/1989, of 10th November, for imposing limitations on the commercialisation and use of certain dangerous substances and preparations, was approved.

(v) Royal Decree 1124/2000, of 16th June (Official State Gazette No. 145, dated 17th June, 2000), by virtue of which Royal Decree 665/1997, of 12th May, oon the protection of workers against hazards associated with exposure to carcinogenic agents in the workplaces was amended.

VLB Chemical agent for which a specific Biological Limit Value exists in this document.

VLBa Chemical agent to which the Biological Limit Value of cholinesterase inhibitors is applied.

VLBm Chemical agent to which the Biological Limit Value of methemoglobin inductors is applied.

VLI Chemical agent with an indicative limit value set up by the EU.

VLIp Chemical agent with an indicative limit value proposed by the EU.

Skin Please refer to point 4 of the document.

(w) Ministerial Order of 9/4/1986 (Official State Gazette No. 108, dated 6th May, 1986) and Council Directive 1999/38/EC, dated 29th April, 1999.

(x) Fibres with a random orientation, with a content in alkaline and alkali-earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) below 18% in weight. Ministerial Order of 11/9/1998 (Official State Gazette No. 223, dated 17th September, 1998), by virtue of which Annexes I and VI to the Regulations for the Notification of New Substances and the Classification, Packing and Labelling of Dangerous Substances, approved by Royal Decree 363/1995, were amended.

(y) Newly classified recently by the International Agency for Research on Cancer (IARC) from Group 2A (probably carcinogenic in humans) to Group 1 (carcinogenic in humans).

(z) It is prohibited the commercialization and use of the pesticides for environmental application which contain this substance, by the OM from 4-February-1994 (BOE nº41, 17-February-1994).

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☑ No ☐

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

According to the SCOEL procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

☑ 1 Availability of data on exposure

☑ 2 Availability of toxicological data

☑ 5 Number of persons exposed

☑ 3 Severity of effects

☑ 4 Epidemiological evidence, including reported cases of ill-health in the workplace

☑ 6 Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

☑ Scientific experts

☑ Social partners – Employers

☑ Social partners – Workers

☑ Public authority - Ministry of Health

☑ Public authority - Ministry of Labour

☑ Public authority – other (please specify) *Ministry of Industry.*

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	No
☑	☐

e) Which kind of limit values are adopted?

- ☑ 8-hour limit values
- ☐ Short-term limit values
- ☐ Ceiling limit values
- ☑ Biological limit values
- ☐ No limit values
- ☐ Other (please explain)

f) Is there a consultation?

Yes	No
☑	☐

If yes, with which parties?

Interested parties, employers, workers and Public Authorities.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	No
☐	☑

(ii) other approach, please describe them

Risk assessment following the SCOEL criteria.

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	No
☑	☐

If yes, please provide the name, address and website details:

INSHT Occupational Exposure Limits Working Group
c/ Torrelaguna 73
MADRID 28027, SPAIN
http://empleo.mtas.es/insht/index.htm

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance
Normally, employment sectors are obtained from the information provided by the interested parties.

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)
During the consultation process, the affected employment sectors evaluate their own technical capability to meet the proposed OEL and report the results to the INSHT Occupational Exposure Limits Working Group.

Compliance can be achieved by the application of good working practices in the identified employment sectors **Yes** ☑ **No** ☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings? **Yes** ☐ **No** ☑

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals **Yes** ☐ **No** ☑

If yes, please specify:

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care **Yes** ☐ **No** ☐

If yes, please specify:

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☐ **No** ☐

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☑

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☑

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes	No
☑	☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

As sources, we consider the SCOEL/SUM documents at first, as well as the criteria documents published by MAK, HSE, DECOS and ACGIH.

i) Are limit values indicative or constraining?

☐ indicative

☑ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☑ 3 Years ☐ Longer time period ☐

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

Data on exposure and on the adverse effects occurred are difficult to obtain, especially from certain settings in SMEs or employment sectors with a lot of SMEs.
Therefore, in most of the cases, available information about epidemiological studies is insufficient.

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs?

Yes	No
☑	☐

m) If yes, how often are limit values revised?
Please specify time period:

At least, every year.

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☑	☐

o) Is exposure monitoring mandatory?

Yes	No
☑	☐

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☑	☐

If yes, please specify:

Please visit the website: http://empleo.mtas.es/insht/mta/mta.htm

q) Is biological monitoring included in the monitoring methods?

