



Guidance for employers on controlling risks from chemicals

Interface between Chemicals Agents Directive
and REACH at the workplace





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The opinion of the Advisory Committee on Safety and Health at work

The Working Party on Chemicals invites the Advisory Committee to endorse the attached guidance, *REACH and CAD¹ in the workplace – Guidance for employers on controlling risks from chemicals*.

Need for the guidance

In 2008, the Working Party on Chemicals identified a need for guidance for employers on the interface between the Chemical Agents Directive (CAD) and REACH. The attached draft guidance has been developed by the Working Party to meet this objective. The guidance sets out, step by step, what employers need to do to meet the obligations of REACH, a relatively new Regulation, and CAD, an established legal framework for which guidance already exists². In particular, it demonstrates that one process of assessing risks can often meet the relevant requirements of both REACH and CAD.

Key messages

The key messages for employers are:

- The arrival of REACH should improve worker health and safety by providing better information, by establishing new channels of communication between employers and suppliers and by removing substances of very high concern from the market.
- Although REACH is a new system, and a new way of thinking, the requirements of CAD (as implemented in Member States' national legislation) continue as before.
- The arrival of REACH does not mean that employers' obligations are duplicated. Where employers are already meeting the requirements of CAD they should, in many cases, have little more to do than review their risk management in the light of new information received as a consequence of REACH, and implement changes where necessary.

Applying the guidance

The intention is that the guide will form a core document, explaining the occupational health and safety requirements of REACH and CAD at European Union level. Member States' national authorities and social partners are invited to adapt the guidance to the particular national conditions and requirements in their own Member State. Such adaptation is important because employers have to comply with the national legislation that implements CAD, as well as with REACH which, as an EC Regulation, applies directly.

¹ In this guide, 'CAD' is used to refer to the relevant occupational health and safety requirements of the European Community 'Framework Directive' (89/391/EEC), collectively with other relevant Directive requirements. Council Directive 89/391/EEC, the 'Framework Directive', introduced measures to encourage improvements in the safety and health of workers at work. The Framework Directive has a number of 'daughter' directives covering a range of subjects including minimum safety and health requirements, personal protective equipment and protection of workers from risks related to exposure to chemical, physical and biological agents. For chemicals, the main subordinate Directives, referred to in this guide as the 'Chemical Agents Directive', are Council Directives on the protection of the health and safety of workers from the risks related to chemical agents at work (98/24/EC), and on the protection of workers from the risks related to exposure to carcinogens and mutagens at work (2004/37/EC).

² <http://bookshop.europa.eu/eubookshop/publicationDetails!print.action?pubuid=259290>



Mandate for this work

The extended mandate for the Working Party up to 2009 included the specific objective to “examine the relationship between REACH ‘derived no effect levels’ (DNELs) and occupational exposure limits (OELs)”. In doing so, the Working Party unanimously agreed that there was no simple relationship between DNELs and OELs, and that the real issue for employers was how to respond to the additional duties imposed by REACH as well as the continuing requirements under occupational health and safety legislation. Although REACH mainly affects manufacturers and importers of substances, it also puts duties on employers (as ‘downstream users’). The outcome was the guidance which the Advisory Committee adopted on 10/12/2009. The specific issue of the relationship between DNELs and OELs is addressed in Annex 2 of the guidance.

Guidance

This guide sets out, step by step, how employers can meet their obligations under REACH and the Chemical Agents Directive (CAD), both of which apply to those who handle chemical substances.³ Although REACH is a relatively new Regulation, and CAD is an established legal framework, one risk assessment can often meet the relevant requirements of both REACH and CAD.

The guide provides a core document, explaining occupational health and safety requirements of REACH and CAD at European Union level. Member States’ national authorities and social partners are invited to adapt the guidance to the particular national conditions and requirements in their own Member State. Such adaptation is important because employers have to comply with the national legislation that implements CAD, as well as with REACH which, as an EC Regulation, applies directly.

