


Service Request on Scoping Study on Safety Data Sheets

Under the Framework Contract for services on technical, scientific, health, environmental and socio-economic questions concerning the implementation of REACH Regulation

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Executive Summary / Abstract

This report aims to provide the basis for ECHA to make a decision on the potential need for additional guidance on REACH-compliant Safety Data Sheets (SDS).

The methodology of the study follows an approach to

- 1) Identify needs for guidance (“demand side”) via expert interviews and a workshop at ECHA
- 2) Check already existing guidance to determine whether it fulfils the needs (“supply side”)
- 3) Conclude whether potential gaps between “demand side” and “supply side” should be filled by ECHA

Three particular priority areas requiring additional guidance and in which ECHA is best placed to provide such guidance were identified:

- a. The interface between exposure scenarios developed in the CSA process (and to be annexed to the safety data sheets) and risk management information in sections 7, 8 and 13 of the extended safety data sheet. While the content and structure of the exposure scenarios is to be dealt with in other guidance and via the CSA Tool, there is a need to better define the risk management information in the main body of the SDS.
- b. The workflows and methods at formulator’s level to convert the incoming risk management information on the individual components into outgoing risk management information for mixtures (preparations). This should include guidance on how to deal with mixtures processed into further mixtures.
- c. An easy to understand overview of upcoming deadlines and timelines for revision of SDSs with regard to REACH and the CLP regulation; the transitional periods for cases where some of the necessary information is not yet available should be highlighted.

For the following further issues guidance is required, but it is not recommended that ECHA provide this guidance:

- a. Guidance for industrial/professional end-users of chemicals on how to read a REACH-compliant SDS and on how to fulfil the corresponding downstream user duties under REACH (reason: Generic ECHA guidance already exists in the Downstream User Guidance; further guidance needs to be written in sector or branch specific language).
- b. Guidance on communication on identified uses and conditions of use up and down the supply chain (Reason: Industrial actors are better placed to organise the communication in the market than ECHA).

Insufficient qualification (in the sense of missing expertise and/or experience) is one major reason for quality deficits of existing safety data sheets. But guidance, although mentioned in this context, cannot compensate for missing training and competence of SDS creators. Thus, training of industry

staff and awareness-raising amongst managers on the need to make sufficient resources available are essential elements to complement technical guidance.

The European Commission has started to revise Annex II in order to bring it as close as possible to the GHS guidance on the preparation of safety data sheets (GHS Annex 4). It is planned to publish the revised Annex II of REACH by the end of the year. It is expected that several uncertainties and problems related to SDS creation will be solved with this revision. Any guidance development related to SDS needs to be closely coordinated with the revision of Annex II.

Currently guidance related to the creation of extended SDSs and related obligations is already available in a number of ECHA documents (e.g. Guidance on CSA, Part G; Downstream User Guidance). During the workshop a need for an overall guidance was expressed. This “umbrella” guidance should be short and comprehensive and lead the different target groups to the relevant chapters in the already available ECHA guidance documents. It should ideally be available in all official EU languages. As a first step the existing ECHA guidance documents should be made more accessible (via a redesign of ECHA’s website) as soon as practicable.

It would be useful if future guidance were to contain example SDSs and one or more commented REACH-compliant SDS templates to explain and illustrate what a good extended SDS should look like and where relevant information is best placed. It would be desirable to publish the guidance as one block and with a stable content (no frequent revisions).

Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CESARS	Chemical Evaluation Search And Retrieval System
CLP	Classification, Labelling and Packaging Regulation EC (No) 1272/2008
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
DU	Downstream User
ECETOC	European Centre for Ecotoxicology and Toxicology Of Chemicals
EEA	European Economic Area
ECHA	European Chemicals Agency
ECLIPS	European Classification and Labelling Inspections of Preparations, including Safety data sheets
ERP	Enterprise response planning
ES	Exposure Scenario
GHS	Globally Harmonised System of classification and labelling
GSBL	Gemeinsamer Stoffdatenpool des Bundes und der Länder
ICSC	International Chemical Safety Cards
IUCLID	International Uniform Chemical Information Database
MS	Member States
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program

OECD	Organisation for Economic Co-operation and Development
OR	Only Representative
PBT	Persistent, Bioaccumulative, Toxic
PNEC	Predicted No Effect Concentration
PPE	Personal Protective Equipment
RMM	Risk Management Measures
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
vPvB	very Persistent, very Bioaccumulative
WHO	World Health Organization

1 Introduction: Background and objectives

1.1 Background

This report was commissioned by ECHA to determine the needs for additional guidance documents from ECHA on how to generate REACH-compliant safety data sheets¹.

The main SDS responsibilities arising from REACH² are assigned to the manufacturers of substances, first formulators (downstream users) of simple mixtures³ and further downstream users (DUs) of more complex end user mixtures. Other actors in the supply chain like distributors (communicating the information up and down the supply chain) and importers of mixtures (needing to obtain information on substance components from non-community manufacturers and users) will also contribute.

The main tasks of these actors relate to creation of SDSs, communication of the necessary information within the supply chain, implementing the recommended risk management measures (RMM) and keeping the information up to date.

Member States Competent Authorities are responsible for the local enforcement of REACH, including monitoring of the quality of SDSs. ECHA is in charge of REACH implementation including provision of necessary IT tools and guidance.

Industry sectors can have an additional active role in collecting information for sector-specific exposure scenarios (ES) and even SDS templates.

The basic IT tools of these actors include at least the existing SDS systems, supplier and customer databases (as standalone applications or as part of the global enterprise resource planning (ERP) systems), IUCLID 5, the Chemical Safety Assessment Tool (CSAT) and additional local or global expert applications.

¹ REACH-compliant SDS means a safety data sheet that fulfils all legal requirements of REACH.

² 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 (OJ L 396, 30.12.2006)

³ Following the terminology of the UN GHS the CLP Regulation introduced the word “mixtures” for “preparations”.

1.2 Objectives

Against this background the tasks of the scoping study can be summarised as follows:

- Identify the REACH related changes of requirements, information sources and flows for creating, communicating and maintaining SDSs for concerned actors
- Characterise available standards and guidance;
- Highlight the expected REACH impact on SDSs and collect the requirements for potential guidance from 15 - 20 key experts by means of a workshop

1.3 Methodology and approach

The methodology of the study follows an approach to

- 1) Identify needs for additional guidance (“demand side”)
- 2) Check already existing guidance to determine whether it fulfils the needs (“supply side”)
- 3) Conclude whether potential gaps between “demand side” and “supply side” should be filled by ECHA

The methodology considers that it is not enough to apply steps 1) to 3) only to new REACH requirements, but that it is also necessary to proceed in the same way with requirements for former SDS elements that remain valid under REACH.

Apart from classical ways of information collection (internet, literature research) more than 30 telephone interviews have been performed with European experts. Additional information originated from the expert workshop at ECHA which facilitated further discussion and information exchange.

The following 4 generic cases are regarded as helpful to demonstrate differences and similarities of the preceding SDS requirements and the new REACH requirements:

Case A: Manufacturer or importer of a substance (SDS creation)

All differences between REACH-compliant SDSs and former SDSs are relevant. With respect to data gathering and communication this case considers a situation in which the creator of an SDS typically has himself detailed information on, or at least access to, the required data. Communication is mainly done down the supply chain.

Case B: Importer of a mixture (SDS creation)

As there is again a need to create an SDS, all differences between REACH-compliant SDSs and former SDSs are relevant. A typical problem in this case is the question of how to convert the incoming risk management information on the individual components of the mixture into outgoing risk

management information on the mixture. In many cases conditions of limited knowledge on the exact composition of the mixture the mixture apply. In contrast to the case of a manufacturer of a substance or a manufacturer of mixtures who himself manufactures the components, the importer of a mixture needs to go upstream to obtain the required data and proper interpretation. As non-EEA suppliers are concerned this is often difficult and it may be that only limited or no information on the composition of the mixture is available.

Case C: Industrial formulator (Downstream user, SDS creation)

For industrial formulators within the EEA several problems related to SDS are similar to case B. However, additional complications may arise if a formulator himself buys formulations to incorporate into his own formulations.

In this case the main sources of information might be more than one step up in the supply chain (e.g. the original manufacturer of the substances) without full access to relevant SIEF data.

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

A professional end user has no obligation to create an SDS. Therefore difficulties and differences related to the creation of former SDSs or REACH-compliant SDSs are not relevant. Nevertheless, there are new communication requirements for professional end users for which a potential need for guidance should be investigated.

The four generic cases are investigated with respect to former SDSs and REACH requirements. Based on the results of this analysis recommendations are derived in order to achieve the objectives of the scoping study.

2 Former SDS requirements

2.1 Legal requirements

The main legal sources for the requirements related to the creation and provision of the former SDSs were Directive 1991/155/EEC in combination with Directive 67/548/EEC for substances and Directive 2001/58/EC in combination with 99/45/EC for mixtures. In contrast to the new regulation the requirements of the former SDSs were based on a Directive which had to be implemented by each Member State into national law. Therefore in some Member States additional requirements applied for the creation and communication of the former SDSs (e.g. Czech Republic, Germany).

The directive prescribed a structure with 16 headings (Article 3) and in the Annex gave more detailed information on which data had to be included under each heading.

The SDSs had to be provided free of charge and with the first delivery of the substance/mixture. The SDSs had to be supplied in the official language(s) of the Member State(s) where the substance or mixture was placed on the market, if required by the Member State(s) concerned.

An update of the SDS was required in case of any significant new information regarding safety and protection of health and the environment. The new, dated version of the SDS, identified as 'Revision: (date)', had to be provided free of charge to all former recipients to whom the substance or mixture had been supplied within the preceding 12 months.

