MILJÖRIKTIG ANVÄNDNING AV ASKOR 1127

Methodology for qualification of wood-based ash according to REACH - prestudy

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värmeforsk

Methodology for qualification of wood-based ash according to REACH - prestudy

Förenklad metodik för kvalificering av aska enligt REACH, förstudie

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Februari 2010
ISSN 1653-1248

Abstract

The new European Union Framework directive on waste will imply that much of what today is regarded as waste will be identified as by-products from the year 2010. Ash from combustion and incineration may then fall under the new European Union regulations REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (Classification, labelling and packaging of substances and mixtures).

The literature on REACH and CLP has been reviewed in order to identify the most efficient alternatives for their implementation. It is recommended that the present methods for classification of waste and for health and environmental impact assessments be supplemented and used also for this purpose.

Sammanfattning

Det nya ramdirektivet för avfall ska implementeras under år 2010. Enligt direktivet kommer mycket av det som i dag betraktas som avfall att i stället betraktas som biprodukt och i därmed ofta falla under den nya EU-förordningen REACH (registrering, utvärdering, godkännande och begränsning av kemikalier). REACH tillämpas tillsammans med CLP (klassificering, märkning och förpackning av ämnen och blandningar).

Övergången till de nya reglerna sker successivt, och för CLP:s del handlar det om övergång från direktiven DSD och DPD, d v s ämnesdirektivet och preparatdirektivet. På liknande sätt kommer det nya avfallsdirektivet att successivt gälla framför det tidigare avfallsdirektivet och en del andra stadganden.

Det finns ett samband mellan avfallsdirektivens regler och reglerna för klassificering och märkning genom att klassningen av avfall (i kategorierna farligt respektive icke farligt avfall) bygger på (men är inte identisk med) reglerna för märkning. På liknande sätt anknyter de svenska reglerna för acceptans för användning av återvunnet material (avfall) i geotekniska konstruktioner till reglerna i REACH beträffande värdering av kemiska risker genom att båda kräver att riskerna ska vara ringa samt att samma eller liknande metodik kan användas för att verifiera detta.

Det finns ett slags ”referensalternativ” i REACH som innebär att omfattande testning måste utföras för att man ska kunna registrera en substans. Registrering är nyckeln till användning av en substans oberoende av om den används som sådan, ingående i en blandning eller med syfte att avges från en vara. REACH, liksom CLP, innehåller samtidigt omfattande möjligheter för användning av litteraturdata, data på liknande ämnen o s v för att undvika onödig provning. Detta gäller särskilt tester på människor och ryggradsdjur.

Värmeforsk har genom sitt askprogram utvecklat såväl metodik och vägledning för klassning av avfall som miljöriktlinjer för askanvändning i anläggningsbyggande. Syftet med föreliggande arbete är att analysera om dessa metoder är tillämpbara även under CLP och REACH, samt om de kan innebära ökad effektivitet jämfört med andra alternativ. Särskild tyngd ska läggas på frågan om de stora variationer som finns beträffande askors innehåll av potentiellt farliga komponenter.

Resultatet av arbetet förutses användas av företag som genererar aska, branschorganisationer, SIEF:s (forum för utbyte av information kring registrering), konsortia och myndigheter.

Resultaten av arbetet innefattar följande (se Avsnitt 8.2 för detaljer). REACH är inte bara en EU-förordning utan också ett förhandlingsprotokoll och ett jätteexperiment. Även om ECHA (Europeiska Kemikaliemyndigheten) har gett ut ett antal vägledningar så är det i ett antal fall fortfarande oklart vad som egentligen gäller. Den viktigaste

frågan är huruvida en aska måste betraktas såsom bestående av bara en substans, i vilket fall det kan bli nödvändigt att testa många askor. Testning på ryggradsdjur ska undvikas så långt som möjligt. Det konstateras att PPORD-alternativet (PPORD = produkt- och processorienterad forskning och utveckling) ger möjligheter till dels att redan planerade forsknings- och utvecklingsinsatser kan utföras, dels att man vinner tid för att det ska klarna vad som gäller ur myndighetssynpunkt. Andra alternativ, t ex UVCB, är lämpliga i de fall där redan utvecklade alternativ marknadsförs.

Ingen anledning har påträffats till varför Värmeforsks arbetssätt inte skulle kunna tillämpas även under REACH och CLP. I stället framstår de som mycket passande och effektiva.

Eftersom framställningen i rapporten bygger på det som presenteras efterhand har Avsnitt 3 lagts efter avsnitt 2. De läsare som önskar en tidig bild av strategi och syfte kan börja med avsnitt 3.

Sökord: REACH, CLP, aska, klassning, återvinning

Summary

The new European Union framework directive on waste is to be implemented during the year 2010. According to this directive, much of what today is regarded as waste will instead be assessed as by-products and in many cases fall under the new European union regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). REACH applies in conjunction with the new European Union regulation CLP (Classification, Labelling and Packaging of substances and mixtures).

There are introductory periods for both of these regulations, and in the case of CLP this regards transition from the present and previous rules under the dangerous substances and dangerous preparations directives (DSD and DPD, respectively). Similarly, the new framework directive on waste supersedes the previous directive and some other statements.

There is a connection between the directives of waste and the rules for classification and labelling in that the classification of waste (in the categories hazardous and non-hazardous) build on (but are not identical to) the rules for labelling. Similarly, the national Swedish rules for acceptance of recycled material (waste) for use in geotechnical constructions relate to the provisions in REACH on assessment of chemical safety in the both request that the risk be assessed to be small, and that the same or similar methodologies can be applied to verify this.

There is a "reference alternative" in REACH that implies substantial testing prior to registration. Registration is the key to use of a substance even though a substance may be used as such, in a mixture, or to be released from an article. However, REACH as well as CLP contain a number of provisions for using literature data, data on similar chemicals e t c in order to avoid unnecessary testing. This especially applies to testing on humans and vertebrate animals.