This guidance does not replace the legal texts, and will be revised in the light of experience in the application of both REACH and CAD. Employers should also refer to relevant guidance on REACH published by the European Chemicals Agency (ECHA) and to any national guidance on CAD as implemented in their Member State.⁴

Introduction

In 2006, Europe agreed a new Regulation called REACH. This is a new EU-wide system to control the use of chemicals. The aims include to:

- Reduce, as far as possible, adverse effects on human health and the environment from chemicals;
- Promote innovation and find new and safer ways to use chemicals; and
- Maintain the market between EU countries.

³ REACH means Regulation 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals. In this guide, ‘CAD’ is used to refer to the relevant occupational health and safety requirements of the European Community ‘Framework Directive’ (89/391/EC), collectively with other relevant Directive requirements. Council Directive 89/391/EEC, the ‘Framework Directive’, introduced measures to encourage improvements in the safety and health of workers at work. The Framework Directive has a number of ‘daughter’ directives covering a range of subjects including minimum safety and health requirements, personal protective equipment and protection of workers from risks related to exposure to chemical, physical and biological agents. For chemicals, the main subordinate Directives, referred to in this guide as the ‘Chemical Agents Directive’, are Council Directives on the protection of the health and safety of workers from the risks related to chemical agents at work (98/24/EC), and on the protection of workers from the risks related to exposure to carcinogens and mutagens at work (2004/37/EC).

⁴ ECHA, the new European Chemicals Agency, has been set up in Helsinki, Finland, to manage the running of the European REACH system. See <http://echa.europa.eu/>.



REACH is a major change in the way chemicals are regulated. It mainly affects companies that manufacture or import into the EU. They have to provide much more information than in the past to their customers, and to authorities, e.g. about safe ways of using chemicals.

REACH also creates duties for companies that use chemicals. Some REACH duties will apply to employers who already have duties to assess risks under CAD.

REACH uses some *new terms*, and this guide explains them.

According to REACH, almost everything can be classed as '*substances*', '*mixtures*' or '*preparations*', and '*articles*'.

A '*substance*' is any chemical element or its compounds. A substance does not need to be hazardous or dangerous for REACH provisions to apply.

A '*mixture*' is a chemical product made up of several substances, but which is not an '*article*'. Examples include most paints, inks, toner in print cartridges or bleach. The word '*preparation*' means the same as '*mixture*'.

An '*article*' is any formed object, the design characteristics of which are more important than its chemical make-up to the way the article works. This sounds complicated, but most of the time it is straightforward. Examples include everyday items such as cars, tables or computers.

A '*downstream user*' means any person (or business) in Europe using a substance or mixture. This includes employers. It does not include the manufacturer or importer of the substance or mixture. Nor does it include distributors, or consumers. In this guide, where REACH duties are concerned, employers are called downstream users.

A '*registrant*' is the manufacturer or importer of a substance. The registrant generates most of the new information that REACH requires.

A '*supplier*' or '*actor in the supply chain*' is any manufacturer, importer, distributor or downstream user who '*places a substance or mixture on the market*'. '*Supplier*' and '*actor in the supply chain*' have slightly different REACH meanings, but they have similar, specific duties relating to supply-chain information.

'*Placing a substance on the market*' means making the substance available to another person in Europe by way of trade, exchange, loan or gift.

An '*exposure scenario*' describes the way a chemical substance or mixture may be used, and includes '*risk management measures*' and '*operational conditions*' that control human and environmental exposure for each scenario (i.e. use).

'*Risk management measures*' and '*operational conditions*' describe the control measures that should apply, for the specific substance or mixture and the exposure scenario. An example includes an extracted booth for spray painting.

The REACH and CAD texts are arranged into numbered legal Articles. To avoid confusion, this guide refers to legal Articles with a capital 'A', and formed objects (articles) with a lower-case 'a'.

How REACH provides information

Under REACH, registrants (manufacturers and importers of substances) must register with ECHA any substance they manufacture in the EU, or import into the EU in quantities of one



tonne or more per year.⁵ Registration is undertaken in accordance with a series of deadlines from 1 December 2010 to 1 June 2018.