An SDS did not need to be supplied in case of dangerous substances or mixtures offered or sold to the general public – provided that the recipients of the substances or mixtures were furnished with sufficient information to enable users to take the necessary measures to ensure safe use. However, on request an SDS had to be supplied to an industrial user.

Case A: Manufacturer or importer of a substance (SDS creation)

The manufacturer – if responsible for placing on the market - had to supply an SDS to a professional user when the substance met the criteria for classification as dangerous according to Directive 67/548/EEC (Article 1, Directive 1991/155/EEC).

Case B: Importer of a mixture (SDS creation)

The importer - if responsible for placing the mixture on the market - had to provide an SDS to a professional user when the mixture met the criteria for classification as dangerous according to European Parliament and council Directive 1999/45/EC. (Article 1, Directive 1991/155/EEC).

In addition on request by a professional user, an SDS providing proportionate information (as set out in Article 3 and in the Annex to Directive 1991/155/EEC), had to be provided in case of mixtures not classified as dangerous according to Articles 5, 6 and 7 of Directive 1999/45/EC, but where the

mixture contained in an individual concentration of $\geq 1\%$ by weight for non-gaseous mixtures and $\geq 0.2\%$ by volume for gaseous mixtures at least:

- one substance posing health or environmental hazards, or
- one substance for which there are Community workplace exposure limits.

Case C: Industrial formulator (Downstream user, SDS creation)

The same legal requirements apply as for case B.

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

These actors were not directly addressed by Directive 91/155/EEC. The directive laid down the right of professional users to request and receive an SDS for non-hazardous mixtures in specific cases.

2.2 Feedback on sources and flows of information needed for creating former SDSs

Case A: Manufacturer or importer of a substance

Key message: The information that was requested to create an SDS was in most cases available. Communication was done typically via associations (horizontal exchange) or direct via publicly available sources. Also professional service providers were contracted. Communication with downstream users was very limited. It sometimes took place via sales staff or it was initiated in case the information in the SDS was not sufficient for the prescribed risk assessment of workplaces. **Existing guidance is appreciated; further guidance on this aspect not major priority.**

Main source of information used by manufacturers and importers:

- Internal sources of information
 - Internal data resulting from tests
 - Internal data from staff
 - Information on former use experience obtained from customer feedback
 - Data provided by associations (sector specific via European or national associations)

- Legally based sources of information
 - Annex I of the Dangerous Substances Directive 67/548/EEC (DSD) and Annex VI of the Classification, Labelling and Packaging Regulation EC N° 1272/2008 (CLP), with information on classification and labelling that can be used in sections 3 and 15 of the SDSs
 - Workplace exposure limit values in EU Member States in which product put on market (section 8)
 - IUCLID at <http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=dat> (mainly data on hazardous properties, with indications of the test conditions)
- Scientific reports and publications (toxicology, ecotoxicology, threshold and non-threshold effect levels safe exposure values)
 - Risk assessment reports such as EU-ESIS, OECD-SIDS, IRIS US-EPA, OECD eChemPortal) (mainly toxicology, ecotoxicology, safe exposure limits, safety measures)
 - IPCS, Concise International Chemical Assessment Documents (WHO).
 - ATSDR, Toxicological profiles
 - NTP reports on carcinogens
 - Documents published by EU, WHO, OECD, US-EPA, ECETOC, INERIS, NIOSH
- Safe handling and use – safety measures
 - Manufacturers of PPE and (potentially) International Chemical Safety cards (ICSC)
- Other sources
 - Databases: Toxnet, HSDB (hazardous properties), CESARS (ecotoxicology), WorldWideScience, GSBL Stoffdaten (Gemeinsamer Stoffdatenpool des Bundes und der Länder),
 - SDSs of competitors
 - Information on the internet
 - Scientific publications (e.g. Science Direct)
 - Chemfinder
 - Data provided by external service providers

A high quality information source was the risk assessment reports compiled within the Existing Substances Regulation EC (No) 793/93 or high production volume and chemical safety programs (OECD, WHO, US-EPA). They contain valuable information on physicochemical and (eco)toxicological properties, a selection of key studies for various end-points, risk assessments of a high scientific level and information on safe levels of exposure and on safety measures. Also the ICSC cards give information on safety measures and personal protective equipment.

The documents compiled by scientific bodies such as ATSDR, NTP, NIOSH are of high quality and are understandable for those with a thorough knowledge of risk assessment.

The above listed databases can be searched by substance name or identification numbers. They contain a wide range of data on toxicity and ecotoxicity. The data have to be assessed and need expert judgement. Description of the test conditions is not always available.

The internet may provide data relevant for SDSs but also this information always needs a quality check and an expert judgement.

All these information sources are readily available.

Data from external service providers could be used in the SDS, but the competence of the provider should be judged in advance.

Another source of information was the SDSs from other manufacturers; the quality of the content of these documents could be very variable, as was shown in the ECLIPS study on SDSs, available at http://www.cleen-europe.eu/projects/ECLIPS_Final_report.pdf

Case B: Importer of a mixture (SDS creation)

Key message: The importers of mixtures typically faced more problems related to the collection of required data than the manufacturer of substances. They could in principle use the same sources of information, but generally less data was available for mixtures than for substances. The SDSs of the non-EEA suppliers were of major importance, however, in many cases problems with missing data or low quality occurred. Communication with downstream users was very limited. **Guidance is required to address the problem of how to convert the incoming risk management information on the individual components of the mixture into outgoing risk management information on the mixture.**

Case C: Industrial formulator (Downstream user, SDS creation)

Key message: Industrial formulators who bought formulations faced similar problems related to the collection of required data as importers of formulations. In many cases the information included in the SDS of the components of the formulation was not sufficient to prepare an SDS for the new mixture. **Therefore guidance needs are similar to those for case B.**

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

Key message: As there was no need to create an SDS, no data sources for SDS creation were used by downstream users. Although there was no obligation to create an SDS, professional end users faced the problem that the information included in the SDS was not always sufficient to carry out a risk assessment of the workplace. Therefore publicly accessible data bases, SDSs of competitors or sector specific information from associations were often used as additional information sources to carry out the risk assessment and for information on relevant risk reduction measures. **Existing guidance is appreciated; no need for further guidance is indicated.**

2.3 Description of sources and flows of information needed for communicating

Key message (valid for all 4 cases): For the former SDSs well targeted communication existed only to a limited extent. This caused problems related to missing, imprecise and sometimes wrong information in SDSs. Various actors argue that guidance would help, but ECHA is not regarded as the institution of choice to provide such guidance as industry activities (e.g. by associations) are likely to be more efficient in this area.

Case A: Manufacturer or importer of a substance

Key message: Horizontal communication was in most cases organised via associations. Communication with downstream users typically took place when specific information was requested due to a lack of information in the SDS or contradictory information in the SDS of competing companies. Upstream communication was typically not done by manufacturers of substances while it was common for importers that do not manufacture a substance themselves.

Case B: Importer of a mixture

Key message: The main weakness in communication was typically in the upstream contact with suppliers. Horizontal communication was in most cases organised via associations.

Case C: Industrial formulator (Downstream user, SDS creation)

Key message: Same situation as for importers of mixtures (case B).

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

Key message: Communication was very limited. It was typically based on own experiences with the substance or mixture, in most cases related to applications and appropriate safety measures; sometimes data from SDSs of competitors were also used to start communication and to clarify contradictions. Guidance is available (e.g. VCI, Gisbau) by means of check lists to identify whether the SDS is formally legal compliant and contains all required information. With this type of check list only formal requirements can be checked, a quality check of the information and data provided is not possible.

2.4 Strengths and weaknesses of former SDSs

A major problem of the former SDSs is the quality of the information. For example in a survey related to the quality of SDS carried out in Germany only 141 SDSs out of 929 examined were classified as “very good” and 169 as “good”. More than 600 SDSs failed and were classified as being of “bad” quality for various reasons (e.g. wrong and missing information). Against the background of such surveys, questions should be asked on the reasons for these quality problems and the question needs to be answered as to whether the existing shortcomings could be compensated by additional guidance.

- 1) In many cases insufficiently qualified staff created SDSs and thus important information was not included or not adequately addressed. To compensate for quality problems it is necessary to
 - a) Provide training for creators of SDSs
 - b) Provide appropriate tools for education of SDS creators
 - c) Raise awareness about the importance of SDSs and qualified staff for creation of SDSs at the management level of companies
 - d) Enable SDS creators to check their qualifications/competence

Guidance is not expected to compensate for missing qualification and competence of SDS creators.

- 2) Lack of access to information, lack of communication or simply lack of available information, are other reasons for quality problems of former SDSs. While REACH will help significantly to improve the scope of available information and also help to access data, the question whether guidance would help to reduce existing difficulties still needs to be answered. From discussions with stakeholders and experts it became obvious within this study that well targeted guidance would contribute to solving these problems, but also that the best source for guidance on these aspects **would be industry rather than ECHA.**
- 3) Another reason for poor quality of former SDSs relates to SDSs for mixtures. As mentioned in chapter 2.3 it is difficult to convert the incoming risk management information on the individual components of the mixture into outgoing risk management information on the mixture. **To solve this problem guidance is requested from ECHA.**
- 4) Furthermore, a major source of quality and uncertainty problems of former SDSs, are national requirements such as different occupational exposure levels. **It is expected that guidance could help to solve this problem but no common view could be identified within this scoping study in particular as to who should provide such guidance (ECHA, European Commission or industry).**
- 5) Finally the absence of a precise specification of the format (or medium) for delivery, is another weakness of former SDSs. This lack of format definition causes many discussions as to whether the provision of an SDS in electronic form is possible and whether the provision of the SDSs on

the homepage of a company is sufficient to comply with the information duties laid down in the Directive. However, this does not directly affect the quality of SDSs.