Yes	No
☑	☐

If yes, please specify:

The biological monitoring is described in our legislation in the Royal Decree 665/1997, which is the regulation brought into force to comply with Council Directives 90/394/EEC, 97/42/EC and 1999/38/EC.

r) How is record keeping on the results of such measurements organised? (please describe)

As the Royal Decree 665/1997 describes, the employer is obliged to keep the monitoring results, the measurements and analytical methods used, as well as a list of the employees affected, during 40 years after exposure. Personal and medical data of the workers must be confidentially treated.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered).

In the document Occupational Exposure Limits for Chemical Agents in Spain. Published by INSHT and annually updated.
http://empleo.mtas.es/insht/practice/vlas.htm

In which languages are these documents available?

Spanish and English

Is it/are they linked to other texts (for example legal documents)?

Yes, it is linked to Safety and Health legislation in force.

t) Which of the following types of information is publicly available?

General Information	Yes	No	Available from (contact point address or web site)
Methodology for identifying priority substances for OEL setting		✓	
Methodology for developing measurement and analytical methods		✓	
Methodology for the derivation of OELs		✓	

Specific Information	Yes	No	Available from (contact point address or web site)
Evaluation documents for individual substances	✓		*http://empleo.mtas.es/insht/practice/dlep.htm#presentacion*
Measurement and analytical methods for individual substances	✓		*http://empleo.mtas.es/insht/mta/mta.htm*

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☑	☐

If yes, how are these limit values applied in practice?

These limit values are applied like the rest of the OELs established.

v) Are there any lists of reprotoxic substances?

Yes	No
☑	☐

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Limit values established for reprotoxic substances are included in the Document Occupational Exposure Limits for Chemical Agents in Spain (http://empleo.mtas.es/insht/practice/vlas.htm).

Sweden

23 April 2008

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Acrylamide	79-06-1	201-173-7	C/M/R	0,03	–	0,1	–	–	–	Skin	The short term value is indicative
Acrylonitrile	107-13-1	203-466-5	C	4,5	2	13	6		–	–	The short term value is indicative
Asbestos			C	–	–	–	–	–	0,1 fibres/cm³	–	8 h limit value
Benzene	71-43-2	200-753-7	C/M	1,5	0,5	9	3	–	–	Skin	The short term value is indicative
Benzo(a)pyrene	50-32-8	200-028-5	C/M/R	0,002	–	0,02	–	–	–	Skin	The short term value is indicative
Benzyl butyl phthalate	85-68-7	201-622-7	R	3	–	5	–	–	–	–	The short term value is indicative
Beryllium* and compounds	7440-41-7		C	0,002	–	–	–	–	–	–	
1,3-Butadiene	106-99-0	203-450-8	C/M	1	0,5	10	5	–	–	–	The short term value is indicative
Cadmium* and inorg. Compounds Resp. dust	7440-43-9*		C/M/R	0,005	–	–	–	Yes	–	–	Respirable dust *= CASno for cadmium
Cadmium* and inorg. Compounds Total dust	7440-43-9*		C/M/R	0,02	–	–	–	Yes	–	–	Total dust *= CASno for cadmium
2-Chloro-1,3-butadiene	126-99-8	204-818-0	C	3,5	1	18	5	–	–	Skin	The short term value is indicative
Chromium (VI)compounds			C	0,005	–	0,015	–		–	–	The short term value is indicative
Dibutyl phthalate	84-74-2	201-557-4	R	3	–	5	–	–	–	–	The short term value is indicative
Di- (2-ethylhexyl) phthalate	117-81-7	204-211-0	R	3	–	5	–	–	–	–	The short term value is indicative