Värmeforsk, through its Programme on Environmentally Friendly Use of Non-Coal Ashes has developed methodologies and guidelines for classification of waste as well as for assessment of impact to environment and health of geotechnical constructions using ash. The purpose of the present work is to analyse if these methods are applicable also under CLP and REACH, and if they might lead to improved efficiency compared to other alternatives. Particular attention is to be paid to the fact that the content of potentially hazardous components in ash is highly variable.

The results of the work are intended to be used by ash generating facilities, branch organisations, SIEF's (SIEF = Substance Information Exchange Fora), consortia and authorities.

The results of the study include the following (see section 8.2 for details). REACH is not only a regulation but also a negotiation document and a giant experiment. Even though ECHA (European Chemicals Agency) has issued a number of guidelines, it is still unclear what is actually required in a number of cases. The most important issue is

that of whether or not ash must be regarded as consisting of just one substance, in which case many ashes might have to be tested. Testing on vertebrate animals is to be avoided as far as possible. It is concluded that the PPORD (Product and Process Orientated Research and Development) alternative would allow for already intended research and development work to take place as well as simultaneously allow time for the regulatory situation to resolve itself. Other alternatives, e g UVCB, are appropriate in cases where well developed applications are marketed.

No reason has been found why the above mentioned domestic methodologies could not be used under REACH and CLP. Instead, they are assessed to be highly suitable and efficient.

In order for subsequent material in this report to build on what has been presented earlier, Section 3 supersedes Section 2. Those readers wanting an early insight in strategy and purpose can start with Section 3.

Keywords: REACH, CLP, ash, classification, recycling

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1 Organisations, definitions and glossaries

1.1 Swedish organisations

English and Swedish names of organizations mentioned in the text can be found in Table 1.

Table 1. English and Swedish names of Swedish organizations mentioned in the text.

English name	Swedish name
The Swedish Chemicals Agency	Kemikalieinspektionen
The Swedish Environmental Protection Agency	Naturvårdsverket
Värmeforsk (The Swedish Thermal Engineering Research Institute)	Värmeforsk
The Swedish Programme on Environmentally Friendly Use of Non-Coal Ashes	Short and commonly used name: Askprogrammet Formal name: Miljöriktig användning av askor
Swedish Waste Management	Avfall Sverige Formerly: Svenska Renhållningsverksföreningen (RVF)
County Administrative Board	Länsstyrelse
Local (Municipal) Authorities	Kommunala myndigheter
SSAB Merox AB	SSAB Merox AB
SSAB	SSAB

1.2 Some terms used for classification and labelling

There are several differences in the nomenclature between on one hand the old rules for classification and labeling, DSD[I] and DPD[II], and on the other hand the new rules, CLP[III]. They are compared and explained in Table 2. See Also Section 6.

CLP = Classification, Labelling and Packaging of substances and mixtures
DSD = Dangerous Substances Directive
DPD = Dangerous Preparations Directive

Table 2. Nomenclature for the old (DSD and DPD) and new (CLP) rules for classification and labeling. The material is taken from Table 6.1 in Reference [1].

Terms Used	DSD / DPD	CLP
Mixture/s	Term not used in DPD; identical to definition of 'preparation' in DPD (DPD Article 2)	This term means the same as "preparation" under DPD; Definition: "A mixture or solution composed of two or more substances" (CLP Article 2(8)). The CLP definition of a mixture differs slightly from that of the UN GHS which may well be applied outside of the EU
Preparation/s	Definition: "Mixtures or solutions composed of two or more substances" (DPD Article 2)	Term not used in CLP; identical to definition of 'mixtures' in CLP
Hazardous	Term not used in DSD or DPD	A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in CLP Annex I, is hazardous (CLP Article 3)
Dangerous	Substances or mixtures fulfilling the criteria for the categories of danger set out in DSD, Article 2 (2)	Term not used in CLP; REACH and other Community acts will refer to explicit CLP classifications which reflect the previous scope of "dangerous"
Category of Danger	The nature of a hazard (danger) of a substance or preparation	Term not used in CLP; REACH and other Community acts will refer to explicit CLP classifications which reflect the previous scope of "dangerous"
Hazard class / hazard category (CLP)	Term not used in DSD / DPD	The nature / severity of a physical, health or environmental hazard (CLP Article 2(1) and 2(2))
Indication/s of danger	A short description of the hazard (danger) posed by a substance For example, 'Explosive' or 'Corrosive'	No equivalent under CLP

Danger Symbol	Pictorial presentation of the danger posed by dangerous substances and mixtures (Annex II to DSD)  For example, this symbol indicates an oxidising substance or preparation	Term not used with the same meaning in CLP; instead, "pictogram" is used. Equivalent but not always identical to the pictograms used under CLP  For example, this pictogram indicates an oxidising substance or mixture
	Many CLP pictograms are similar but not identical to the symbols relating to certain categories of danger under DSD and DPD	
Pictogram (See "Danger Symbol")	Term not used in DSD; instead, "danger symbol" is used. Equivalent but not always identical to the danger symbols used under DSD and DPD	A graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information on the hazard concerned (CLP Article 2(3))
Signal word	No equivalent in DSD or DPD	The words 'Danger' or 'Warning' are used to indicate the severity of the hazard (CLP Article 2(4))
Terms Used Risk phrase (R phrase)	DSD / DPD Indication of intrinsic hazards (DSD Article 23, as set out in Annex III to DSD) For example, R38: Irritating to the skin	CLP Term not used in CLP; instead, "hazard statement" is used. Equivalent but not always identical to the hazard statements under CLP For example, H315: Causes skin irritation
Hazard statement	Term not used in DSD / DPD; instead, "risk phrase" is used. Equivalent but not always identical to the risk phrases used under DSD (DSD Article 23, as set out in Annex III to DSD) For example, R38: Irritating to the skin	Hazard statements describe the nature of the hazards of a substance or mixture, including, where appropriate, the degree of hazard (CLP Article 2(5)) For example, H315: Causes skin irritation

Safety phrase (S phrase)	Phrases related to the safe use of the substance (DSD Article 23, as set out in Annex IV to DSD) For example, S2: Keep out of the reach of children	Term not used in CLP; instead, "precautionary statement" is used. Equivalent but not always identical to the precautionary statements used under CLP For example, P102: Keep out of reach of children
Precautionary statement	Term not used in DSD or DPD; instead, "safety phrase" is used. Equivalent but not always identical to the safety phrases under DSD (DSD Article 10) For example, S2: Keep out of the reach of children	A description of the measure or measures recommended to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use (CLP Article 2(6)) For example, P102: Keep out of reach of children
Supplier	Term not used in DSD or DPD	Any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture (CLP Article 2(26)), see also section 2 of this guidance document
Substance/s	Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the mixtures and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (DSD Article 2)	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any identified impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (CLP Article 2(7))

1.3 General glossary

Abbreviations, terms and expressions used in this report and in the major references are presented in Table 3.