Major weaknesses are compiled in the following list:

Weakness
Often poor quality and many gaps in the SDSs due to missing information (independent of the qualification of the person who creates the SDSs)
No precise definition of the expression “competent person” → SDSs are often prepared by unqualified staff resulting in poor quality SDSs
Often SDSs are for a mixture and data quoted are for component substances with no clear mentioning of this fact.
No or little information related to the use/application of the substance or mixture
SDSs are created in some cases just to fulfil a legal obligation and not as a tool to communicate possible hazards and risks → information is reduced to a minimum
Often unclear expressions or abbreviations are used (e.g. often it is not clear whether data are “not applicable” or simply “not available”)
Lack of primary references to justify the information put in the SDSs
National specific requirements have to be taken into consideration for many sections

On the other hand it needs to be emphasised that despite the above-mentioned problems, the preceding SDSs have generally been seen as a well structured documents which addressed all important issues.

They were perceived as a good instrument to communicate important health and environmental risks related to substances or mixtures – as long as the SDSs had been created properly by a competent person.

Major strengths of the SDS system are compiled in the following list:

Strengths
Well structured, all important issues are addressed
Good instrument to communicate important health and environmental risks related to substances or mixtures (SDS are established even without a need to have them, e.g. for certain articles or non hazardous materials)
Recognized and internationally accepted standard format
Sufficient software is available to create SDS efficiently

3 New REACH requirements and information flows for SDSs

3.1 Legal requirements

Note: references to articles or annexes are references to articles or annexes of the REACH Regulation, unless otherwise stated.

SDSs are addressed within article 31 and Annex II (Guide to the compilation of safety data sheets) of the REACH Regulation. The European Commission has started to revise Annex II in order to bring it as close as possible to the Globally Harmonised System of classification and labelling (GHS) guidance on the elaboration of safety data sheets (UN-GHS annex 4). It is planned to publish the revised Annex II by the end of 2009. Any guidance development related to SDSs needs to be closely coordinated with the revision of Annex II.

REACH-compliant SDSs will continue to contain information on the hazards of substances and mixtures as well as information on the RMMs to adequately control any risks to human health and the environment.

The format with the 16 headings, the content of which is explained in Annex II, will have to be used to create REACH-compliant SDSs. In addition, for all those substances for which a chemical safety assessment (CSA) is required the relevant exposure scenario for each downstream user along the supply chain shall be annexed to the SDS. The exposure scenario includes RMMs, where required.

The information in the SDSs should be consistent with the information in the CSA for that substance or mixture, if a CSA for the mixture is available. Legal requirements for the four generic cases are presented below. The general requirements are applicable for every actor dealing with SDSs; the applicability of the specific requirements depends on the role of the actor in the supply chain.

General legal requirements:

A REACH-compliant SDS should be supplied in the official language(s) of the corresponding Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned indicates otherwise. An SDS shall be provided free of charge on paper or electronically.

Suppliers⁴ shall update the SDSs without delay on the following occasions:

- as soon as new information which may affect the RMMs becomes available
- as soon as new information on hazards becomes available
- once an authorisation has been granted or refused
- once a restriction has been imposed

The new, dated version of the SDS, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom the suppliers have supplied the substance or mixture within the preceding 12 months.

The labelling requirements indicated on the SDS must correspond to the label on the package. Deadlines for updating the labelling of the package when new information becomes available are stipulated in article 30 of the CLP Regulation:

1. *The supplier⁴ shall ensure that the label is updated, without undue delay, following any change to the classification and labelling of that substance or mixture, where the new hazard is more severe or where new supplemental labelling elements are required under Article 25, taking into account the nature of the change as regards the protection of human health and the environment. Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling without undue delay.*
2. *When labelling changes are required other than those referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months.*

The supplier of an SDS shall ensure that the classification and labelling information on the SDS is updated accordingly.

Specific legal requirements for the four different cases are given below:

Case A: Manufacturer or importer of a substance (SDS creation)

A REACH-compliant SDS is required as soon as a substance falls within one of the following categories:

- it meets the criteria for classification as dangerous (as mentioned in the DSD 67/548/EEC) and the DPD 1999/45/EC) gradually replaced by the CLP Regulation 1272/2008⁵)
- it is PBT or vPvB (Annex XIII)
- it is on the candidate list in accordance with article 59(1)

A manufacturer has the obligation to annex exposure scenarios to the SDS for registered substances, manufactured in quantities of 10 tonnes or more per year. This obligation also applies to substances for which the manufacturer applies for an authorisation below the tonnage trigger of 10 tonnes. The exposure scenario covers identified uses and includes use and exposure categories. The manufacturer must, where applicable, recommend appropriate measures to adequately control the risks within the SDSs which he supplies.

⁴ supplier of a substance or a preparation means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation (Art. 3)

⁵ Both the DSD 67/548/EEC and DPD 1999/45/EC will be repealed on 1 June 2015

Case B: Importer of a mixture (SDS creation)

A REACH-compliant SDS is required for a mixture when the mixture meets the criteria for classification as dangerous (67/548/EEC; 1999/45/EC; CLP Regulation 1272/2008)⁶

Where a mixture does not meet the criteria for classification as dangerous, the supplier shall provide the recipient at his request with an SDS when the mixture contains at least one of the following:

- for non-gaseous mixtures: at least one substance in a concentration of $\geq 1\%$ by weight, posing human health or environmental hazards
- for gaseous mixtures: at least one substance in a concentration of $\geq 0,2\%$ by volume, posing human health or environmental hazards
- for non-gaseous mixtures: at least one substance in a concentration of $\geq 0,1\%$ by weight, that is PBT or vPvB in accordance with the criteria set out in Annex XIII
- a substance on the candidate list in accordance with Article 59(1)
- a substance for which there are Community workplace exposure limits.

In addition the CLP Regulation requires an SDS on request for mixtures that contain at least:

- one substance in a concentration of $\geq 0,1\%$ by weight, that is carcinogenic category 2, toxic to reproduction category 1A, 1B or 2, a respiratory sensitiser category 1 or has effects on or via lactation (CLP Regulation, Article 59(2))
- one specific target organ toxicant category 2 in a concentration of $\geq 1,0\%$ (CLP Regulation, point 3.9.3.4.1 Note 1)

The importer is a registrant and must include relevant exposure scenarios for identified uses when compiling his own SDS for an imported mixture. The obligation to annex exposure scenarios to the SDS of a mixture has to be fulfilled by importers for registered substances in mixtures in quantities of 10 tonnes or more per year.

The obligation also applies to substances in mixtures for which the importer applies for an authorisation below the tonnage trigger of 10 tonnes. If the importer has prepared a CSA for the imported mixture, it is sufficient if the information in the SDS is consistent with the chemical safety report (CSR) for the mixture, instead of with the CSR for each substance in the mixture.

If the non-EEA manufacturer of a formulation or the non-EEA supplier of substances used by the formulator, appoints an only representative (OR), the importers become downstream users (DU) (see below). The OR shall keep available up-to-date information on the supply of the latest update of the SDS (Art. 8(2)).

⁶ Both the DSD 67/548/EEC and DPD 1999/45/EC will be repealed on 1 June 2015

Case C: Industrial formulator (Downstream user, SDS creation)

A REACH-compliant SDS is required for a mixture when the mixture meets the criteria for classification as dangerous (67/548/EEC; 1999/45/EC; CLP Regulation 1272/2008)⁶

Where a mixture does not meet the criteria for classification as dangerous, the supplier shall provide the recipient at his request with an SDS when the mixture contains at least one of the following:

- for non-gaseous mixtures: at least one substance in a concentration of ≥ 1 % by weight, posing human health or environmental hazards
- for gaseous mixtures: at least one substance in a concentration of $\geq 0,2$ % by volume, posing human health or environmental hazards
- for non-gaseous mixtures: at least one substance in a concentration of $\geq 0,1$ % by weight, that is PBT or vPvB in accordance with the criteria set out in Annex XIII
- a substance on the candidate list in accordance with article 59(1)
- a substance for which there are Community workplace exposure limits.

The DU must include relevant exposure scenarios and use other relevant information from the SDS supplied to him when compiling his own SDS for which he has passed on information up to the registrant (identified uses). The obligation to annex exposure scenarios to the SDS of a mixture has to be fulfilled by formulators for registered substances in mixtures in quantities of 10 tonnes or more per year. The obligation also applies to substances in mixtures for which the DU applies for an authorisation below the tonnage trigger of 10 tonnes.

The DU has to recommend risk reduction measures.

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

The end-user has to apply the risk reduction measures indicated in the REACH-compliant SDSs he receives from his suppliers.

3.2 Sources and flows of information needed for creating REACH-compliant SDSs

Case A: Manufacturer or importer of a substance (SDS creation)

Sources of information

- Chemical Safety Report (CSR)
- Technical dossier

- Classification and labelling inventory on the ECHA website
- Publicly available information from registration dossiers, at the ECHA website
- Other sources: see point 2.2

The most important and valuable source will be the CSR. The information on the following topics in the SDS will be available in the CSR:

- Exposure scenarios (ES)
- Derived No Effect Level (DNELs) and Predicted No Effect Concentrations (PNECs)
- Persistent-Bioaccumulative-Toxic (PBT) assessment
- Non-classifiable hazards
- RMMs
- Waste management measures
- Technical measures for safe handling and storage

As a member of the SIEF, the manufacturer will have good knowledge and understanding of the content of the CSR and will be able to transfer the relevant information on effects to the SDSs. The exposure scenarios will be compiled within the SIEF or separately by the registrant alone, but that makes no difference for the transfer to the SDSs. How the transfer will be organised in practice is not yet fully clarified.