[1] Please specify
[2] Please specify

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
1,2-Dichloro ethane	107-06-2	203-458-1 215-077-8	C	4	1	20	5	–	–	Skin	The short term value is indicative
Dinitrotoluene	25321-14-6	246-836-1	C	0,15	–	0,3	–	–	–	Skin	The short term value is indicative
Epichlorohydrine	106-89-8	203-439-8	C	1,9	0,5	4	1	–	–	Skin	The short term value is indicative
Ethylene glycole monoethyl ether	110-80-5	203-804-1	R	19	5	40	10	–	–	Skin	The short term value is indicative
Ethylene glycole monoethyl ether acetate	111-15-9	203-839-2	R	30	5	50	10	–	–	Skin	The short term value is indicative
Ethylene oxide	75-21-8	200-849-9	C,M	2	1	9	5	–	–	Skin	The short term value is indicative
Lead* and inorg. compounds, total dust	7439-92-7*		R	0,1	–	–	–	Yes		–	
Lead* and inorg. compounds respirable dust	7439-92-7*		R	0,5	–	–	–	Yes			
2-Nitro propane	79-46-9	201-209-1	C	7	2	20*	6*	–	–	–	*Binding ceiling limit value
2-Nitrotoluene	88-72-2	201-853-3 215-311-9	C	6	1	11	2	–	–	Skin	The short term value is indicative
Phenyl glycidyl ether	122-60-1	204-557-2	C	60	10	90	15	–	–	–	The short term value is indicative
Propylene oxide	75-56-9	75-56-9	C	5	2	25	10	–	–	–	The short term value is indicative
Trinickel disulphide	12035-72-2	234-829-6	C	0,01	–	–	–	–	–	–	The short term value is indicative
Vinyl chloride	75-01-4	200-831-0	C	2,5	1	13	5			Skin	The short term value is indicative
Wood dust Inhaleble dust			C	2	–	–	–	–	–	–	
All 8 hour values are binding											
The substances below are not allowed to use except for research of carcinogenic substances or developing analytical methodology. For that work you need permission from the Swedish work environment authorithy											
4-Aminodiphenyl	92-67-1	202-177-1	C	—	–	–	–	–	–		
Benzidine	92-87-5	202-199-1	C	–	–	–	–	–	–		
Bis(chloromethyl) ether	542-88-1	208-832-8	C	–	–	–	–	–	–		
Chloromethyl methyl ether	107-30-2	203-480-1	C	–	–	–	–	–	–		

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
1,2-Dibromo-3-chloropropane	96-12-8	202-479-3	C,M	–	–	–	–	–	–		
Hexamethylphosphoric triamide	680-31-9	211-653-8	C,M	–	–	–	–	–	–		
ß-Naphtylamine	91-59-8	202-080-4	C	–	–	–	–	–	–		
4-Nitrodiphenyl	92-93-3	202-204-7	C	–	–	–	–	–			
				–	–	–	–	–			
The substances below need a permission from the Swedish work environment authorithy before use											
p-Aminoazo-benzene	60-09-3	200-453-6	C	–	–	–	–	–			
Benzotrichloride	98-07-7	202-634-5	C	–	–	–	–	–			
4,4'-Diamino-3,3'-dichloro-diphenylmethane	101-14-4	202-918-9	C	–	–	–	–	–			
2,4-Diamino-1-methoxybenzene	615-05-4	210-406-1 [	C	–	–	–	–	–			
2,4-Diamino-toluene	95-80-7	202-453-1	C	–	–	–	–	–			
Dianisidine	119-90-4	204-355-4	C	–	–	–	–	–			
Diazomethane	334-88-3	206-382-7	C	–	–	–	–	–			
1,2-Dibromo-ethane	106-93-4	203-444-5	C	–	–	–	–	–			
3,3'-Dichloro-benzidine	91-94-1	202-109-0	C	–	–	–	–	–			
1,2:3,4-Diepoxy-butane	1464-53-5	215-979-1	C,M	–	–	–	–	–			
Diethyl sulfate	64-67-5	200-589-6	C,M	–	–	–	–	–			
1,1-Dimethyl-hydrazine	57-14-7	200-316-0	C	–	–	–	–	–			
1,2-Dimethyl-hydrazine	540-73-8	Missing	C	–	–	–	–	–			
Dimethyl sulfate	77-78-1	201-058-1	C	–	–	–	–	–			
Ethyleneimine	151-56-4	205-793-9	C,M	–	–	–	–	–			
Ethylene thiourea	96-45-7	202-506-9	R	–	–	–	–	–			
Hydrazine	302-01-2	206-114-9	C	–	–	–	–	–			
4,4'-Methylene-dianiline	101-77-9	202-974-4	C	–	–	–	–	–			

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
N-Nitrosodimethyl-amine	62-75-9	200-549-8	C	–	–	–	–	–			
1,3-Propane sultone	1120-71-4	214-317-9	C	–	–	–	–	–			
β-Propiolactone	57-57-8	200-340-1	C	–	–	–	–	–			
1,2-Propylene-imine	75-55-8	200-878-7	C	–	–	–	–	–			
Thioacetamide	62-55-5	200-541-4	C	–	–	–	–	–			
o-Tolidine	119-93-7	204-358-0	C	–	–	–	–	–			
Urethane	51-79-6	200-123-1	C	–	–	–	–	–			
Ethylene glycol methyl ether	109-86-4	203-713-7	R	–	–	–	–	–			
Ethylene glycol methyl ether acetate	110-49-6	203-772-9									
N,N'-Ethylene thiourea	96-45-7	202-506-9	R	–	–	–	–	–			
			R								

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No X

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.
They are part of the normal procedure of prioritization of substances for OEL setting in Sweden. We prioritize substances that are used in a lot of work places and if there are indications of problems with them.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

5 Availability of data on exposure

1 Availability of toxicological data

4 Number of persons exposed

3 Severity of effects

2 Epidemiological evidence, including reported cases of ill-health in the workplace

5 Availability of measurement methods

☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

X Scientific experts

X Social partners – Employers

X Social partners – Workers

☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☐ Public authority – other (please specify)

☐ Other (please explain)

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	No
X	

e) Which kind of limit values are adopted?