Table 3. Abbreviations, terms and expressions used in this report and in the major references. In some cases, both the full name and the corresponding abbreviation may be included for the convenience of the reader.

Alloy: A metallic material, homogenous on a macroscopic scale, consisting of two or more elements combined in such a fashion that they cannot be readily mechanically separated.
Article: An object which during production is given a specific shape, surface or design, which determines its function to a greater degree than its chemical composition.
Authorisation: Pre-market approval procedure for substances of very high concern (SVHCs) listed in Annex XIV REACH. It may apply to category 1 or 2 carcinogens, mutagens, substances classified as toxic for reproduction (CMRs), PBTs, vPvBs, and other substances of equivalent concern (e.g. endocrine disruptors).
Bridging: See Section 1.4.
By-products: (from article 5 of the revised waste framework directive) A substance or object, resulting from a production process, the primary aim of which is not the production of that item, may be regarded as not being waste referred to in point (1) of Article 3 but as being a by-product only if the following conditions are met: (a) further use of the substance or object is certain; (b) the substance or object can be used directly without any further processing other than normal industrial practice; (c) the substance or object is produced as an integral part of a production process; and (d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts.
C&L: Classification and Labelling.
CA: Competent Authority.
Chemical Safety Assessment: Considers the use of the substance on its own (including any major impurities and additives), in a preparation and in an article, as defined by the identified uses. It must consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and is based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions. Annex I of REACH provides general provisions for assessing substances.

Chemical Safety Report: Provides the information collected in the chemical safety assessment (see above); Annex I of REACH provides general provisions for preparing the report.
CLP: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
CLH dossier: Dossier with proposal for harmonised classification and labeling.
CMR: Carcinogenic, mutagenic or toxic for reproduction.
Competent Authority: The entity (i.e. authority or body) established by each Member State to carry out obligations on the national level.
CSA: Chemical Safety Assessment.
CSR: Chemical Safety Report.
Distributor: Any natural or legal person established within the European Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.
DNEL: Derived No Effect Level.
Downstream user: Natural or legal person established in the European Community, (but not the manufacturer or importer) who uses the substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer who has been exempted will be regarded as a downstream user.
DPD: Dangerous preparations directive.
DSD: Dangerous substances directive.
DU: Downstream User.
ECHA: European Chemicals Agency.
EINECS: The European Inventory of Existing Commercial Chemical Substances; it is a list of existing chemical substances that have been commercially available in the European Community between January 1, 1971 and September 18, 1981 (approximately 100,000 entries).
ELINCS: European List of Notified Chemical Substances; it is a list of chemicals that have been placed on the European market since September 18, 1981. More than 4500 substances have been notified since then.
ES: Exposure Scenario.

EU: European Union.
Exposure Scenario: The set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.
Full study report: A complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed.
GCL: General Concentration Limits.
GHS: Globally Harmonised System for classification and labeling.
GLP: Good Laboratory Practice
Harmonized classification: Concenrns CLP. The decision on classification for a particular hazard of a substance is taken at Community level. Harmonized classifications of substances are included in the Tables of Part 3 of Annex VI to CLP.
Identified use: A substance's use (on its own or in a preparation) or a preparation's use, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.
IUCLID 5: International Uniform Chemical Information Database is software for the submission of dossiers, which will be used by industry, the European Chemical Agency and Member States' authorities.
IUPAC: International Union of Pure and Applied Chemistry.
Manufacturer: Any natural or legal person established within the European Community who manufactures a substance within the European Community.
Manufacturing: Production or extraction of substances in the natural state.
NGO: non-governmental organization.
Not chemically modified substance: A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation (e.g. to remove impurities).

Notified substance: A substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC (which relates to the classification, packaging and labelling of dangerous substances).
OECD: Organisation for Economic Co-operation and Development.
PBT: Persistent, bioaccumulative and toxic.
Phase-in substance: A substance that was either: (a) an existing chemical, documented as on the market in 1981, and currently listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) (about 100,106 substances); (b) not placed on the market in the 15 years prior to 1 June 2007, even though it was manufactured in the EC (or in countries acceding to the EU on 1 January 1995 and 1 May 2004), and the manufacturer has documented evidence; or (c) a "no-longer polymer" as notified under Directive 67/548/EEC, and placed on the market in the EC (or in countries acceding to the EU on 1 January 1995 and 1 May 2004) before 1 June 2007 by the manufacturer or importer, who has documented evidence. [Note: For phase-in substances imported or manufactured for at least three consecutive years, quantities per year are based on the average volumes for the three preceding calendar years.]
Placing on the market: Supplying or making available, for payment or free of charge, to a third party. Import (see above) falls under this definition.
PNECs: Predicted No Effect Concentrations.
PPORD: Product and Process Oriented Research and Development: Any scientific development relating to product development or the further development of a substance (on its own, in preparations or in articles) that involves a pilot plant or production trials to develop the production process and/or to test the fields of application of the substance.
Preparation: Mixture or solution composed of two or more substances (see below).
Producer of an article: Any natural or legal person who makes or assembles an article (see above) within the European Community.
QSAR: Quantitative Structure Activity Relationship; results of such relationships may be used instead of testing when certain conditions are met. Guidance from the Agency to follow.
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals[IV].