The technical dossier for registered substances will mainly offer necessary information on the physicochemical, toxicological and ecotoxicological properties. Robust summaries of the available key studies for every relevant end-point will also be part of the technical dossier. These robust summaries are a good starting point for writing the summaries that must be included in section 11 and 12 of the SDSs. However, questions remain as to how extensive they should be and to whom they should be addressed: (medical doctors, legal experts, safety engineers, DU, consumers.)

Guidance should be given on the level of the technical language that should be used for the summaries. Illustration with some examples would be very helpful. The following information from the technical dossier will be transferred to the SDS:

- Exposure scenarios
- Name of the substance
- Registration number and other identification numbers
- Identification of the manufacturer
- Identified uses
- Uses advised against
- Available information on intrinsic hazardous properties

- Robust summaries of toxicity and ecotoxicity studies
- Classification and labelling (according DSD (67/548/EEC and CLP Regulation (1272/2008))
- Information on endocrine disrupting potential

The main data sources mentioned in Table 1 should be enough to create a high standard REACH-compliant SDS. Manufacturers producing a substance in a quantity of less than one tonne do not have to register that substance, so they will have no technical dossier. A valuable source of information will be the C&L inventory and the non-confidential information from registration dossiers that will be made publicly available on the ECHA website. Other data sources as listed under point 2.2 can also add value to content of the REACH-compliant SDS, just as they could for the former SDS.

SECTION	TITLE	Information in the SDS:	Source
1.1	Identification of the substance	Name and registration number	Technical dossier
1.2	Use	Identified uses	Technical dossier
1.3	Identification of the company	Person responsible for placing the substance on the market	Technical dossier
		The e-mail address of a competent person responsible for the SDS	Manufacturer
1.4	Emergency phone	Phone number and the hours of reachability (office hours, 24/24)	Manufacturer
2.	Hazard identification	Classifiable and non-classifiable hazards	Technical dossier CSR
		CLP classification	Technical dossier C&L inventory
3.	Composition	Registration number	Technical dossier
		Other identification numbers	Technical dossier
		DSD and CLP classification	C&L inventory
4.	First aid measures	For all routes of exposure	Manufacturer
5.	Fire-fighting measures		Manufacturer
6.	Accidental release measures		Manufacturer
7.	Handling and storage	Technical measures to prevent exposure	CSR
8.1	Exposure limit values	DNELs and PNECs	CSR
		OELs	EU recommendations MS legislation
8.2.	Exposure controls	Specific RMMs for the identified uses	CSR
9	Physicochemical properties		Technical dossier
10	Stability and reactivity		Technical dossier
11	Toxicological information	Summaries	Robust summaries in the technical dossier
12	Ecological information	Summaries on ecotoxicity	Robust summaries in the technical dossier

SECTION	TITLE	Information in the SDS:	Source
		Bioaccumulation and biodegradation	Technical dossier
		Results of PBT/ vPvB assessment	CSR
		Information on the endocrine disrupting potential	Technical dossier
13	Disposal considerations	Waste management measures	CSR
14	Transport information		ADR, RID, IMDG, IATA
15	Regulatory information	Indicate whether a CSA has been carried out	CSR
		Labelling according to the CLP regulation	Technical dossier C&L inventory
		Authorisation provisions	Manufacturer
		Restrictions	Annex XVII
		MS specific information	MS legislation
16	Other information	Uses advised against	Technical dossier
ANNEX		Exposure scenarios	CSR

Table 1: Data sources for creating a REACH-compliant SDS

It is to be expected that data on exposure might be scarce. Exposure models are available to estimate exposure in order to perform a solid risk assessment. Results of exposure modelling always need expert judgement. These models will be mainly used for the CSA and the results will be transferred to the SDSs.

Case B: Importer of a mixture (SDS creation)

Importers of mixtures are not usually familiar with the data sources listed under chapter 3.2 Case A. Generally the only information source they have, if any, are the SDSs from the non-EEA formulator. These SDSs are written in a different format and often lack information that is required for a REACH-compliant SDS.

Conversion to a REACH-compliant SDS is often necessary. Translation may be a linguistic problem but finding the appropriate technical wording is more difficult. It is also time consuming when the text is not standardised. Libraries with standard phrases in all EU languages would certainly be welcomed. An importer is a registrant. If he fulfils the conditions for compiling a CSA, he is required to write a CSR for the substances in the mixture he imports.

This CSR is an important source of information. Although the importer is a member of the SIEF, the technical level of the content of the CSR may be too complicated to enable him to fully understand it and to transfer the relevant information to the SDS. By contrast to the case of manufacturers of substances, importers of mixtures have little experience and knowledge of test reports on substances.

Importers will need guidance on how to select the information about the ingredients from the CSRs to be incorporated into the REACH-compliant SDSs for mixtures and on where to find information that is Member State specific such as occupational exposure limit values. External consultancy may be a solution, but the responsibility for the quality of the SDS still lies with the importer.

Case C: Industrial formulator (Downstream user, SDS creation)

REACH is a substance-oriented regulation and therefore CSAs for mixtures will seldom be available. Gathering data on a mixture is not easy. As a consequence, the information for creating a REACH-compliant SDS for a mixture will be mainly based on information about the ingredients. The data gathering will be easier for a manufacturer who is a DU of his own substances than for a DU buying formulations. Three sub cases of DUs are elaborated below.

Manufacturer of a substance is also the first formulator (both within one company)

If the manufacturer has registered the substances he uses for his formulation, the information necessary for compiling the REACH-compliant SDS for the mixture will be available, including the exposure scenarios when a CSA was performed.

Sources of information

- Sources of information for the manufacturer (see chapter 3.2 Case A)
- Specific data on the mixture (e.g. volatility/vapour pressure)
- Legislation on classification of mixtures

Formulator buys substances

Sources of information

- SDSs or REACH-compliant SDSs from the supplier for each substance
- Specific data on the mixture (e.g. volatility/vapour pressure)
- Legislation on classification of mixtures
- Data provided by external service providers

Formulator buys formulation

The starting point is the SDS for the formulation from the suppliers of the formulation and for the other substances that will be used in the new mixture. The SDSs for the formulation obtained from the supplier contains information on its composition e.g. identification of the components and their concentration or concentration range. The latter may be a problem, leading to a worst case classification of the mixture.

Sources of information

- SDS from the supplier of the formulation
- SDS from the suppliers of substances used in the new mixture
- Specific data on the mixture (e.g. volatility/vapour pressure)
- Legislation on classification of mixtures
- Data provided by external service providers

Difficulties for formulators

The following difficulties have been identified:

- obtaining sufficient data from the suppliers and suppliers' suppliers
- assessing all of the received SDSs for every substance is time consuming
- sorting out which data are relevant for the SDSs of the mixture
- selecting the 'lead substance' for the SDSs and the RMMs
- downstream users have a diverse level of knowledge of the chemicals legislation and the specific terminology
- DUs are often SMEs without a legal department; as a consequence the level of knowledge of the chemicals legislation and the resources may be too low to apply this legislation sufficiently
- translation, often into many languages
- some of the necessary information (e.g. registration numbers, CSR) may not be available yet during the transition periods (last registration deadline is 1 June 2018, CLP deadline for substances is 1 December 2010, for mixtures 1 June 2015)

An easy to understand overview of upcoming deadlines and timelines for revision of SDSs with regard to REACH and the CLP regulation during which some of the necessary information will not be available yet, would be welcomed.

Due to a lack of expertise and resources in the past, the quality of the SDSs from DU was not always good. Under the former SDS legislation it was common practice for DU to use the SDS from the supplier as a basis for their own SDS. With a minimum of changes, they created a new SDS for their formulation. As a consequence DUs currently often do not have experience of creation of high quality SDSs that fulfil all the legal requirements. **Clear guidance is needed to help DUs to enhance the quality of their SDSs.**

This should include guidance on:

- which information from the SDSs on the ingredients is needed for the SDS for the formulation
- how to make a choice within the selected ingredient information (e.g. what kind of gloves to choose for the mixture when the SDSs of the ingredients advise different gloves); guidance on prioritisation of the information would be helpful
- which information on the mixture itself must be in the SDS
- how to apply the CLP regulation and what to do during the transitional period
- where to find information that is needed to comply with Member State (MS) specific obligations on SDSs
- how to keep the SDSs up to date

The expert interviews and the expert workshop clearly identified additional guidance on the workflows as a priority for formulators. However, training of industry staff and awareness-raising amongst managers on the need to make sufficient resources available were also considered to be essential elements to complement technical guidance.

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

An end-user does not have to create an SDS.

3.3 Description of sources and flows of information needed for communicating

Unlike the old legislation, REACH introduces mandatory information flow between all actors in the supply chain (Art. 32 and 34).

Case A: Manufacturer or importer of a substance (SDS creation)

In the past, the manufacturer had to make the SDSs for substances and their updates available to the DU, on paper or electronically. This will continue to be the case in the future. Additionally, REACH requires more intense communication. Mandatory communication is new and therefore clear guidance will help manufacturers to learn to communicate effectively and to optimise the efficiency of the communication through the whole supply chain in order to fulfil the REACH requirements. Guidance is needed on:

- the advantages of a well organised communication and information flow along the supply chain

- what kind of information has to be obtained from direct customers
- what kind of information has to be obtained from further downstream the supply chain
- what is the required timescale for the information to be available
- who is responsible if relevant information reaches the manufacturer after the registration deadline

Case B: Importer of a mixture (SDS creation)

Importers of mixtures have the obligation to communicate with their direct customers. They have to make available SDSs (and their updates) of the mixtures on paper or electronically.

Since an importer is a potential registrant, the obligation to communicate and the need for guidance on how to organise this communication will be the same as for a manufacturer (Case A).