X	8-hour limit values	Binding
X	Short-term limit values	Indicative
X	Ceiling limit values	Binding
X	Biological limit values	Just two, for lead and cadmium
X	No limit values	Some substances are forbidden to use and for some you need a permission for using them
☐	Other (please explain)	

f) Is there a consultation?

Yes	No
X	☐

If yes, with which parties?
The consultation is with the labour unions organizations and the employers organizations.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes	No
X	☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes	No
X	☐

If yes, please provide the name, address and website details:

The Swedish criteria group (the web information is just in swedish):
http://www.av.se/teman/hygieniska/kriteriegruppen/

Johan Högberg (chairman)
He is chairman for the Swedish Criteria Group which produces risk assessment documents used for setting legally binding occupational exposure limits in Sweden.
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The Nordic expert group:
http://www.av.se/arkiv/neg/

Gunnar Johanson (chairman)
The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals (NEG) consists of scientific experts from the Nordic countries representing different fields of science, such as toxicology, occupational hygiene and occupational medicine. The main task is to produce criteria documents to be used by the regulatory authorities of the Nordic countries as the scientific basis for setting occupational exposure limits (OELs) for chemical substances. Thus, the actual setting of an OEL is a national concern.

Gunnar Johanson is also a member of the Swedish criteria group and the scientific committee of occupational exposure of limit values (SCOEL) in EU.

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Technical Feasibility criteria
How do you identify which:
(i) employment sectors use the substance
In the Nordic countries we have the product register where the suppliers and users must make an announcement of the use and the amount of the substance in question.
http://195.215.251.229/fmi/xsl/spin/SPIN/maininfo.xsl?-db=SPINstof&-lay=SpinNavn&-max=1&-findall

(ii) for these identified employment sectors how do you evaluate the technical *capability to meet the OEL (e.g. compliance is ensured by good practice)*
We perform an investigation of the cost for the investment that has to be made to comply with the new limit value. Then we have to do an impact assessment for our proposal to a new limit value. We also take contact with the companies in order to get a picture of how they will coup with the new situation.

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes	**No**
X	☐

Compliance can be achieved, but not instead of limit values.

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes	No
☐	X

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes	No
X	☐

If yes, please specify:
When we e.g. propose a very low limit value, the employers need to invest in a new ventilation system to comply with the new value. We calculate the cost for a company and then multiply the cost with the amount of companies that are working with the substance. We publish these Impact Assessments in a report on our web site:
http://www.av.se/dokument/inenglish/reports/2006_10.pdf

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure for health care

Yes	No
X	☐

If yes, please specify:
We try to do that when we have information.

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary?

Yes	No
☐	X

If yes, please specify:

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used:

Yes	No
☐	X

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified.

Yes	No
☐	X

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes	No
X	☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:
We implement the limit values in EU-commission directives.

i) Are limit values indicative or constraining?

☐ indicative

X constraining

Our short term limit values are indicative but the 8-hour limit values and the ceiling limit values are binding.

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year X 3 Years ☐ Longer time period
Sometimes the time is longer if the industry needs more time for the adjustment.

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:
When dose-response data and dose-effect data are not available and we still have to present a limit value.

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs?	**Yes**	**No**
	☐	**X**

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☐	X

o) Is exposure monitoring mandatory?

Yes	No
X	☐

When there is reason to suspect that an occupational exposure limit is being exceeded, exposure measurement shall be carried out in order to make clear whether and to what extent this is the case.
When it is obvious that the air contaminants are causing exposure which is unacceptable with reference to the occupational exposure limit values, measures shall, however, be taken immediately to reduce the exposure to an acceptable level. The results of the measures taken shall if necessary be verified by means of exposure measurement.
In connection with handling of ethylene oxide, propylene oxide, cadmium, silica, lead, radon and in the handling of reactive monomer (styrene and vinyl toluene) during production of ester plastics the employer shall always see to it that an exposure measurement is carried out, unless, having regard to the nature and extent of the work, it is clearly apparent that the concentration of these compounds are less than 1/10 of the applicable exposure limit values.
Exposure measurement shall be carried out promptly and not more than three months after handling has commenced or been altered, in such a way that a previous measurement is not applicable. Measurement shall subsequently be carried out once per calendar year.

p) Are there specific measurement methods laid down, or recommended?