Read across: See Section 1.4.
Recipient of a substance/ preparation: A downstream user or a distributor supplied with a substance or a preparation.
Recipient of an article: An industrial or professional user, or a distributor, supplied with an article. This does not include consumers.
Registrant: The manufacturer or the importer of a substance or the producer or importer of an article who submits a registration for a substance.
Registration: Any manufacturer or importer of a substance (on its own or in one or more preparations, including substances in articles if intentionally released) in quantities of 1 tonne or more must follow the procedure under Title II of REACH, which requires submitting information to the Agency. Certain exemptions apply.
Restriction: Any condition imposed or prohibition on manufacturing, using or placing on the market.
RIPs: REACH Implementation Projects; seven individual projects are being conducted to develop guidance and IT tools for implementing REACH. The projects are intended to assist the Agency, industry and Member States' authorities.
RMM: Risk Management Measures.
Robust Study Summary: A detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report (see above).
Safety Data Sheet: The document includes the following: identity of the substance/preparation, uses, classification, composition, handling and storage requirements, first aid/fire measures to be taken, accidental release measures, exposure controls and personal protection and means of disposal. Annex II of REACH provides the "Guide to the Completion of Safety Data Sheets."
Self-classification*:* Concerns CLP. The decision on a particular hazard classification and labeling of a substance or mixture is taken by the manufacturer, importer or downstream user of that substance or mixture. (Special rules apply to articles).
Scientific Research and Development: Any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne/year.
SDS: Safety Data Sheet.

SIEF: Substance Information Exchange Forum; all potential registrants, downstream users and third parties who have pre-registered phase-in substances or whose substances have been regarded as registered due to applicable plant protection/biocidal products legislation, or registrants who have submitted a registration before the applicable phase-in substance deadline, become participants in a substance-specific SIEF. Participants in respective SIEF are subject to data sharing/data generation obligations.
SME: Small and Medium Sized Enterprise.
Study Summary: A summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study.
Substance which occurs in nature: Naturally occurring substance, unprocessed or processed only by manual, mechanical or gravitational means, dissolution in water, flotation, extraction with water, steam distillation, or heating solely to remove water, or that is extracted from air by any means.
Substance: Chemical element and its compounds, in the natural state or obtained by any manufacturing process, including any additives necessary to preserve its stability and any impurity deriving from the process used. It does not include any solvent which may be separated without affecting the stability of the substance or changing its composition.
SVHC: Substance of very high concern: Some substances of very high concern require authorisation, which are defined by REACH to include: CMRs, persistent bioaccumulative toxics (PBTs), and very persistent, very bioaccumulative (vPvB) substances. There are an estimated 1,500 substances of very high concern.
UVCB substance substances of Unknown or Variable Composition, Complex reaction products or Biological materials.
vPvB – very Persistent and very Bioaccumulative substances.

1.4 Vocabulary for describing the nature of matter

It is essential for the full understanding of the implications of CLP and REACH that their vocabulary for describing the nature of matter be explained. It is not the same as in textbooks on chemistry. Thus, a substance is a type of matter that is tested or equivalent, e g so-called read across. A substance can thus consist of one or several chemical compounds.

A preparation (DPD) as well as a mixture (CLP) consists of a blend of two or more substances. The words preparation and mixture have the same meaning except that they refer to different legislations. For a preparation and a mixture, the hazardous properties

with regard to health and environment can in many cases be evaluated using the known properties of the ingredient substances. This method of evaluation is called bridging. It must not be used for evaluation of the properties of a substance.

The distinction between on one hand substance and on the other hand preparation and mixture is essential since the properties of a preparation / mixture can in many cases be determined from known properties of the ingredient substances whilst fewer tools are available for comparison between substances.

In spite of their paramount importance, the words “bridging” and “read across” do not appear in any of the glossaries found, including the one at the ECHA webb site. Nonetheless, explanations have been found as follows:

Bridging From CLP[III] preample 23	*“If sufficient information is available on similar tested mixtures, including relevant ingredients of the mixtures, it is possible to determine the hazardous properties of an untested mixture by applying certain rules known as ‘bridging principles’. Those rules allow characterisation of the hazards of the mixture without performing tests on it, but rather by building on the available information on similar tested mixtures. Where no or inadequate test data are available for the mixture itself, manufacturers, importers and downstream users should therefore follow the bridging principles to ensure adequate comparability of results of the classification of such mixtures.”*
Read across From REACH[IV] Annex VI	*“Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. The Agency, after consulting with relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances sufficiently in advance of the first registration deadline for phase-in substances.”*

1.5 Definitions of terms used for legislation

1.5.1 Swedish legislation

There are three levels of ***legislation*** in Sweden.

1 ***Law*** which is issued by the Parliament and as authorized by the people in Sweden

2 ***Ordinance*** which is issued by the Government, under the laws issued by Parliament and after authorization by the Parliament

3 ***Regulation*** which is issued by a Competent Authority such as the Swedish Environmental Protection Agency (Naturvårdsverket, www.naturvardsverket.se) and the Swedish Chemicals Agency (Kemikalieinspektionen, www.kemi.se). A regulation is issued under the laws and ordinances and after authorization by the Government.

Laws, ordinances and regulations are legally binding and the compliance of them is overseen and assured by the legal system, including the courts.

In addition, a Competent Authority can issue general advice with regard to a certain regulation. It can contain clarification as to what the actual regulation is intended to mean and may also provide examples. General advice is not legally binding and compliance must not necessarily be upheld in a court decision.

Competent Authorities – like everybody else, e g a branch organization – can also issue guidance documents. They reflect good practice, but cannot necessarily be relied on for compliance with legislation.

1.5.2 European Union legislation

The European Union Legislation is issued largely in the form of ***regulations*** such as the REACH[IV] and the CLP[III] regulations, where

REACH = *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, and*

CLP = *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.*

A European Union regulation is in force directly in the European Union countries and does thus not require any implementation in any national legislation. In this regard, it has the same effect in Sweden as a national law. As any other legislation, it must be harmonized with all other legislation, but it should not be regarded as legislation issued under any special national law such as is the case for our national ordinances and regulations, cf Section 1.5.1. It is thus somewhat confusing to use the word "regulation" for such different purposes. The nomenclature is, however, in concordance with Reference [2].