In order to get information for the creation of the REACH-compliant SDS, the importer will have to communicate up-stream with his non-EEA formulator. In the past, communication with the non-EEA formulator often proved to be very difficult. One of the reasons was the fear of misuse of the information disclosed (e.g. on composition) when the reason for the request for this information was unclear. Since REACH is an EU Regulation, non-EEA formulators are not always able to assess the relevance of the request for information. Going further up the supply chain the willingness to provide information may be further reduced because the link with REACH is even further away. So it is of utmost importance for the importer to clearly indicate which information is needed from the non-EEA supplier and to explain that this information is required to be able to fulfil the REACH obligations. This is a very important issue and should be dealt with in a guidance document.

The non-EEA formulator or manufacturer should make provisions for the transmission of the information that is required for the registration, the CSA or the creation of an REACH-compliant SDS.

Case C Industrial formulator (Downstream user, SDS creation)

The DU in the supply chain of a substance or a mixture has to transmit information to the next actor in the supply chain, up the supply chain as well as down the supply chain.

In the communication up the supply chain he has to transmit:

- Information on identified uses
- Proposals for changes of the exposure scenarios described in the Annex of the SDS he received from his supplier.
- Proposals to change operational conditions and the RMM as proposed in the Annex of the SDS.
- New information on hazardous properties

- Any information that might have influence on the RMMs in the SDS supplied to him (only for identified uses)
- Information relevant for the creation / update of the SDS of the supplier

In the context of his communication down the supply chain the DU will:

- Supply the SDS and its updates
- Forward the relevant exposure scenarios to the customer
- Take into account the demands of the client to adapt the exposure scenario or to change the RMMs.
- Transfer documents from the supplier to the client when these documents must cover the whole supply chain

Horizontal communication:

- Communication with the DU associations.

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

In the past, the communication between the supplier and the end-user was often restricted to the supply of an SDS. The mandatory REACH communication requirements are completely new to end-users.

- The end-user will need to check whether his exposure scenario is described in the Annex of the SDS. Because of the diverse level of knowledge of the chemicals legislation and the specific terminology, it is important to keep the message short and clear, e.g. with standardised sentences
- The end-user has to implement the RMMs
- For uses advised against or uses not covered by the supplier's SDS, the end user has to identify the RMMs and have them applied by his workers (Article 37.4 and 37.5)
- An end-user may provide information to assist in the preparation of the SDS up the supply chain

The mandatory communication is new to all actors in the supply chain. But the potential new guidance is to address the preparation of an SDS and not the communication between the actors of the supply chain. Industry itself seems to be the best placed actor to organise the communication in the market.

3.4 Sources and flows of information needed for maintaining a REACH-compliant SDS up to date

The issue of maintaining an SDS can be divided into two processes:

- Inclusion of new information becoming available
- Communication of this new information upstream or downstream.

When new information becomes available, the process to get the information into the right section of the SDS is comparable to the process to create an SDS, with the difference that in most cases new information will only influence some sections of the SDS. The needs for guidance for those updating will be essentially the same as the needs of SDS creators (point 3.2). The potential new guidance on REACH-compliant SDS should cover this part of the maintenance of the SDS.

The other process concerns the communication of the updated or new information to the relevant users. This process is similar to the communication for creating an SDS (point 3.3) and is outside the scope of a potential guidance on the REACH-compliant SDS.

Case A: Manufacturer or importer of a substance (SDS creation)

An SDS has to be updated as soon as new information on hazards or information which may affect the RMMs becomes available, once an authorisation has been granted or refused or once a restriction has been imposed.

Sources of new hazard information are updates of legislation (such as the CLP Regulation on classification and labelling of substances and mixtures) and new measured or calculated data on physicochemical properties, toxicity or ecotoxicity. A change of the operational conditions may have an influence on the RMM's and information from DUs (e.g. a new use of the substance) will also trigger an update of the SDS. When an authorisation has been granted to a manufacturer or when there is a new provision on restrictions (Annex XVII), section 15 will have to be updated accordingly.

Case B: Importer of a mixture (SDS creation)

Changing composition of the mixture by the non-EEA formulator may influence the content of the SDS.

Case C: Industrial formulator (Downstream user, SDS creation)

Information on new uses, new industrial processes, change of operational conditions etc. may have an influence on the RMMs and must be communicated upstream to the manufacturer in order to update the SDS. As a consequence the DU will also have to update his SDS.

Case D: Industrial/professional end user (no SDS creation, but communication along the supply chain)

Change in personal protection equipment must be applied by the end-user. The end-user has to be informed effectively by means of an updated SDS.

3.5 Experiences with the supply chain communication (four generic cases)

Guidance is in particular requested on how to communicate in the supply chain. A specific focus should be on formulators without own manufacture of substances because they depend a lot on good communication. In this chapter we will highlight that existing experiences with communication indicate a lot of difficulties.

Case A: Manufacturer or importer of a substance (SDS creation)

An increasing number of manufacturers provide SDSs electronically, which makes the distribution of updates a lot easier than with a paper version.

Manufacturers are very busy trying to implement REACH in their company for all their substances; they prefer not to have to deal with questionnaires in multiple formats. Manufacturers have normally already pre-registered and are now collecting information on exposure routes (uses). Too often manufacturers try to find the information in-house without consulting the DUs. Manufacturers want to first compile the dossier and the REACH-compliant SDS and only then send the SDS to the DU for verification. Remarks from the DU may therefore reach the manufacturer after the registration deadline.

Guidance on how to communicate in a time-saving way on these aspects is outside the scope of a potential SDS guidance from ECHA (see also chapter 3.3).

Case B: Importer of a mixture (SDS creation)

Experience shows that it is often difficult for an importer to get enough information on the composition of the mixture from the non EEA-supplier. Guidance is needed on how to convince companies exporting to the EEA and non EEA-suppliers (including the manufacturers at the top of the supply chain) to provide the information that is necessary for a REACH-compliant SDS. Attention should be paid to explaining the advantages of good communication. This communication on data gathering should not be part of a guidance document on the creation of an SDS. It is up to industry to clarify REACH to the companies exporting to the EU and to convince them that the information they provide will not be misused.

In the past the communication downstream was restricted to the supply of an SDS. Importers will need guidance on how to extend the scope of communication and on how to communicate in an efficient way (see also chapter 3.3.)

Case C: Industrial formulator (Downstream user, SDS creation)

It is not an EU legal requirement that an unchanged SDS should be updated. The obligation to update an SDS is triggered by changes. Major changes such as a change of classification demand an update without delay (see point 3.1).

Often the DU has to ask for a new SDS to replace an outdated one.

It is up to the DU to clearly communicate about specific items such as the importance of ensuring that the uses become identified uses.

DUs are anxious to receive information from their suppliers because they want to be sure they can continue to buy their products in the future.

DUs are also concerned about the RMMs proposed in the SDSs from the suppliers. If the RMMs are not realistic, the DU may not have enough time to give feedback to the manufacturer before the registration deadline, taking into account that a supply chain can consist of many actors. Communication in the supply chain is very diverse and it involves people with different levels of knowledge of the legislation and the technical terminology and with different levels of practical experience with chemical products. Therefore concrete guidance on communication is very important to make it work throughout the whole supply chain. The supply chain can be very long and communication can only be effective when every actor knows his rights and his obligations and how to fulfil them.

Case D: Industrial/professional end-user (no SDS creation, but communication along the supply chain)

The experience is that a lot of efforts are made by organisations representing SMEs, to make professional users aware of the possible impact of REACH, including the communication requirements. Frequently it is assumed that REACH is only for manufacturers.

4 Comparison of former and REACH-compliant SDS

4.1 Similarities

Although there is guidance on the preparation of an SDS in Annex 4 of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) of the United Nations, the GHS document has no formal legal status in the EU. Most of the provisions of GHS are being implemented into EU legislation via the CLP Regulation. However, recital 40 of CLP explicitly states that *“Since the provisions on safety data sheets are included in Regulation (EC) No 1907/2006 which uses the safety data sheet as the main communication tool within the supply chain of substances, it is appropriate not to duplicate the same provisions in this Regulation.”* In practice therefore, the mechanism that will be used to further align REACH requirements for SDSs with those of GHS is via an amendment to Annex II of REACH.

The lay-out of the former SDS and the REACH-compliant SDS are very similar: both contain the same 16 headings. The fact that the 16 headings were set as a worldwide standard, is an indication of the strength of the former SDS Directive (Directive 91/155/EEC).

The content of the REACH-compliant SDS is similar to the content of the former SDS, but it is extended with additional information. The most important extra information will come from the CSR. Moreover, lots of information that was not available for the former SDS, will become available in the CSR. As a consequence the REACH-compliant SDS will contain less empty fields, so the quality of the SDS as an instrument of communication will be enhanced.

The main requirements, concerning who needs to prepare an SDS and to whom and when it is supplied do not change. Basically, the SDS-requirements are extended to PBT/vPvB substances and substances on the candidate list (substances on their own or in mixtures).

4.2 Main differences and their consequences

The improvements of the REACH requirements in comparison with the former status mainly arise from additional data sources and new ways to communicate. Consequently the gathering of information and the required data sources define major differences between the former situation and the situation under REACH.

New data sources will be available under REACH. The appropriate use of these sources defines a need for guidance. The compilation of a REACH-compliant SDS is quite challenging, especially for the formulators of mixtures with multiple ingredients.

Guidance is needed to lead formulators through the process of selecting relevant information on the relevant ingredients.

It must be explained what is meant by ‘appropriate information’ (e.g. RMMs, toxicology and ecotoxicology, waste management measures) and by relevant ingredients’ (e.g. classified as dangerous, PBT/vPvB, substances triggering the classification of the mixture).

An overview of the differences in information requirements for the REACH-compliant SDS compared to the former SDS is given in Table 2.