Yes	No
X	☐

If yes, please specify:
The methods are published in a scientific series called Arbete och Hälsa:
https://gupea.ub.gu.se/dspace/bitstream/2077/4231/1/ah2000_23.pdf
We also have an updated database with this information that is under construction for internet.

q) Is biological monitoring included in the monitoring methods?

Yes	No
☐	X

If yes, please specify:
They are published in an ordinance called Medicinska kontroller i arbetslivet (medical controls in the working life) AFS 2005:6.

r) How is record keeping on the results of such measurements organised? (please describe)

The measurement reports that we at Swedish work environment authority perform and those that we get from the employers are stored in a data base at the authority.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

They are published in Swedish and in English in the scientific series Arbete och Hälsa:
http://www.medicine.gu.se/avdelningar/samhallsmedicin_folkhalsa/amm/aoh/

t) Which of the following types of information is publicly available?

General Information	Yes	No	Available from (contact point address or web site)
Methodology for identifying priority substances for OEL setting		X	
Methodology for developing measurement and analytical methods		X	
Methodology for the derivation of OELs		X	

Specific Information	Yes	No	Available from (contact point address or web site)
Evaluation documents for individual substances	X		**http://www.av.se/dokument/inenglish/reports/2006_10.pdf** **http://www.medicine.gu.se/avdelningar/samhallsmedicin_folkhalsa/amm/aoh/**
Measurement and analytical methods for individual substances			*https://gupea.ub.gu.se/dspace/bitstream/2077/4231/1/ah2000_23.pdf* *We also have an updated database with this information that is under construction for the internet.*

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
X	☐

If yes, how are these limit values applied in practice?

They are used in the risk assessment. For example if you are planning to have a baby you should avoid exposure to these substances. These substances can be a danger for both men and women. We have a special ordinance for pregnant or breastfeeding women where you can read more about this AFS 2007:5.

v) Are there any lists of reprotoxic substances?

Yes	No
X	☐

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

There are published criteria documents of all our limit values at
http://www.medicine.gu.se/avdelningar/samhallsmedicin_folkhalsa/amm/aoh/
There are also a report of the impact assessments of the proposals of the limit values that are published on our web site: http://www.av.se/dokument/inenglish/reports/2006_10.pdf

United Kingdom

11 September 2007

A. List and table of OELs for carcinogenic and mutagenic substances

PLEASE LIST ALL SUBSTANCES WITH A NATIONAL LIMIT VALUE

Existing OELs for substances classified as category 1 and category 2 carcinogens and mutagens in the EU classification system - List of substances for which occupational exposure limit values have been set at the national level:

In the UK, three legal duties attach to WELs; substances must be controlled according to the principles of good practice; the WEL must not be exceeded; substances classified or meeting the criteria for classification as a Category 1 or 2 carcinogen or mutagen (R45, R46, R49) or an asthmagen (R42) must be controlled to as low a level as is reasonably practicable. Substances that are classified or meet the criteria for classification as a Category 1 or 2 carcinogen or mutagen are assigned a Carc notation. Substances that are classified or meet the criteria for classification as an asthmagen (R42) are assigned a Sen notation.

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m3]	ppm	[mg/m3]	ppm				
Acrylamide	79-06-1	201-173-7	C2 M2 R3	0.3	-	-	-	No	Carc	Yes	MDHS 57
Acrylonitrile	107-13-1	203-466-5	C2	4.4	2	-	-	No	Carc	Yes	MDHS 72 MDHS 80 MDHS 96
Arsenic and arsenic compounds except arsine (as As)			C1	0.1	-	-	-	No	Carc	No	MDHS 41/2
Benzene	71-43-2	200-753-7	C1 M2	-	1	-	-	No	Carc	Yes	MDHS 72 MDHS 80 MDHS 96
Benzyl chloride	100-44-7	202-853-6	C2	2.6	0.5	7.9	1.5	No	Carc	No	
Beryllium and beryllium compounds (as Be)			C2	0.002	-	-	-	No	Carc	No	MDHS 29/2
Bis(chloromethyl)ether	542-88-1	208-832-6	C1	0.005	0.001	-	-	No	Carc	No	