A European Union ***directive*** is not in force directly to various individuals and legal entities. It applies to Parliaments and Governments who are obligated to implement European Union Directives into national legislation.

For instance, the

Council Directive 91/689/EEC of 12 December 1991 on hazardous waste [V]

has been implemented into Swedish legislation through

The Ordinance of Waste (Avfallsförordningen, SFS[1] *2001:1063)* [VI]

(and possibly other legislation).

The Directive of hazardous waste has now been superseded by the

DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives [VII]

Nonetheless, the Ordinance of waste[VI] is still in force (November 2009) and the new framework Directive on waste[VII] does not have to be implemented into Swedish legislation until end of December 2010.

European Union regulations and directives as well as guidance documents issued by any European Union authority are to be issued in concordance with certain basic principles as documented in various European Union agreements. A few such principles relevant for the present work are presented in Appendix H.

[1] SFS stands for "svensk författningssamling" which translates to *Swedish code of statutes*.

2 Background

In most cases, and until now, ashes from combustion and incineration have been regarded as waste, at least until they have been put in place in some kind of utilization. Consequently, there has seldom been reason to analyze in any detail what would have applied had an ash been regarded as a chemical product. Such details might have included labeling according to the previous and still (to a certain extent) existing rules for labeling as published in primarily two European Union Directives [I-II] and their implementation into Swedish legislation[I,VIII-X]. Thus, utilization of ash has in most cases been conducted under the waste legislation.

In contrast, and for the steel slags generated by SSAB, utilization has since decades been carried out under the legislation for products[I-II,VIII-X].

2.1 Classification of ash according to the hazardous waste Directive

A first requirement under the waste legislation is to determine if an ash should be classified as hazardous waste or as non-hazardous waste. Such a classification is to be based on the rules in the *Ordinance of waste* (Avfallsförordningen) [VI], which is the primary Swedish implementation of the Directive of hazardous waste[VII]. This ordinance also regulates how waste must be handled and managed, depending on its classification.

Basically, the classification according to the Ordinance of waste is based on whether the ash in question should be regarded as having certain hazardous properties. This, in turn, can be based on whether the ash contains certain amounts of substances having certain hazardous properties. These properties (R-values) are the same as the properties (risk phrases) mentioned in the old rules for labeling of chemical products[VIII].

Ash has varying chemical composition and structure depending on fuel, furnace, point of exit and ageing. In addition, the chemical form is complex and the trace elements – which are those of primary interest with regard to health and environment – do for the most part not form phases of their own (i e phases in which they are major elements). Instead, they typically appear in the form of solid solution in phases defined by the major elements of the ash in question. These forms of those elements that have the highest probability of forming hazardous substances do not usually appear in data bases of substances having hazardous properties.

Värmeforsk (The Swedish Thermal Engineering Research Institute)has therefore through its *Programme on Environmentally Friendly Use of Non-Coal Ashes* (Askprogrammet), and in collaboration with *Swedish Waste Management* (Avfall Sverige, formerly Svenska Renhållningsverksföreningen {RVF}) developed a methodology for the cautious but practical classification of ash and similar waste.[3-7]

The key feature of the method is the selection of one reference substance for each element where the reference substances reflect the actual properties in a cautious manner

but does not necessarily represent a worst case. A reference substance must appear in the data bases on hazardous properties.

Domestic Swedish general approaches to classification according to the Ordinance of waste can be found in References [8-9], and an example of an internationally available general approach can be found in Reference [10].

The methodology will be described further in Section 4.2.

2.2 Qualification of ash for geotechnical construction purposes

The utilisation of ash for the purpose of geotechnical constructions is governed in Sweden by the Ordinance on environmentally hazardous activities and protection of health[11]. It states the following:

Utilisation for geotechnical construction purposes of waste in such a manner that it might lead to contamination of land and soil, water area or groundwater, and where the risk is not insignificant (Swedish: inte endast är ringa).	Utilisation for geotechnical construction purposes of waste in such a manner that it might lead to contamination of land and soil, water area or groundwater, and where the risk is insignificant (Swedish: är ringa).
Permit is required for such activities. Application for permit should be applied for at the County Administrative Board.	The Local (Municipal) Authorities must be notified.

There exists no legally binding document specifies how “not insignificant” and “insignificant” are to be interpreted.

However, Värmeforsk, through its Programme on Environmentally Friendly Use of Non-Coal Ashes has investigated what might reasonably be an appropriate interpretation based on the levels of risk put forward as acceptable in other similar cases.[11-12, see also 13] This work is based on a methodology presented in [14] and developed further in [15] which is a remit version. The final version is presently in print[16]. It forms the basis for a recent publication on screening values.

The underlying prerequisite[12,17-18] is that the detriment to health must not be larger than one incidence of cancer (fatal as well as non-fatal) in 100 000 for life-time exposure of an individual in a critical group. A critical group is the group of people that have the highest exposure. This corresponds to one (additional) incidence per year for the entire Swedish population provided that all Swedes are members of a critical group getting a maximum exposure each year. Another prerequisite[12,17] is that 75 % of all soil organisms are protected.

The screening values are generic and based on cautiously selected parameters for the equilibrium concentration of the various species in the groundwater. This follows from the methodology since these parameters show large variations with the type of soil, and the result must not be overly optimistic. In addition, and as has already been pointed out,

ash has varying properties depending on fuel, furnace, point of exit and ageing and other parameters.

The Swedish Environmental Protection Agency presently has sent out a document on reuse of recycle material for geotechnical construction purposes for remit. The purpose of this guidance is to facilitate recycling by defining lower limits than what corresponds to "insignificant risk" in the Ordinance on environmentally hazardous activities and protection of health[XI], cf above.

The work on qualification of ash for geotechnical construction purposes is further described in Section 4.3.