Registration involves submitting electronically a dossier of technical information to ECHA. This might mean the registrant getting new information about the substance to fill gaps in knowledge about its hazards and risks. Information for protecting health and the environment is made publicly available, including to downstream users. It includes the identity of the registrant, the identity of the substance, the identified uses of the substance and, where necessary, relevant use and exposure information.⁶

The obligations are most far-reaching for substances that are classified as 'hazardous'. Substances that are not classified as hazardous involve lighter obligations, and the downstream user needs less guidance about how to use the substance safely in the workplace.

If the substance being registered is manufactured or imported in quantities of 10 tonnes or more per year, registrants must undertake a chemical safety assessment (CSA) and complete a chemical safety report (CSR).⁷

Any measures identified in the CSA to adequately control risks must be passed down the supply chain to downstream users in 'safety data sheets'.⁸ Where the substance is classified as:

- hazardous according to the Classification, Labelling and Packaging Regulation (CLP);
 - until 1st December 2010, as dangerous according to the Dangerous Substances Directive;
- or
- has certain environmental properties;

registrants may need to identify exposure scenarios for all identified uses of that substance.^{9, 10, 11} These exposure scenarios must be annexed to the safety data sheet.¹²

The downstream user must check that the way they use the substance is covered by an exposure scenario.

REACH also provides for downstream users to pass information back up the supply chain to suppliers and registrants.¹³ It may be that a downstream user has a special use for a substance. Downstream users can tell their supplier about this use and request the registrant's support of that use in a CSA and CSR. Actors in the supply chain must pass such a request back up the supply chain.¹⁴ But if the downstream user wants their special use kept secret from suppliers, they have additional duties: see paragraph 2.10 and Annex 1 to this document.

Registrants who have duties to include exposure scenarios in their CSA are obliged to respond to such a request. Their response must provide either the requested support, or a

⁵ The duty to register substances on their own, or in mixtures (or preparations), is set out in REACH Article 6.1.

⁶ REACH Article 10.a

⁷ REACH Article 14.1

⁸ REACH Articles 14.6 and 31

⁹ The 'Classification, Labelling and Packaging Regulation', or CLP, is Regulation (EC) 1272/2008 of the European Council and the Parliament of 16 December 2008 on classification, labelling and packaging of substances and mixtures. CLP takes over many aspects of Dangerous Substance Directive (DSD) provisions, and amends the parts of REACH referring to DSD accordingly.

¹⁰ The Dangerous Substances Directive, or DSD, is Directive 67/548/EEC, which relates to the classification, packaging and labelling of dangerous substances.

¹¹ REACH Article 14.4

¹² REACH Article 31.7

¹³ REACH Article 37.1

¹⁴ REACH Article 37.2



justification that such a use is not safe, depending on certain conditions.¹⁵ Registrants can only refuse to support a use of their substance on the grounds of protecting human health or the environment. Registrants must give the reasons in writing, both to the downstream user and to ECHA.¹⁶ Where a registrant refuses to support a use, or if a downstream user is not prepared to inform their supplier about their use, the downstream user might, for example, seek an alternative supplier who does provide the necessary support.

Telling registrants about uses gives them the information they need in order to establish relevant risk management measures for that exposure scenario. In addition, downstream users and other actors in the supply chain must pass certain information back up the supply chain. This includes information that calls into question the appropriateness of risk management measures for an exposure scenario, as published in the safety data sheet.¹⁷ The registrant can then adjust the risk management measures as necessary. In return, downstream users should get information based on how they actually use the substance.

Where a downstream user is not prepared to tell their supplier about their special use, they have to take the responsibility for preparing a CSR themselves, in line with REACH Article 14 (see Annex 1).¹⁸ However, there are many conditions for downstream users to meet and they are likely to seek to avoid this eventuality.¹⁹

It might not be clear at first sight whether a registrant's stated exposure scenario is the same as the downstream user's actual use. If the downstream user is unclear, they should take the precaution of informing their supplier (and via the supplier, the registrant) about their use. The registrant can then decide whether the downstream user's actual use matches their exposure scenario; and act accordingly.