[1] Please specify. C1 = Category 1 carcinogen, C2 = Category 2 carcinogen, M2 = Category 2 mutagen, M3 = Category 3 mutagen, R3 = Category 3 reproductive toxicant

[2] Please specify

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value[2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Buta-1,3-diene	106-99-0	203-450-8	C1 M2	22	10	-	-	No	Carc	No	MDHS 53/2 MDHS 63/2
Cadmium and cadmium compounds except cadmium oxide fume, cadmium sulphide and cadmium sulphide pigments (as Cd)			C2	0.025	-	-	-	No	Carc (applies to cadmium metal, cadmium chloride, fluoride and sulphate)	No	MDHS 10/2 MDHS 91
Cadmium oxide fume (as Cd)	1306-19-0	215-146-2	C2 M3 R3	0.025	-	0.05	-	No	Carc	No	
Cadmium sulphide and cadmium sulphide pigments (as Cd)	1306-23-6	215-147-8	C2 M3 R3	0.03	-	-	-	No	Carc (applies to cadmium sulphide)	No	
1-Chloro-2,3-epoxypropane (Epichlorhydrin)	106-89-8	203-439-8	C2	1.9	0.5	5.8	1.5	No	Carc	No	
Chromium (VI) compounds (as Cr)			C2	0.05	-	-	-	10 µmol chromium/mol creatinine in urine	Carc Sen	No	MDHS 12/2 MDHS 52/3 MDHS 61
Cobalt and cobalt compunds (as Co)			C2	0.1	-	-	-	No	Carc (applies to cobalt dichloride and cobalt sulphate) Sen	No	MDHS 30/2
1,2-Dibromoethane (Ethylene dibromide)	106-93-4	203-444-5	C2	3.9	0.5	-	-	No	Carc	Yes	
1,2-Dichloroethane (Ethylene dichloride)	107-06-2	203-458-1	C2	21	5	-	-	No	Carc	Yes	
2,2'-Dichloro-4,4'-methylene dianiline (MbOCA)	101-14-4	202-918-9	C2	0.005	-	-	-	15 µmol total MbOCA/ mol creatinine in urine	Carc	Yes	MDHS 75 (aromatic amines)
Diethyl sulphate	64-67-5	200-589-6	C2 M2	0.32	0.05	-	-	No	Carc	Yes	MDHS 89

Substance name	CAS number	EINECS number	C/M/R [1]	8 hour limit value		Short-term-limit value		Biological Limit Value [2]	Other	Skin notation	Remarks, comments (for example constraining/indicative, limitation to certain processes, specific notation)
				[mg/m³]	ppm	[mg/m³]	ppm				
Dimethyl sulphate	77-78-1	201-058-1	C2 M3	0.26	0.05	-	-	No	Carc	Yes	MDHS 89
Ethylene oxide	75-21-8	200-849-9	C2 M2	9.2	5	-	-	No	Carc	No	MDHS 96
Hardwood dust	-	-		5	-	-	-	No	Carc Sen	No	
Hydrazine	302-01-2	206-114-9	C2	0.03	0.02	0.13	0.1	No	Carc	Yes	MDHS 86
4,4'-Methylene dianiline (MDA)	101-77-9	202-974-4	C2 M3	0.08	0.01	-	-	50 µmol total MDA/mol creatinine in urine	Carc	Yes	
Nickel and its inorganic compunds (except nickel tetracarbonyl):								No	Carc (applies to nickel oxides and sulphides) Sen (applies to nickel sulphate)	Yes	MDHS 42/2
Water-soluble nickel compounds (as Ni)				0.1	-	-	-				
Nickel and water-insoluble nickel compounds (as Ni)			C1	0.5	-	-	-				
2-Nitropropane	79-46-9	201-209-1	C2	19	5	-	-	No	Carc	No	
Propylene oxide	75-56-9	200-879-2	C2 M2	12	5	-	-	No	Carc	No	
Refractory Ceramic Fibres and Special Purpose Fibres	-	-	C2	5	1 fibre/ millilitre	-	-	No	Carc	No	
Rubber fume	-	-		0.6	-	-	-	No	Carc	No	MDHS 47/2 The limit relates to cyclohexane soluble material
Rubber process dust	-	-		6	-	-	-	No	Carc	No	MDHS 47/2
o-Toluidine	95-53-4	202-429-0	C2	0.89	0.2	-	-	No	Carc	Yes	
Trichloroethylene	79-01-6	201-167-4	C2 M3	550	100	820	150	No	Carc	Yes	
Triglycidyl isocyanurate (TGIC)	2451-62-9	219-514-3	M2	0.1	-	-	-	No	Carc	No	MDHS 85
Vinyl chloride	75-01-4	200-831-0	C1	3	-	-	-	No	Carc	No	MDHS 96

B. Questions Specific to OELs for Carcinogens and Mutagens

Please answer the following questions:

B1)Selecting and prioritisation of carcinogenic and mutagenic substances for OEL setting

a) Is there a specific procedure for selecting substances for OELs for carcinogenic and mutagenic substances?