2.3 Qualification of slags for geotechnical construction purposes

Slag from production of steel has been used for building and construction purposes for centuries. Moreover, SSAB Merox AB, at the site of the SSAB steel works at Oxelösund, has maintained a strategy of utilization of residues from steel production for many decades. This implies that considerable efforts have been spent on product qualification and marketing. It is a natural extension of this long-time strategy to work with REACH in a proactive and timely manner.

There are many similarities between ash and slag with regard to materials properties and possible applications. Consequently, there is much to learn for the ash community from those who work continuously with slag as a product.

2.4 The framework Directive for waste

In the past, Authorities have recurrently maintained that an ash is a waste until it is actually utilised and put in place in its construction.

The prerequisites for this approach may have changed on November 19th, 2008 when The European union issued its new framework Directive on waste[VII]. It is to be implemented in the member states no later than December 2010.

It states in Article 5 that a residue is a by-product and not a waste if the following conditions are met:

"(a) further use of the substance or object is certain;

(b) the substance or object can be used directly without any further processing other than normal industrial practice;

(c) the substance or object is produced as an integral part of a production process; and

(d) further use is lawful … "

If an ash is not a waste, then it should not be dealt with under the waste legislation, but under the legislation for chemical products.

The framework Directive for waste is further described in Section 5.

2.5 Legislation for chemical products

The rules for classification, packaging and labelling were inaugurated in 1967 when the European Community adopted its Council Directive 67/548/EEC on the classification, packaging and labelling of chemical products[I]. It is commonly called the Dangerous Substances Directive, or DSD.

The DSD was supplemented in 1999 by another directive that covered the case of mixtures of substances with known properties.[II] It is commonly called the Dangerous Preparations Directive, or DPD.

Both of DSD and DPD have been implemented into Swedish legislation through [VIII-X]. Of these references, [VIII] contains the Swedish regulation on classification and labeling, and previous versions of the regulation [X] contain the rules in force until recently on safety data sheets.

At present, we are going through a transition from the rules just mentioned to the new EU regulations CLP[III] and REACH[IV].

CLP stands for Classification, Labeling and Packaging, and constitutes the new rules for labeling of substances as well as mixtures. The word "preparations" appearing in the preparations Directive is thus replaced by the word "mixtures".

REACH stands for Registration, Evaluation, Authorization and Restriction of Chemicals. It addresses the production and use of chemical substances together with their potential impacts on both human health and the environment.

Various special provisions apply regarding the transition to REACH, including the possibility to pre-register previously marketed substances. Under the shelter of such a pre-registration, a manufacturer or importer could and can carry on marketing his product for perhaps even several years before having to comply fully with REACH (depending on the quantities).

This grace period of pre-registration ended on November 30th 2008, less than two weeks after the framework Directive for waste[VII] had come into force and more than two years before it has to be implemented into national legislation.

Thus, generators of residues now face a double shift of paradigms, firstly that from waste to chemical products, and secondly that to the new regulations for chemical products. The Wikipedia in English states[2] that "*its 849 pages[3] took seven years to pass, and it has been described as the most complex legislation in the Union's history and the most important in 20 years. It is the strictest law to date regulating chemical substances and will impact industries throughout the world*."

[2] Search for "REACH" together with "regulation".
[3] CLP contains 1355 pages.

2.6 Acknowledgements

The present work has been financed jointly by The Programme on Environmentally Friendly Use of Non-Coal Ashes that operates under the auspices of Värmeforsk, and SSAB Merox AB. The former organization has supported the project mainly by financing the work carried out by one of the authors, Rolf Sjöblom, at Tekedo AB, and by appointing and operating a reference group (see further below). The latter organization has contributed by freely sharing its knowledge and knowhow on marketing of by-products from steel manufacturing operations including the application REACH to such materials. SSAB Merox AB has also contributed by sharing the actual work in the project. The major part of this has been carried out by the REACH co-ordinator for the SSAB Group, Anna-Maria Tivegård. Significant contributions in this regard have also been made by the President for SSAB Merox AB, Torbjörn Carlsson.

The work has been supported by a reference group comprising the following persons:

Viktoria Dernstedt	Skellefteå Kraft AB
Helen Dömstedt	Mälarenergi AB
Mikael Norell[4]	E.ON Värme Sverige AB
Claes Ribbing[5]	The Programme on Environmentally Friendly Use of Non-Coal Ashes that operates under the auspices of Värmeforsk

This group has supported the project enthusiastically and skilfully. It has been particularly valuable to the project that the members themselves are actively working with REACH-related issues. Thus the various complex issues on interpretation of REACH as well as their implications for the report (see Section 3.3) have been discussed at some depth during the no less than seven meetings of the group in about as many months. This support is highly appreciated and gratefully acknowledged by the authors.

A long quotation in the text (see Section 7.2.6) as well as Appendix F are taken from the magazine Chemical Watch, who have kindly consented to our republication of their material. This support to our paper is hereby gratefully acknowledged.

[4] Part of the duration of the project.
[5] Affiliated member

3 Strategy for REACH compliance and basis for the present work

3.1 Strategy for REACH compliance

The implementation of REACH is to be overseen not only by national Authorities, but also by a European Union Authority called "European Chemicals Agency" (ECHA). It is presently receiving registrations of various chemical substances as well as issuing various guidance documents.

The guidance documents are very important because REACH is largely a result of negotiations. Consequently, REACH is open to interpretation in a number of cases. However, the guidance documents are not legally binding and not entirely coherent. In addition, there are no court cases.

In view of the situation, it might appear tempting to follow the main stream and do all the testing and paperwork as advised. The cost for such an approach may amount to M€ 0,2 – 4 per substance. It is possible to carry such a cost if a fairly large consortium can be formed with a number of ash generators.

But what about the variability of the ash, and should a consortium work primarily with the worst case? Or should some ashes be excluded? And what about the conscientious work already conducted on classification according to the Ordinance of waste[VI], and on environmental guidelines to meet the requirements of the Ordinance on environmentally hazardous activities and protection of health[XI]?