A short comparison of REACH and CAD

The Directives which make up CAD have been implemented by Member States by transposing Directive requirements into national legislation, though Member States can make additional requirements. On the other hand, REACH is a single, broad ranging, EU Regulation that applies directly.

CAD places responsibility on employers to protect the health and safety of workers from the risks from all chemical agents. This includes chemical agents such as fume generated by processes, and substances that become hazardous because of the way they are used. CAD requires employers to identify, assess and control – by eliminating if possible, or otherwise by minimising – such risks. Central to this process is the employer's risk assessment, drawing on information, such as labels, safety data sheets or published guidance, to identify and use control measures appropriate to the way the chemical agent is used in their workplace.

REACH applies to worker health without prejudice to CAD, which means that CAD is not affected. However, REACH also applies to protection of the environment and public health more generally. Under REACH, manufacturers or importers must assess the risks their substances might pose to human health or the environment, and communicate to

¹⁵ REACH Article 37.2. Other considerations include timing - REACH Article 37.3 provides that, for 'phase-in' substances (where the deadline for submission of the registration dossier and accompanying CSR may be some years in the future), the registrant or downstream user who is undertaking relevant CSA work needs to comply with a request to support a use before the relevant phase-in deadline, provided that the downstream user makes the request at least 12 months before that deadline.

¹⁶ REACH Article 37.3

¹⁷ REACH Article 34

¹⁸ http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm

¹⁹ REACH Article 37.4



downstream users (employers) how these risks should be reduced. REACH makes registrants (manufacturers and importers at the top of the supply chain) accountable for the availability of information on substances, and establishes new communication channels between registrants, ECHA and downstream users. Registrants must tell downstream users (employers) how to reduce these risks. With this additional information, it is expected that employers' risk assessments under CAD will improve.

Although REACH introduces a responsibility for registrants to develop risk management measures where necessary, employers' duties under CAD remain. Employers will still have to assess risks and decide how to control them in their own workplaces. The additional information generated by registrants and supplied to downstream users under REACH should improve the way risks are managed in the workplace.

How the REACH and CAD requirements fit together

There should be no conflict between REACH and CAD – the requirements of each reinforce and complement the other. Table 1 below describes the main features of REACH and CAD that are relevant to employers and workers, and shows that together they form a comprehensive regime for controlling risks arising from chemicals in the workplace.

Table – Comparison of key REACH and CAD provisions for workplace risk assessment

	REACH	CAD	Together
Scope	<p>REACH applies to most substances and mixtures, and to some articles, that are manufactured or imported, placed on the market or used in the EU. Specific requirements are set out for each actor in the supply chain and reflect how hazardous the substance is to workers, consumers and the environment, and in what quantity it is manufactured or imported.</p> <p>REACH requires that:</p> <ul style="list-style-type: none"> - all substances manufactured in, or imported into, the EU at 1 tonne per year or more must be 'registered', unless they are specifically exempt. - all registrations at 10 tonnes or more per year must be accompanied by a Chemical Safety Report detailing an assessment of risks associated with use of the substance concerned. 	<p>CAD applies where chemicals are manufactured or used. It requires all hazardous substances and non-hazardous substances that become hazardous by the way they are used in the workplace to be controlled, including process-derived substances, e.g. wood and flour dust, rubber and diesel exhaust fumes, etc.</p> <p>The Carcinogens and Mutagens Directive (2004/37/EC) applies to all category 1 and 2 carcinogens (substances which may cause cancer) and mutagens (substances which may cause changes to genetic material) present in the workplace (corresponds to category 1A and 1B in the Classification, Labelling and Packaging Regulation EC 1272/2008).</p>	<p>A comprehensive regime that together serves to protect workers, consumers and the environment.</p>