Yes ☐ No ☒

If yes, please provide a brief summary description of the selection and/or prioritisation procedure.

b) **Which of the following selection criteria do you use?**
Please tick and number the criteria below in order of priority (number from 1 to n in decreasing order of priority)

- ☒ (4) Availability of data on exposure
- ☒ (5) Availability of toxicological data
- ☒ (3) Number of persons exposed
- ☒ (1) Severity of effects
- ☒ (2) Epidemiological evidence, including reported cases of ill-health in the workplace
- ☒ (6) Availability of measurement methods
- ☐ Other (please explain)

c) Who makes proposals for setting up a limit value or for modification of an existing limit value?

- ☐ Scientific experts
- ☐ Social partners – Employers
- ☐ Social partners – Workers
- ☐ Public authority - Ministry of Health

☐ Public authority - Ministry of Labour

☒ Public authority – other (please specify)

☐ Other (please explain)

Proposals for setting a limit or modifying an existing limit are ratified by the Health and Safety Commission.

B2) Derivation of OELs for carcinogenic and mutagenic substances

d) **Do you have a national system for the derivation of OELs that includes the scientific evaluation of substances and consideration of feasibility factors?**

Yes	**No**
☒	☐

e) Which kind of limit values are adopted?

☒ 8-hour limit values

☒ Short-term limit values

☐ Ceiling limit values

☒ Biological limit values

☐ No limit values

☐ Other (please explain)

f) Is there a consultation?

Yes	**No**
☒	☐

If yes, with which parties?

Tripartite discussion of scientific evidence (by independent experts nominated by the trade unions, industry and the Health and Safety Executive) followed by tripartite discussion of socioeconomic issues (between individuals representing the trade unions, industry and independent experts) followed by a public consultation exercise.

g) Where a national system exists does it contain criteria for the key components of the system, including:

Scientific Evaluation

(i) do you have a documented methodology for the scientific evaluation of substances

Yes ☒ **No** ☐

(ii) other approach, please describe them

(iii) Are there specific scientific bodies set up for the scientific evaluation process?

Yes ☒ **No** ☐

If yes, please provide the name, address and website details:

Scientific evaluation is performed by a tripartite committee, the Working Group on Action to Control Chemicals (WATCH). Information about this committee can be found at:

http://www.hse.gov.uk/aboutus/hsc/iacs/acts/watch/index.htm

Technical Feasibility criteria

How do you identify which:

(i) employment sectors use the substance

Track chemicals through the supply chain, track process generated carcinogens through industry and trade union consultation.

(ii) for these identified employment sectors how do you evaluate the technical capability to meet the OEL (e.g. compliance is ensured by good practice)

Tripartite consulation on the ability of industry to control exposures after the scientific evaluation has been completed.

Compliance can be achieved by the application of good working practices in the identified employment sectors

Yes ☒ **No** ☐

Socio-Economic Feasibility criteria

Do you have data on the extent and distribution of economic consequences and the types of costs and savings?

Yes ☒ **No** ☐

In particular:

(i) data on compliance costs to employers that are manufacturers or users of chemicals

Yes ☒ **No** ☐

If yes, please specify:

Costs for provision of controls (including LEV/containment and PPE) are considered.

(ii) data on economic benefits stemming from avoiding costs e.g. less expenditure

for health care **Yes** ☒ **No** ☐

If yes, please specify:
Expenditure on healthcare is taken into consideration.

(iii) Do you have information on societal and/or individual benefits for health described in terms other than monetary? **Yes** ☒ **No** ☐

If yes, please specify:
The benefits of reducing ill-health are taken into consideration.

(iv) Other criteria: please describe them

Administrative and policy criteria

(i) do you have a criteria on the acceptability of risk?
For example "x" additional cancer case(s) per "y" persons exposed over a defined time period. Yes/no and where applicable please state factor used: **Yes** ☐ **No** ☒

(ii) are derogations to the OEL possible for certain employment sectors?
For example where an initial difficulty in complying with a new, or revised, OEL has been identified. **Yes** ☐ **No** ☒

(iii) Other administrative or policy criteria (please describe)

h) Do you ever adopt OELs from other sources?