SECTION	TITLE	REACH-compliant SDS: required additional information	Former SDS
1.1	Identification	Name and registration number as provided in the technical dossier	Name as provided on the label
1.2	Use	Identified uses included in the CSR that are relevant to the recipient of the SDS	Uses as far as they are known
1.3	Identification of the company	The e-mail address of a competent person responsible for the SDS	Address
1.4	Emergency phone	Specify the hours of reachability (office hours, 24/24,)	Phone number
2.	Hazard identification	Classifiable and other hazards e.g. cross-sensitisation, high potency for odour or taste, ozone depletion, photochemical ozone depletion potential.	Classifiable hazards
		CLP classification	DSD/DPD classification
3.	Composition	Registration number	-
		≥ 0.1% PBT, vPvB	-
		Substance is on the candidate list	-
		DSD and CLP classification	DSD classification
		Indicate reason for being mentioned in this section	-
8.1	Exposure limit values	OELs DNELs and PNECs	OELs -
8.2.	Exposure controls	List of the RMMs for the identified uses; measures related to man (including consumers) and the environment	Protection and prevention measures i.e. safety measures
8.2.1	Occupational exposure controls	In order of priority (general measures personal equipment)	Exposure controls
11	Toxicological information	Summaries of the information on toxicological properties, including comparison with classification criteria on CMR cat 1 and 2	Description of the toxicological effects
12.1	Ecotoxicity	Summaries of the information on ecotoxicity	Description of the ecotoxicological effects

SECTION	TITLE	REACH-compliant SDS: required additional information	Former SDS
12.5	Results of PBT/ vPvB assessment	For substances $\geq 0.1\%$	-
12.6	Other adverse effects	Information on the endocrine disrupting potential	-
13	Disposal considerations	Waste management measures	Safety measures
15	Regulatory information	Indicate whether a CSA has been carried out for the substance or a substance in a mixture	-
		Labelling according to the CLP regulation	According to DSD or DPD
		Authorisation and restriction provisions	Restriction according to Directive 76/769/EEC
16	Other information	Uses advised against	-
ANNEX		Exposure scenarios	-
GENERAL		Classification and labelling must be consistent with - Annexes 1 and 6 of the DSD - Annexes I and VI of the CLP Regulation 1272/2008 - the DPD ⁷ - the classification and labelling inventory	C&L must be consistent with - Annexes 1 and 6 of Directive 67/548/EEC, - the Preparations Directive 1999/45/EC -
		Information in the REACH-compliant SDS must be consistent with the information in the technical dossier and the CSR	-
		Updates must be made when there is - information with influence on RMMs - new information on hazards - a new or changed provision about authorisation or restriction	-
		Changes in the revision should be brought to the attention of the recipient and identified as 'Revision: (date)'	Changes in the revision should be brought to the attention of the recipient

Table 2: differences in information requirements for the REACH-compliant SDS compared to the former SDS

⁷ Both the DSD 67/548/EEC and DPD 1999/45/EC will be repealed on 1 June 2015

In general there will be more emphasis on the intrinsic hazardous properties. The accessibility for the consumer of information on ingredients in mixtures and on their hazardous properties will be enhanced.

The former SDS contained safety measures, the REACH-compliant SDS gives information on RMMs. They are a crucial item in the REACH-compliant SDS. They should be carefully and clearly described in order to give recommendations to the user of the chemical on how to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and of all the environmental compartments. REACH covers the whole life cycle, so the RMMs should also include waste management measures to avoid exposure of man and of the environment during waste disposal or recycling.

4.3 Conclusions

- The former SDS is a solid basis to start from when compiling a REACH-compliant SDS. It is clear from the conclusions of Chapter 3 that additional guidance is requested and would be appreciated by concerned actors.
- The major additions that deal with safety are the ES (Annex), the exposure controls (section 8), PBT assessment (section 12.3), the waste management measures (section 13), the CLP driven labelling (section 15) and the uses advised against (section 16). Also the inclusion of a registration number was addressed as a new element. It became clear from interviews that these additions are not easy to implement correctly and define major challenges for the creation of an SDS. Problems are in particular expected for formulators that do not manufacture the substances themselves.
- To realise the creation of high standard SDSs as the most important communication tool in the supply chain related to chemicals, clear guidance seems to be essential for most actors. However, the need for guidance is in particular addressed for exposure scenarios where uncertainty of SDS creators on how to proceed is high.
- Guidance is in particular important for formulators. Formulators will receive SDSs on every dangerous ingredient of the mixtures they formulate. The number of ingredients may be very high. The relevant information will have to be selected and transferred to the SDS of the mixture. How to do this in an effective way that still results in an SDS of high quality is one of the major concerns of the formulators.
- Examples of REACH-compliant SDSs and standardisation/translation of phrases (e.g. on RMMs) would be very useful and would enhance the readability of the technical content of the SDS.
- Currently guidance related to the creation of extended SDS is already available in Annex II and in a number of ECHA documents (e.g. Guidance on CSA, Part G; Downstream User

Guidance). As a first step the existing ECHA guidance documents should be made more accessible (via ECHA's website) as soon as possible.

- An overall guidance fact sheet would be welcomed. It should be short and comprehensive and lead the different target groups to the chapter in the available ECHA guidance documents. It should be available in all MS languages.
- Intensive communication is a main challenge of REACH and is new to most actors in the supply chain. But the potential new guidance is to address the preparation of a REACH-compliant SDS and not the organisation of the communication in the supply chain.
- The issue of confidentiality (e.g. composition of mixture) was well covered and clearly explained in the former SDS legislation; it is integrally transferred to Annex II. No extra guidance is needed.

5 Preceding documentation (EU and MS)

5.1 Overview of available guidance

This chapter presents a (non-exhaustive) list of guidance documents available for former SDSs provided by national authorities and international organisations.

Austria

“A Guide to Compiling Safety Data Sheets” (Austrian SDS guidance document, 2002)

This guidance was translated and adopted for Bulgaria, Poland and Slovakia

http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/chemikalien/SDS_Guidance_2002.pdf

Denmark

“Leverandørbrugsanvisning (sikkerhedsdatablad) og teknisk datablad for stoffer og materialer”

<http://www.at.dk/sw8871.asp>

The Danish Working Environment Authority’s guideline about SDSs in Danish includes lots of examples (May 2003). An updated version of the guidance is in progress and will elaborate on SDSs.

France

La fiche de données de sécurité

[http://www.inrs.fr/inrs-pub/inrs01.nsf/intranetobject-accesparreference/ed%20954/\\$file/ed954.pdf](http://www.inrs.fr/inrs-pub/inrs01.nsf/intranetobject-accesparreference/ed%20954/$file/ed954.pdf)

Fiches de sécurité

http://www.ac-nancy-metz.fr/enseign/physique/chim/sc_fds.htm

Recherche de fiches de données de sécurité sur Internet

<http://www.uvmt.org/Toxicologie/FDS/FDS.htm>

Recherche de FDS en France

<http://www3.3m.com/search/fr/fr001/msdssearchform.do>

Germany

TRGS 220 “Sicherheitsdatenblatt”

Technical Guidance with legal binding character. It includes German specific requirements with respect to the creation and content of the SDSs.

“The Quality of Safety Data Sheets”

Report on the assessment of the member companies’ Safety Data Sheets 2004

“Standard phrases for establishing safety data sheets”

Federation of German Industry (BDI) - standard phrases catalogue: Contains standard phrases for the preparation of SDSs. Available in the updated version (see chapter 6).

“Leitfaden Sicherheitsdatenblatt“

This guidance document on SDSs, prepared by the German chemical industry association (VCI), is available in the updated version (see chapter 6).

Sweden

“The art of reading safety data sheets” - Checklist for the assessment of SDSs

http://www.plastkemiforetagen.se/Publikationer/PDF/Checklista_eng_bed_090115.pdf

A guide to assess the quality of SDSs for chemical products, produced by the Swedish Plastics and Chemicals Federation.

The checklist is intended to be an aid for those who use chemical products in order to make sure that the SDS contains all information they need, or see if there is a need to contact the supplier and ask for more information.

UK

“The compilation of safety data sheets (Approved code of practice)”

This HSE Approved Code of Practice forms part of the CHIP regulations. UK, the Chemical Industries Association (CIA) <http://www.hsebooks.co.uk>

“Why do I need a safety data sheet?”

<http://www.hse.gov.uk/pubns/indg353.pdf>

International

UNECE GHS – Annex 4: “Guidance on the preparation of safety data sheets (SDS)”

UN Economic and social council (2008)

http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/English/08e_annex4.pdf

It contains requirements of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

“Material Safety Data Sheet User's Guide”

<http://www.reptox.csst.qc.ca/documents/simdut/GuideAng/pdf/DC200-338-4A%20materiel%20saf.pdf>

Commission de la santé et de la sécurité du travail du Québec (2002)

Manuals on labelling with a chapter dealing with SDSs:

Guidance document on labelling and SDSs:

“Chemical products, Basic Guide on Labelling and Safety Data Sheets” provided by Junta de Andalucia (Spain, 2002), author: Ms. María Tarancón Estrada

Manual on CLP:

“Training Program on Classification, Labelling and Packaging of Chemicals” (2001)

Baltic States guidance document from BACCON (Baltic States Regional Projects on Chemicals Control) for BEF (Riga), EMI-ECO (Tallinn), LPPC (Riga) and APINI (Kaunas)

Moreover, SDSs for some substances/mixtures are available on internet. For some small companies this is seen as kind of guidance.

5.2 Common elements in the existing approaches

Only general (no sector specific) guidance is known on former SDSs from all kinds of organizations and administrations (local, national, health and environmental authorities....).