	<p>- use of 'substances of very high concern' which are listed in Annex XIV to the Regulation must be specifically 'authorised'.</p> <p>REACH 'restrictions' can be applied to any substance that poses a particular threat, including those that do not require registration.</p> <p>For all hazardous substances, and mixtures containing hazardous substances above certain concentration thresholds, any risk management measures indicated in the Chemical Safety Report must be included in a safety data sheet supplied to all downstream users.</p>		
Risk assessment	<p>REACH places the onus on registrants to establish risk management measures for safe use of the substances they produce, import or place on the market. In some cases, downstream users have to take on the responsibility of registrants to prepare the information that is required under REACH.</p>	<p>CAD requires employers to assess risks to the health and safety of employees and others from exposure to hazardous substances and non-hazardous substances that become hazardous.</p> <p>Where appropriate for the protection of the health of their employees, CAD also requires employers to ensure that their employees are under suitable health surveillance.</p>	<p>Each actor in the chain of manufacture, importation, supply and use of chemicals has responsibilities under REACH and CAD.</p> <p>REACH risk management measures should be part of the CAD risk assessment by downstream users (i.e. employers).</p>
Substitution	<p>REACH aims at progressively replacing substances of very high concern, e.g. certain carcinogenic, mutagenic or reprotoxic substances, by suitable alternative substances or technologies where these are economically and technically viable.</p>	<p>Under CAD, employers have to eliminate or minimise risks from chemicals, preferably by substituting (replacing) them with a chemical agent or process which is not hazardous or less hazardous.</p> <p>In the case of carcinogenic or mutagenic substances, substitution is mandatory if technically feasible.</p>	<p>REACH will progressively provide more data that will help employers to assess which chemicals are less hazardous than ones previously used. This will contribute to better workplace risk assessments.</p> <p>Substances of very high concern will be taken off the market, encouraging the</p>



			development of safer substitutes.
Exposure reference levels	REACH requires the registrant to develop health-based Derived No-Effect Levels (DNELs). These are used to establish risk management measures that must be communicated to employers. DNELs apply to all routes of exposure (inhalation, dermal, oral) and for workers and consumers.	Under CAD, the European Commission proposes health-based indicative occupational exposure limit values (IOELVs) which Member States have to take into account when setting their national Occupational Exposure Limits (OELs). OELs apply to worker exposure by inhalation, with a notation to indicate the potential for uptake via the skin. There are also a small number of binding limit values (BOELVs) that are based on assessments of risk to health and socio-economic factors required to control exposure.	Although both DNELs and IOELVs are health-based, they are not necessarily set in the same way. The primary duty is to comply with risk management measures and good control practice. This should also mean compliance with relevant exposure reference levels.
Control	REACH requires downstream users to comply with Risk Management Measures.	CAD requires employers to follow good control practice and guidance, and to maintain control measures.	Control successful in minimising exposure.
Information and training	REACH brings a large range of substances under scientific evaluation where potential health effects will be assessed in detail. Information, including risk management measures, must be communicated to employers. This will mean that more information is available to employers on how to control risks from the chemical products they use.	CAD requires employers to ensure that workers are provided with information and training on the safe use of chemical agents in the workplace.	Together REACH and CAD will result in employers and workers being better informed about the chemicals they use.

Step by step approach for employers

Although downstream users/employers are faced with two sets of obligations under REACH and CAD, they should only need to do things once.

As an employer you must:

- Identify the presence of substances in the workplace that are hazardous to workers or the environment.



Study any REACH risk management measures in the safety data sheet and its associated 'exposure scenarios' for the chemicals you use.

Where appropriate, inform your suppliers of the use you intend to make of any particular substance and provide information to the manufacturer, importer or distributor who supplies the substance to help them prepare an exposure scenario as required by REACH.