Yes ☒ **No** ☐

If yes, from which sources e.g. other national limit setting organisation. Please specify them:

EU limits
Historically the UK has adopted Threshold Limit Values from the ACGIH

i) Are limit values indicative or constraining?

☐ indicative

☒ constraining

j) Setting OELs for carcinogens and mutagens is a complex process and it can take a considerable period of time from substance prioritisation to adoption of an OEL. How long in practice does it take from a proposal to adoption of an OEL?

Please specify time period: 1 Year ☐ 3 Years ☐ Longer time period ☒

k) In your experience, which elements of the process are the most complex to manage? Please give a brief description of the difficulties encountered:

Generally most difficulties are encountered during tripartite discussions on the socioeconomic impact of a new or revised limit, particularly for substances that have many different uses.

B3) Revision of OEL for carcinogenic and mutagenic substances

l) Is there a specific procedure for the revision of OELs? **Yes** ☐ **No** ☒

m) If yes, how often are limit values revised?
Please specify time period:

C. Measurement and analytical methods for monitoring workers exposure to carcinogenic and mutagenic substances.

n) Are there specific measurement requirements linked to the OELs for carcinogenic and mutagenic substances?

Yes	No
☒	☐

Monitoring may be required depending on the outcome of the employer's risk assessment.

o) Is exposure monitoring mandatory?

Yes	No
☐	☒

In most cases exposure monitoring is not mandatory but there are two situations where exposure monitoring is mandatory. Monitoring is mandatory for vinyl chloride monomer and for hexavalent chromium relating to electrolytic chromium processes.

p) Are there specific measurement methods laid down, or recommended?

Yes	No
☒	☐

If yes, please specify:

Methods for measuring the concentration of substances in the air are described in the Methods for Determination of Hazardous Substances (MDHS) series of publications.

q) Is biological monitoring included in the monitoring methods?

Yes	No
☒	☐

If yes, please specify:

Biological monitoring may be included for those carcinogens for which a biomarker has been identified.

r) How is record keeping on the results of such measurements organised? (please describe)

Dutyholders (employers) have the responsibility to maintain monitoring records in accordance with the UK COSHH regulations.

D. Availability of documentation - Supporting documents

Availability of scientific and technical documents supporting OEL (list of limit values, criteria documents, explanatory notes).

s) In what document/s are the OELs for carcinogenic and mutagenic substances published? Availability of these documents (Webpage, publications index, contact where those publications can be ordered). In which languages are these documents available? Is it/are they linked to other texts (for example legal documents)?

The HSE publication EH40 provides a list of limit values, called Workplace Exposure Limits (WELs). Supporting data is published in EH64 summaries. These are available in English.

The list of WELs is available at: http://www.hse.gov.uk/coshh/index.htm
EH40/2005 Workplace Exposure Limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended) (ISBN 0-7176-2977-5) is available via HSE Books at: http://www.hsebooks.co.uk/Books/.

WELs take their legal force from the Control of Substances Hazardous to Health Regulations 2002 (as amended) (ISBN 0-7176-2981-3).

EH64 summaries can be obtained from the ACTS Secretariat at the address below and will be made available via the HSE website

t) Which of the following types of information is publicly available?

General Information	**Yes**	**No**	**Available from (contact point address or web site)**
Methodology for identifying priority substances for OEL setting		**x**	
Methodology for developing measurement and analytical methods		**x**	
Methodology for the derivation of OELs	**x**		**Described in EH40.**

Specific Information	**Yes**	**No**	**Available from (contact point address or web site)**
Evaluation documents for individual substances	**x**		**ACTS secretariat** ACTS Secretariat can be contacted at: Health & Safety Executive, Floor 9SW, Rose Court, 2 Southwark Bridge, London SE1 9HS or email: androulla.michael@hse.gsi.gov.uk
Measurement and analytical methods for individual substances	**x**		**MDHS series** **Documents in the MDHS series are available via the HSE website at** **http://www.hse.gov.uk/pubns/mdhs/index.htm**

E. Reprotoxic substances

u) Are there any limit values defined for reprotoxic substances?

Yes	No
☒	☐

If yes, how are these limit values applied in practice?

Where a limit has been set for a reprotoxic substance it will be applied in the same way as a limit value for any other type of substance.

v) Are there any lists of reprotoxic substances?

Yes	No
☒	☐

Certain reproductive toxicants are assigned limit values in EH40.

w) Availability of scientific and technical documents supporting establishing of the OEL (list of limit values, criteria documents, explanatory notes)

Where a limit has been set, the documentation will be available from the ACTS secretariat.