All these documents help to enhance knowledge about SDSs for people that will not read or consult regulations, but instead will search for information at their local administration, or in their companies association, etc

Guidance produced by Member State regulators can have the benefit of establishing a framework and broad principles of interpretation of the requirements of the legislation, which help guide and inform the industry initiatives. It also sets out the expectations, from a regulator’s perspective, of the sort of information that might be included in an SDS. It often includes information concerning national legal acts from related regulations (for example waste, environmental protection).

General guidance documents on SDSs after a short introduction explain the required content chapter by chapter; give some examples and other useful additional tools such as websites, databases, further information on correct classification and labelling. They nevertheless remain short and therefore are ideal for companies which have to compile SDS or have to use them but they are of minor help for explaining the supply chain.

The manuals for classification and labelling known to us have a chapter about SDSs. Here the target group is companies with a very low level of knowledge about chemicals legislation. They give only an overview about the required contents and use of SDSs.

As these documents rely almost completely on the officially published legislation their contribution to clarification is minor.

5.3 Differences in existing approaches

General guidance documents are mainly targeted at the editor of an SDS.

Manuals on labelling with a chapter dealing with SDSs are for the use of downstream users who are at a very low level of knowledge on the legal provisions.

GHS provisions are only included in the official UN GHS-Annex 4 document “Guidance on the preparation of safety data sheets (SDS)”.

The checklist for the assessment of SDSs “The art of reading safety data sheets” follows another approach - namely to check the SDS from a supplier perspective and hence is aimed at downstream users.

5.4 Existing experiences and acceptance

All SDS guidance documents are accepted by their respective target group. National guidance has the advantage of being written in the national language and may have national legal provisions included.

A guidance document should be written in common language, provide examples and not exceed a certain length. If this is not the case acceptance is limited.

Existing guidance often does not use a common language and often merely repeats the legal text. It does not explain how and where to include required data. Hence, for a “beginner” there are often too many open questions remaining, e.g. where to find necessary information or in the case of a mixture how to deal with missing information or how to consolidate available information from suppliers (RMMs, concentration ranges instead of exact percentages).

5.5 Conclusions

In general it can be stated that sufficient guidance is available for the former SDSs. However, for many companies it was not easy to follow this guidance. This may have contributed to the poor quality of SDSs often observed.

Some of the existing guidance can be taken as an input for best practice for drafting future guidance, for example:

“Material Safety Data Sheet User's Guide”, Québec:

This guide is easy to follow and contains pictures, tables, glossary etc. and therefore is judged to be very user friendly, particularly since it also includes training elements.

UN GHS – Annex 4: “Guidance on the preparation of safety data sheets (SDS)”:

This document not only gives information on requirements but also advises which data should be used and how they are supposed to be recorded. See following excerpt:

“The data included in this subsection should apply to the substance or mixture as used. The toxicological data should describe the mixture. If that information is not available, the classification under GHS and the toxicological properties of the hazardous ingredients should be provided.”

6 REACH-compliant standards and guidance (EU and MS)

6.1 Existing ECHA Guidance Documents

Currently the following guidance documents related to REACH-compliant SDSs are available from ECHA:

- Guidance on information requirements and chemical safety assessment. Part G: Extending the SDS (May 2008, v 1.1)
- Guidance for downstream users (January 2008)

While Annex II of the REACH regulation and the Guidance on Information Requirements is known by most authorities and associations the Guidance for downstream users is often not associated with SDSs.

6.2 Overview on further available guidance

In the following an overview on guidance already available on REACH-compliant SDSs is provided.

General available guidance:

- „Leitfaden Sicherheitsdatenblatt“
<http://www.vci.de/default~cmd~shd~docnr~115596~lastDokNr~1.htm>
Guidance document on SDS prepared by the German chemical industry association (VCI), April 2008)
- „Das erweiterte Sicherheitsdatenblatt aus Sicht der Anwender“
<http://www.lubw.baden-wuerttemberg.de/servlet/is/48132/>
This PowerPoint presentation by RheinChemie gives an introduction to the information flow within SDSs and ES.
- “Safety Data Sheet according to Regulation (EC) No 1907/2006 (REACH)”
http://REACH.bdi.info/GHS_SDB_Leerformular_SDS_Substance_and_Preparation_EN_10022009.pdf
A standard format for the structure of an SDS with very good remarks and additional information required for the extended SDS also including GHS elements, prepared by the Federation of German Industry (BDI), January 2009)
- “Standard phrases for establishing safety data sheets”
<http://REACH.bdi.info/378.htm>

Federation of German Industry (BDI) - standard phrases catalogue, version 10.1, January 2009

- “Checkliste für Sicherheitsdatenblätter gemäß EG 1907/2006”
http://www.gisbau.de/service/SDB/check/SDB-Check-Liste_Version_11_2003.pdf
Mainly prepared for recipient of SDS to check the completeness of a received SDS but could also be used by creators of SDS to check if all requirements have been fulfilled. In most cases only a formal quality check is possible.
- Commented template SDS
http://www.bdi-online.de/Dokumente/Umweltpolitik/2007_08_23_Leerformular_SDB_Stoff_und_Zubereitung_EN_mit_Kommentaren.pdf
This template for a REACH-compliant SDS contains comments to each topic addressed by the SDS. In addition Germany specific requirements are addressed.
- Työterveyslaitos: Alustavien altistumiskenaarioitten kehittäminen metanolille. Loppuraportti. Työterveyslaitos, Helsinki 2008. 110 p. (In Finnish. An English summary included.)
- “The art of making safety data sheets“ - Checklist for the compilation of SDSs
http://www.plastkemiforetagen.se/Publikationer/PDF/Checklista_eng_090115.pdf
A guide to better SDSs for chemical products, produced by the Swedish Plastics and Chemicals Federation
This checklist is intended to be a guide and aid for those who compile SDSs for chemical products but it does not give advice with regards to extended SDS.
- “Safety Data Sheets for products placed on the Swedish market”
<http://www.kemi.se/upload/Trycksaker/Pdf/Faktablad/FbSafetyDataSheetsSept07.pdf>
Factsheet prepared by the Swedish Chemicals Agency (KEMI), September 2007. Very short leaflet with REACH requirements but not mentioning the REACH-compliant SDS.
- The Federation of Norwegian Industries has prepared interactive courses in English supported by the Norwegian State Pollution Control Authority (SFT) and in cooperation with the Swedish and Danish industry. (The Slovenian industry is preparing a translation for Slovenia.)
<http://www.trainingportal.no/content/view/352/185/lang,en/>
There is an introduction course and three in depth courses (communication in the supply chain, registration and GHS).
You need an access to the web-based courses. For every course also a text book is available.
Contact person: Cecilie R- F Skarning, Federation of Norwegian Industries, phone: +47 23 08 88 12

Guidelines under development:

- The general guidance from the Danish Working Environment Authority when it is updated will include REACH-compliant SDS.
- There is an ongoing Danish project on an exposure scenario modifier tool focusing on all formulating industry sectors and their customers. It is an IT-tool especially for formulating DU companies and small trading companies importing from outside the EU.
- DUCC, the Downstream Users of Chemicals Co-ordination group, has drafted a document for formulators aiming to interpret legislative deadlines. It will give advice how to handle and consolidate information from different suppliers. CLP related changes will be taken into account as well.
- CEMBUREAU (the European Cement Association) is revising an existing guidance document “GUIDELINES FOR THE SAFETY DATA SHEET FOR CEMENT” in order to adapt it to the CLP and REACH requirements. Cement is a mixture and components may require ES but at the moment no ES will be included to the document, they will be added as they become available.
- CEFIC activities:
 - 1)VCI/BAuA/CEFIC: Library of occupational RMMs: The existing BDI catalogue of risk management phrases was developed further in a collaborative process. The standard phrases are in English and German and the catalogue will be maintained over time. No further translation is planned. It is available already: <http://REACH.bdi.info/378.htm> Version 10.1 includes already the RMM library (prepared by CEFIC) and the sector specific phrases coming from the work of the solvent sector (ESIG/ESVOC) on developing Generic Exposure Scenarios. Input from other sectors is asked for via BusinessEurope.
 - 2)CEFIC: Standard letters and templates for communication in the supply chain (<http://www.cefic.org/Templates/shwStory.asp?NID=494&HID=714&PHID=720&PPHID=494>):
 - a. Holding letter: Statement for suppliers and customers to inform about preferred approach and avoid premature communication on uses in the supply chain (on website).
 - b. Specific Exposure Scenarios (SES): Dialogue Template for SES building and explanatory cover letter (will be on the CEFIC website by the beginning of March 2009).

- 3)VCI/Ökoinstitut/CEFIC: Practical guidance document on “chemical safety assessment for dummies” with practical examples in English and German language (planned to be published mid March 2009).
- 4)VCI/Ökoinstitut/Deutscher Lackverband/CEFIC: A guidance document on extended SDS is ready for substances and will be extended to mixtures. It will also cover the update of recommendations concerning the SDS based on experiences and results from the ECHA initiative on developing a CSA/CSR Tool. The publication in English and German language will probably be at the beginning of 2010.
- 5)VCI/sector groups/CEFIC: Further developing of guidance on the so called “DPD+” method. This is an approach on how to identify those components in a mixture that will drive the risk management for the whole mixture. The method is based on the existing classification rules for dangerous mixtures. The outcome will partly be incorporated into the guidance document described under point 4.

Regarding Exposure Scenarios, there seem to be some initiatives going on in different sector groups. However, there are some fundamentals (e.g. the format of the ES) that probably need resolution before this work can be continued.

6.3 Existing experiences and acceptance

The identified guidance documents have very different approaches. They vary from general guidance documents, standard forms, commented templates, standard phrases to a checklist. Not all documents could be assessed to date.

It is too early to judge the quality and acceptance of these very new documents. In general big companies which are familiar with REACH tend to be happy with existing guidance. Authorities from countries with a lot of SMEs (rather than manufacturing industry or multinational groups) and SMEs themselves ask for additional guidance although they are not aware what guidance is available already. There is a barrier to consulting the ECHA guidelines because of their sheer volume.