Assess whether use of a hazardous substance can be eliminated or if a less hazardous alternative can be found to substitute for it. Employers should have already undertaken this assessment under CAD, but now there is likely to be more information available that should be taken into account.²⁰

Where exposure to a hazardous substance is unavoidable, continue to follow CAD requirements. In particular, you must:

Assess the risks to the health and safety of workers, taking into account the hazardous properties of the substance, information from suppliers, the level, type and duration of exposure, the amount of chemical used, national occupational exposure limits and conclusions from health surveillance where this is needed.

Continue to follow CAD requirements which set out general principles for prevention and control.²¹

Compare the existing risk assessments/control measures under CAD for the workplace substance with the corresponding risk management measures from REACH.

A REACH 'extended Safety Data Sheet' may carry new information on the chemical, and so trigger the requirement under CAD to review your assessment of chemical risks.

You must be able to demonstrate that your assessment is adequate - that you have identified and applied all appropriate measures to adequately control risks, based on the information provided by your supplier (for example safety data sheets) or other relevant sources of information. This may make further exposure assessment, such as air sampling etc., necessary.

If you can demonstrate that your existing control measures, derived according to your CAD risk assessment, are sufficient to achieve the DNEL communicated in the extended safety data sheet, you do not need to apply the risk management measures recommended therein where they differ from your own measures. If you have implemented alternative risk management measures which provide an equally effective level of protection, it depends on certain specific conditions whether or not you have to prepare a downstream user's Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR), as described in Annex 1 to this document. To find out about these conditions, please consult the ECHA *Guidance for downstream users*, and in particular the section regarding compliance with the exposure scenario²².

Importantly, if you do not accept that some, or all, of the risk management measures recommended under REACH are appropriate, you must provide feedback to your suppliers. They must then pass this back up the supply chain until it reaches the registrant, or anyone else conducting a required CSA. It will enable them to check that assessment, and either adjust it, or advise you that the

²⁰ CAD Articles 5.2 and 6

²¹ CAD Article 5

²² http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm



assessment should stand. You will need to be able to justify your view of the adequacy of your CAD risk assessment, and demonstrate that the alternative risk management measures you have implemented provide an equally effective level of protection.

Where new information from REACH requires it, you should change the existing control measures, for example, if the new information shows that the existing control measures cannot be considered adequate.

Make sure that the resulting control measures fulfil the criteria of CAD, including the rules on substitution, the measures in order of priority for reducing the risks, and restrict the use of personal protective equipment to cases where the risks cannot be controlled adequately by other means.²³

For the large majority of situations, employers should find that following the above steps meets their obligations under both REACH and CAD. However, Annex 1 to this document provides further information on what to do when a downstream user intends to use a substance outside the conditions described in an exposure scenario, or in ways the supplier has advised against, or if the downstream user doesn't communicate the intended use up the supply chain. Annex 1 also provides information on what a downstream user must do if they want to use a substance of very high concern or a substance subject to restriction under REACH.²⁴

Summary of key points

The arrival of REACH should improve worker health and safety by providing better information, by establishing new channels of communication between employers and suppliers and by removing from the market substances of very high concern.

Although REACH is a new system, and a new way of thinking, the requirements of CAD as implemented into national legislation continue as before.

The arrival of REACH does not mean that employers' obligations are duplicated. Where employers are already meeting the requirements of CAD they should, in many cases, have little more to do than review their risk management in the light of new information received as a consequence of REACH, and implement changes where necessary.

Annex 1: Other aspects of REACH that may affect employers

Uses not supported by the registrant

Where the downstream user does not wish to make their use known to their supplier (e.g. for reasons of commercial confidentiality), or if the party responsible for conducting the CSA refuses to support the proposed use, then REACH provides the opportunity for the downstream user to continue using the substance by taking over the registrant's responsibility to prepare a Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR),²⁵ and by doing so to provide certain information to ECHA before commencing or continuing with a particular use.²⁶

²³ CAD Article 6

²⁴ http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm

²⁵ http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm

²⁶ REACH Articles 37.4 and 38.1



The information reported to ECHA includes the identity of the downstream user, the substance registration number and identity, the identity of the supplier, and a brief description of use and conditions of use.²⁷

However, reporting to ECHA is not required for a substance (on its own or in a mixture), which is used by a downstream user in quantities of less than 1 tonne per annum for that particular use.