After all, the classification according to the Ordinance of waste actually builds on DSD and DPD. And the environmental guidelines actually provide the answer to that which REACH asks for, namely a clear declaration of the consequences for human health and the environment as well as clear instructions on how to go about in order to protect health and the environment.

This raises the question if there might be support in the CLP and REACH regulations for utilising the methods applied and results already obtained for their purposes.

Consequently, a mini-search was conducted prior to the commencement of the present work. It indicated that there may be a number of different possibilities to utilise existing methodology and data. They are tailored to accommodate for the variability between different streams and batches of ashes and this may be especially advantageous in conjunction with REACH.

Some of the findings in REACH[IV] are as follows.

From point 38 in the preamble:

"The generation of information by alternative means offering equivalence to prescribed tests and test methods should also be allowed, for example when this information comes

from valid qualitative or quantitative structure activity models or from structurally related substances. To this end the Agency, in cooperation with Member States and interested parties, should develop appropriate guidance. It should also be possible not to submit certain information if appropriate justification can be provided. Based on experience gained through RIPs, criteria should be developed defining what constitutes such justification."

Point 1 in Article 13 which is on "*General requirements for generation of information on intrinsic properties of substances*":

"Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3."

Point 0.4 in Annex I on "*General provisions for assessing substances and preparing chemical safety reports*":

"Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or 'category' of substances are adequately controlled then he can use that chemical safety assessment for the other substance or group or 'category' of substances. The manufacturer or importer shall provide a justification for this."

REACH[IV] does not include generic or site specific health and environmental impact assessments from use of materials in geotechnical constructions. Such consequences must in any case be evaluated under the Ordinance on environmentally hazardous activities and protection of health[XI], and as described in Section 2.1.2.

However, REACH does cover much or all of the characterisation of the material required. This is obvious from Annex II which is a *"guide to the compilation of safety data sheets"*.

The annex specifies that the nature and content of any hazardous substances be declared as well as any decomposition products that may be relevant for the assessment of impacts to health and the environment. "*Possible effects, behaviour and environmental fate of the substance or preparation in air, water and/or soil*" are also to be described.

A safety data sheet must also include "*relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants*".

A safety data sheet prepared under the REACH regulation[IV] may thus comprise most or all of the ash specific together with at least some of the site generic data required for assessments of the health and environmental impact according to the Ordinance on environmentally hazardous activities and protection of health[XI], cf Section 4.3 and References [11,14].

Details on the alternatives offered in and in relation to REACH will be dealt with in some detail later on in the present report. It should be put forward already here, however, that they are several, and it may make a lot of difference which alternative is selected.

It can thus be concluded already initially, that an ash generator should not rush to pay his share of M€ 0,2-4 for a standard registration as designed for ordinary chemical products. There appears to be possibilities to utilize existing material which is specially designed to cope with the chemical complexity and compositional variability of ash. Health and environmental impact assessments will have to be carried out anyway, and they need to be co-ordinated with the registration for REACH. Also in this case can existing material be utilised in the REACH registration. The possibility to consider the special prerequisites for ash varies between the alternatives in REACH. Thus, a comprehensive view will have to be taken also with regard to these alternatives together with their interrelation with the prerequisites for ash.

3.2 Purpose and scope of the present work

The conclusion of the previous Section (3.1) is that an ash generator needs to answer two major questions:

1 Should I register under REACH and in such a case, what alternative under REACH should I use?

2 How can the present methodologies for classification and impact assessment as well as the present knowledge base in the publications of the Programme on Environmentally Friendly Use of Non-Coal Ashes best be utilized?

It is the purpose of the present work to provide a basis for decisions on questions 1 and 2 above. The purpose is also to provide a basis for the planning of the further work on the compliance with REACH for ash.

It is assumed in this regard, see Section 5, that an ash generator has a certain amount of leeway in his choice between the legislation for waste and that for chemical products.

Various legislations are issued for various purposes, and it is obvious that the question of residues came into consideration late in the lengthy process[19] leading to REACH. It is taken for granted in the present report that high ambitions apply with regard to protection of health and the environment. However, REACH might not be the optimal tool to reach this end in the case of ash utilisation. Therefore, the purpose is also to find

if the REACH regulation may impose unwarranted burdens on the generators and users of residues from combustion and incineration.

The scope of the present work is to summarize and analyse the following:

1 Relevant past work in the Programme on Environmentally Friendly Use of Non-Coal Ashes and at SSAB Merox AB
2 Relevant parts of the new frame Directive on waste
3 Old and new legislation on classification and labeling of chemical products
4 REACH regulation

The analysis should focus on the following issues:

1 Possibilities to utilize features in the existing methodology for classification of ash according to CLP and registration according to REACH
2 Possibilities to utilize features in the existing methodology for environment and health impact assessment in conjunction with REACH
3 Possibility to utilize experience from The Programme on Environmentally Friendly Use of Non-Coal Ashes and from SSAB Merox AB for the preparation of safety data sheets according to REACH
4 Comparative analysis of alternatives in REACH with regard to existing prerequisites for ash

The conclusions should include the following:

1 A structured description of the alternatives and interdependencies
2 Descriptions of advantages and disadvantages with different alternatives
3 Proposed further work if ash is to be registered under REACH. This includes possibilities to use features in existing methodology for classification and health impact assessment of ash.

The purpose of the present report is not to go into any detail on the chemistry basis for the classification methodology or any details on the various test methods. Information on the chemistry of ashes and the associated interpretation for the classification methodology can be found in References [3-7].

3.3 The structure of the present report

As is presented in Section 3.2, the purpose of the present work is to analyse the REACH regulation with the scope of identifying if and how the knowledge that has been developed and accumulated in The Programme on Environmentally Friendly Use of Non-Coal Ashes under the auspices of Värmeforsk on classification and risk analyses can best be utilised to improve efficiency and compliance. The purpose is also to identify potentially discriminating factors, and to propose methodology and schemes for qualification.