6.4 Strengths and limitations

Available ECHA guidance is quite detailed and well-structured but very technical. Moreover the documents lack practical instructions for the compilation and maintenance of a REACH-compliant SDS. In particular the following problems are defined:

- Under which section is a topic best placed?

- What is a legal requirement and what is a “good to have”?
- What is a significant change? -> timing for SDS update
- Consolidation of SDS and ES from different suppliers: format (ES) and content (SDS and ES) can be critical
- How to react on different information from DUs (e.g. varying risk reduction measures)?
- Other guidance documents often do not contain enough information with regard to REACH-compliant SDSs.
- How to react in the transitional period where some of the necessary information is not available yet?

Various industry organisations provide continuing support. The following useful tools can especially be mentioned in this regard:

1. The “Leitfaden Sicherheitsdatenblatt” prepared by the VCI is an exhaustive guidance and contains recommendations, references, practical advice and a glossary. Nevertheless it is very clearly structured and easy understandable. However it is available only in the German language.
2. The BDI standards are also very much appreciated. CEFIC is trying to complement them with as many sector specific elements as possible.
3. The interactive course on communication in the supply chain prepared by the Federation of Norwegian Industries seems to be a very educational way of explaining the new REACH requirements.

6.5 Conclusions

Currently the available ECHA guidance is ‘hidden’ within other guidance documents that are not always read by non-target groups e.g. it is not obvious that a manufacturer should read the TGD for DUs, which includes a chapter on the REACH-compliant SDS.

Hence the need for a standalone overall short guidance is expressed by all stakeholders. This “umbrella” guidance should be short and comprehensive and lead the different target groups to the relevant chapters in the already available ECHA guidance documents. It should be available in all official EU languages. Clear instructions and examples will contribute to better understanding and acceptance.

The ongoing initiatives by CEFIC and some sector organisations will complement the range of supporting instruments with very useful practical tools.

7 Summary of the expert workshop

7.1 Purpose and organisation of the workshop

ECHA arranged a workshop on 18 February 2009 in Helsinki to exchange views with experts on the need for additional guidance related to (extended) Safety Data Sheets. First results of this scoping study served as a basis for discussion.

The agenda for the workshop and the list of invited experts and participants are attached as Annex 1 and 2.

Discussions during the workshop took place in small break out groups. Questions and materials were prepared and are attached in Annex 3.

7.2 Summary of the results of the workshop

The key messages and conclusions of the workshop have been summarized as follows:

1. The overall target is to enable persons creating SDSs under REACH to implement the requirements of Annex II in such a way that correct, complete and useful information (= good quality information) is made available to the industrial and professional users of dangerous substances as such or in mixtures. Guidance is essential in this respect because the legal text as it stands does not contain sufficient practical advice and as such will not lead to harmonised implementation.
2. At the same time, guidance cannot compensate for missing qualification and competence of SDS creators. Thus, training of industry staff and awareness raising of managers on the need to make sufficient resources available are essential elements to complement technical guidance.
3. Guidance by ECHA is needed where harmonisation and acceptance across sectors, supply chains and member states is to be achieved. In this respect ECHA has suitable structures in place to involve stakeholders in developing and agreeing on guidance. However guidance provided by ECHA cannot replace sector specific guidance and training that trade and industry organisations should provide to their membership
4. Three particular priority areas requiring additional guidance and where ECHA is best placed to provide such guidance were identified:
 - a. Relationship between exposure scenarios developed in the CSA process (and to be Annexed to the SDSs) and risk management information in the sections 7, 8 and 13 of the extended SDS. While the content and structure of the exposure scenarios is to

- be dealt with in other guidance and the CSA Tool, there is a need to better define the risk management information in the main body of the SDS.
- b. Workflow and methods at formulator's level to convert the incoming risk management information on the individual components into outgoing risk management information for the mixtures. This should include guidance on how to deal with mixtures processed into further mixtures.
 - c. An easy to understand overview of upcoming deadlines and timelines for revision of SDSs with regard to REACH and the CLP regulation; the transitional periods for cases where some of the necessary information is not yet available should be highlighted.
5. The following items were identified as being out of scope, or not a priority for being addressed in an SDS guidance produced by ECHA:
- a. Guidance for industrial/professional end-users of chemicals on how to read an SDS and on how to fulfil the corresponding downstream user duties under REACH (reason: Generic ECHA guidance already exists in the *Downstream User Guidance*; further guidance needs to be written in sector or branch specific language).
 - b. Guidance on communication on identified uses and conditions of use up and down the supply chain (Reason: The guidance is to address the preparation of SDS. The SDS is a vehicle for transmitting information but not an instrument to generate the information. Also the market actors are better placed to organise the communication in the market than ECHA).
 - c. Guidance on exposure scenario development (reason: Guidance exists already and will be further developed in a separate documentation).
 - d. Specific guidance for importers of substances and mixtures, re-fillers or distributors (reason: all these actors have their particular challenges and roles, but these do not affect the creation of SDSs as such).
6. The European Commission has started to revise Annex II in order to bring it as close as possible to the GHS guidance on the preparation of SDSs (GHS Annex 4). It is planned to publish the revised Annex II of REACH by the end of the year. It is expected that several uncertainties and problems related to SDS creation will be solved with this revision. Any guidance development related to SDS needs to be closely coordinated with the revision of Annex II.
7. Currently guidance related to the creation of extended SDSs is already available in a number of ECHA documents (e.g. Guidance on CSA, Part G; Downstream User Guidance). During the workshop a need for an overall guidance was expressed. This "umbrella" guidance should be short and comprehensive and lead the different target groups to the chapter in the available ECHA guidance documents. It should be available in all MS languages.

8. As a first step the existing ECHA guidance documents should be made more accessible (via ECHA's website) as soon as possible.
9. It would be useful if future guidance were to contain examples and a commented REACH-compliant SDS template to explain and illustrate what good extended SDS should look like and what information belongs where. It would be desirable to publish the guidance as one block and with a stable content (no frequent revisions).
10. CEFIC informed about various activities organised within industry. It was felt at the meeting that some sort of coordination between these activities and ECHA guidance development would be useful. This concerns for example:
 - a. CEFIC will publish on its website the BDI catalogue of risk management phrases developed in a collaborative process within the German industry. The standard phrases are in English and German and the catalogue will be maintained over time. No further translation is planned.
 - b. CEFIC will start a project on writing harmonised industry guidance on SDS elaboration under REACH, involving the major sector organisations having worked on that so far, including AISE and CEPE.
 - c. In 2009, CEFIC and VCI will run a project on further developing and testing guidance on the so called "DPD+" method. This is an approach on how to identify those components in a mixture that will drive the risk management for the whole mixture. The method is based on the existing classification rules for dangerous mixtures.

8 Conclusions on the need for additional guidance

The results of the scoping study and the outcome of the workshop lead to the following conclusions:

The former SDSs had some shortcomings and the new REACH-compliant SDSs will also face problems. However, the current and future difficulties can be reduced by appropriate means. Guidance is essential in this respect because the legal text as it stands does not contain sufficient practical advice and as such will not lead to harmonised and targeted implementation. Nevertheless, even with appropriate guidance some quality problems will remain as guidance cannot compensate for missing qualification and competence of SDS creators. Thus, training of industry staff and awareness raising of managers on the need to make sufficient resources available are essential elements to complement technical guidance. Three particular priority areas were identified requiring additional guidance and where ECHA is best placed to provide such guidance:

- a. Interface between exposure scenarios developed in the CSA process (and to be annexed to the SDSs) and risk management information in sections 7, 8 and 13 of the extended SDS. While the content and structure of the exposure scenarios is to be dealt with in other guidance and the CSA Tool, there is a need to better define the risk management information in the main body of the SDS.
- b. Workflow and methods at formulator's level to convert the incoming risk management information on the individual components into outgoing risk management information for the mixtures. This should include guidance on how to deal with mixtures processed into further mixtures.
- c. An easy to understand overview of upcoming deadlines and timelines for revision of SDSs with regard to REACH and the CLP regulation; the transitional periods for cases where some of the necessary information is not yet available should be highlighted.

For the following issues guidance is required, but it is not recommended that ECHA provides this guidance:

- a. Guidance for industrial/professional end-users of chemicals on how to read an SDS and on how to fulfil the corresponding downstream user duties under REACH (reason: Generic ECHA guidance already exists in the Downstream User Guidance; further guidance needs to be written in sector or branch specific language).
- b. Guidance on communication on identified uses and conditions of use up and down the supply chain (Reason: Industrial actors are better placed to organise the communication in the market than ECHA; The interactive course on communication in the supply chain prepared by the Federation of Norwegian Industries provides practical training and exercises).

For the following issues guidance is requested, but it is already available in existing documents:

- a. Currently guidance related to the creation of extended SDSs is already available in a number of ECHA documents (e.g. Guidance on CSA, Part G; Downstream User Guidance).
- b. CEFIC is compiling standardised phrases (e.g. on RMMs) from various sectors. It will be useful to enhance the readability of the technical content of the SDSs and fulfil corresponding requirements of companies. The issue of confidentiality (e.g. composition of mixture) was well covered and clearly explained in the former SDS legislation; it is integrally transferred to Annex II. No extra guidance is needed.

9 References

1. Corrigendum to 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 (OJ L136, 29.5.2007, p. 3)
2. Commission Directive 2001/58/EC of 27 July 2001 amending for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous mixtures in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets) EC (OJ L212, 7.8.2001, p. 24)
3. Technical guidance Documents on the different processes and methods under REACH at http://guidance.echa.europa.eu/guidance_en.htm
4. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L353, 31.12.2008, p. 1)

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