Using substances of very high concern or substances that are restricted

REACH requires 'Substances of Very High Concern' (SVHC) to be subject to 'authorisation'.²⁸ Such substances include certain carcinogens and mutagens. They will be listed in Annex XIV of REACH.

In many cases, authorisation to use a substance of very high concern is likely to have been obtained by an actor further up the supply chain (e.g. by the registrant). In such circumstances, the downstream user does not have to obtain a separate authorisation, provided that the use of the substance is in accordance with the conditions of that authorisation and set out in the safety data sheet, and that the downstream user has notified ECHA of the intended use within 3 months of the first supply of the substance to them.²⁹

If a downstream user intends to use an Annex XIV substance which is not authorised for that use, they must apply to ECHA for authorisation prior to using it.

ECHA will hold a register of downstream users who are using Annex XIV substances, and this information will be available to the competent authorities of the Member States.³⁰

Where a substance of very high concern has not been granted an authorisation for the use envisaged, the employer cannot re-apply for the same use. They must stop using it.

As consideration of substitution with available alternatives is mandatory under the Carcinogens and Mutagens Directive, the employer has to check the possibility of substitution so far as is technically possible under his specific conditions of use, even where an authorisation under REACH has been granted.

REACH, and where appropriate the Carcinogens and Mutagens Directive, require the employer to ensure that any exposure to an Annex XIV substance is reduced to as low a level as is technically and practically possible.³¹ The downstream user should compare the conditions of the authorisation with control measures identified and adopted under CAD, and make a decision based on section 5 of this guide.

Annex XVII of REACH also lists substances, mixtures and articles where restrictions apply to the manufacture, placing on the market and/or use of a substance. It sets out the conditions of the restrictions for each. Downstream users must comply with these conditions.³²

²⁷ REACH Article 38.2

²⁸ REACH Articles 55 to 66

²⁹ REACH Article 56.2 and 66.1

³⁰ REACH Article 66.2

³¹ Article 5 of the Carcinogens and Mutagens Directive prescribes a hierarchical system of controls to ensure exposure is kept as low as technically possible. Also see REACH Article 60.10

³² REACH Article 67.1 and Annex XVII



Annex 2: Exposure reference levels

General

Occupational exposure limits (OELs) are reference levels for control of exposure to hazardous substances. An OEL is the level that describes 'adequate control of exposure by inhalation'.

The European REACH Regulation introduces a new system of setting exposure reference levels based on human health and environmental effects. REACH will require manufacturers and importers to establish 'Derived No-Effect Levels' (DNELs) for humans by inhalation, ingestion and dermal routes of exposure and 'Prescribed No-Effect Concentrations' (PNECs) for environmental exposure.

Other types of exposure reference level apply in specific circumstances. For example, Acceptable Operator Exposure Levels (AOELs) in setting the conditions of use for plant protection products (pesticides).

OELs, DNELs, AOELs and PNECs co-exist, and in some circumstances may apply simultaneously to some work activities. The key point is that users apply the control measures, risk management measures or conditions of use, that control exposure within the relevant reference level.

A brief account of the main characteristics of each type of limit is set out below.

Occupational Exposure Limits (OELs)

An OEL represents an airborne concentration at which it is unlikely that significant adverse health effects occur in the overwhelming majority of an exposed workforce.³³ OELs are established by regulatory authorities using extensive scientific input. Member States set national OELs. Obligations for compliance with national OELs differ in the various Member States. Where national OELs are binding, they have to be complied with even if the DNEL for the same substance is higher.

Indicative Occupational Exposure Limit Values (IOELVs) are non-binding, health-based limits below which adverse health effects should not occur. They are established under the Chemical Agents Directive (98/24/EC) and adopted in Commission Directives. Member States are required to set national exposure limits that take account of IOELVs. However, Member States can set national limits at different levels where this is considered appropriate. Presently, there are about 90 IOELVs.³⁴

Binding Occupational Exposure Limit Values (BOELVs) are established in Annex 1 of the Chemical Agents Directive (98/24/EC). These reflect feasibility factors, whilst maintaining the aim of ensuring the health of workers. Where a BOELV is established, Member States are required to set a national OEL at a value that does not exceed the BOELV.³⁵ Binding limits are also established in Annex III of the Carcinogens and Mutagens Directive.³⁶

³³ This may not be the case where new data on health effects has become available, e.g. under REACH, since the limit was set.

³⁴ Presently there are two Commission Directives establishing IOELVs – Directives 2000/39/EC and 2006/15/EC. A third IOELV Directive has recently been agreed.

³⁵ Presently Annex 1 of Directive 98/24/EC contains only one entry – for inorganic lead and its compounds.

³⁶ Presently Annex III of Directive 2004/37/EC contains only three entries – for benzene, vinyl chloride monomer and hardwood dusts.



Acceptable Operator Exposure Levels (AOELs)

AOELs relate to people who use plant protection products and biocidal products. The AOEL is based on an internal dose or 'body burden', an amount taken into the body by skin contact and by inhalation. The AOEL is used in risk assessment that compares the modelled (predicted) dose for a defined product and task with that AOEL, to define approved uses of that product.

Derived No-Effect Levels (DNELs) and Prescribed No-Effect Concentrations (PNECs)

REACH requires manufacturers and importers to establish 'Derived No-Effect Levels' (DNELs). Annex I of REACH defines the DNEL as the dose above which humans should not be exposed. DNELs apply to all routes of exposure (oral, dermal or inhalation) and all populations (workers, consumers and indirect human exposure via the environment, including certain sub-populations such as children or pregnant women). There is a systematic and well-defined approach to using uncertainty factors for deriving DNELs.

Manufacturers and importers are required to calculate DNELs as part of their Chemical Safety Assessment (CSA) for any chemical substances for which thresholds for safe exposure can be derived and which are used in quantities of 10 tonnes or more per year. DNELs should be set out in the manufacturer's/importer's Chemical Safety Report. DNELs are part of risk characterisation. The extended safety data sheet (SDS) should quote the DNELs and any OEL.

'Adequate control' means exposure below a DNEL for humans, or below a Predicted No-Effect Concentration (PNEC), for the relevant environmental 'compartment' (e.g. aquatic/sediment, terrestrial, and atmospheric).

Discussion

In principle, comparing exposure levels with a DNEL provides a tool for downstream users. Whilst there is no direct relationship between a DNEL and an OEL, each is useful in establishing what is needed to secure adequate control of exposure. Where OELs have in the past not provided quantitative information on skin absorption, DNELs should provide a more complete assessment of what needs to be done to control exposure.

Where both a national OEL and a DNEL (for both the same duration and the same route of exposure) have been derived for a substance, and the risk management measures in the safety data sheet are significantly more restrictive, employers continue to remain responsible for the protection of their employees, and should seek to resolve the situation with their suppliers and, as appropriate, with the relevant national authorities.

AOELs and DNELs can be compared. Systematic application of uncertainty factors and default values are important in identifying these reference levels, but as yet the use of uncertainty factors in setting OELs has been less systematic.

The European Commission has produced a paper on IOELVs and DNELs.³⁷ IOELVs set by the European Commission can, in certain circumstances, be used as the exposure reference level for inhalation exposure instead of DNELs in the REACH process. However, where there are other exposure routes (e.g. dermal) or durations of exposure different to those covered by the IOELV, the registrant should derive a DNEL.

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http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_b_en.pdf



It is not currently feasible to monitor for $DNEL_{oral}$ or $DNEL_{skin}$, except in specific cases using biological monitoring techniques.

The following styles should be used for headings and subheadings.