It is strongly emphasized, that albeit the work is directed towards attempts for simple and easy procedures, the intent is very clearly to do this whilst fulfilling all the requirements under REACH to letter as well as to intent, and with a margin (e g to make up for uncertainty).

The present report is thus neither a summary of nor a handbook on REACH, nor is it a reporting on how to go about in order to register ash under REACH. The latter actually exists in the form of a report - "*Why and how to make a REACH registration of combustion ash*"[20] - published by Värmeforsk, The Programme on Environmentally Friendly Use of Non-Coal Ashes. This material will in general not be repeated here since it constitutes a separate, readily accessible and complementary source. General information on REACH can be found e g in References [21-26] and on the ECHA webb page, www.echa.eu.

The present report was originally intended to comprise around 35 pages and to give a summary of the pertinent alternative strategies under REACH. This was before the full nature of REACH was realized by the authors. Reach is not only a complex European Union legislation covering many hundred pages. It is also a negotiation protocol and a giant experiment. Statements are frequently ambiguous and necessary clarifications absent. This greatly enhances the significance of guidance by ECHA, although such guidance is not legally binding and might not hold in court. Guidance by ECHA is fragmented since several of the guidelines intended are either available only partially and/or in a draft form, or not at all. There are even occurrences of conflicting information. Waste related issues are dealt with in a stepmotherly fashion.

In addition, ash itself does not conform well with the underlying assumptions in REACH. The ash itself (e g from virgin wood) is essentially harmless whilst it is the impurities from some recycled wood that may be potentially harmful to man and environment. The mainstream presumption in REACH is the other way around, namely that it is the "active" substance (chemical compound) - the one produced intentionally - that might be hazardous and that the impurities are usually unimportant.

As a result of these deviations from what was expected, the original scope had to be modified to include much more than intended originally of interpretation and discussion. The consequence was also that considerable quantities of text had to be quoted in order for the reader to see from where the basis for analysis was taken and to follow the steps of reasoning.

Unfortunately, this has lead to a report that is larger than desirable and more cumbersome to read, but here is some advice as to how to avoid or mitigate at least some of the difficulties.

The European Union directive on waste is described in Section 5. The directives and regulation on labeling are described in Section 6. None of these directives and regulations has the deficiencies mentioned for REACH. Although they are complex, interpretation is not more difficult than one would expect. They are nonetheless dealt

with in some detail in Sections 5 and 6, since such background is necessary for the understanding of the chapter on REACH (Section 7). It should be observed, that material that is common to both on one hand DSD, DPD and CLP and on the other hand REACH is mostly dealt with in the chapter on labeling (Section 6) since it does not share the ambiguity with the material solely under REACH. The issue of reaction mass registration is mostly dealt with under REACH, however.

Those readers familiar with the new waste directive as well as the legislation for labeling do hardly need to read Sections 5 and 6.

The many and long quotations are either included in the appendices, or appear in italic style. Those readers who only want an overview can in many cases skip quotations.

Generally, material that is included in the appendices can be skipped without loss of continuity. The nature of the appendices is usually clear from the main text, and thus the reader is supplied with some basis for deciding whether or not to read an appendix.

It is advised that the reader initially familiarizes her- or himself with the chapter on organizations, definitions and glossaries (Section 1). The most treacherous of it all is perhaps the meaning of chemical compound, substance and mixture/preparation. Their interrelations are dealt with e g in Sections 1.4, 6.3.6-7 and 7.2.

The work has to a certain extent been one against a moving target. ECHA is continually emitting guidance documents that would preferably have been published before REACH went into force. Thus, a few of the guidelines are in a draft form. The latest one was discovered during the final editing. It is the for the present work very important guidance on waste and recovered substances[27]. Consequently, the text frequently refers to older material. It has been checked, however, that no important statements have been missed. Extensive quotations from this guidance document are compiled in Appendix G.

4 Previous work in Sweden on ash and slag

4.1 Introduction

District heating supplies about 50 % of the heating required in Sweden for domestic and other buildings at a total capacity of 50 TWh/year. Large quantities of heat are also generated at paper mills. The vast majority of such heating comes from wood based fuels, including virgin fuels, peat, recycled fuels, by-products from paper mills and waste. The latter includes about 2 Mtonnes of domestic waste which are incinerated annually and which correspond to almost half of all domestic waste generated. The total quantity of ash generated exceeds 1 Mtonne per year and constitutes by far the largest category of waste deposited and used at municipal landfills.

Comparable quantities of residues of mainly inorganic composition are also generated at steel mills and other metal works including various slags from metallurgic operations and sludges from e g treatment of liquids from pickling.

4.2 Classification of ash according to the Directive on hazardous waste

The management, handling and conceivable future fate of such residues – as well as the possible impact on health and environment - strongly depend on an appropriate classification according to the European Union Directive on hazardous waste [V] as implemented into the Swedish legislation in the form of the Ordinance of waste[VI].

According to this Ordinance, all generators of waste must know its classification, that is, if the waste is hazardous or non-hazardous. The Ordinance regulates how waste is to be handled, managed and in some cases also deposited.

For many wastes, this classification is simple and straightforward, namely in those cases where the relevant EWC-codes are unambiguous with regard to classification as hazardous or non-hazardous waste, and there is no reason to suspect that any other classification might be appropriate. EWC stands for European Waste Codes, and they are listed in Appendix 2 of the Ordinance of waste.[VI]

In other cases, there may be so-called mirror entries (Swedish: “spegelingångar” or “dubbla ingångar”) where the same type of waste is to be given different codes depending on whether or not it contains hazardous substances. In such cases, Appendix 3 of the Ordinance of waste need be consulted. It provides two means of determining the classification of a waste.

Firstly, ***alternative A***, a waste may possess certain properties that render it hazardous. The properties in question are as follows:

H1 Explosive

H2 Oxidizing

H3-A Highly flammable

H3-B Flammable
H4 Irritant
H5 Harmful
H6 Toxic
H7 Carcinogenic
H8 Corrosive
H9 Infectious
H10 Teratogenic
H11 Mutagenic
H12 Substances and preparations which release toxic or very toxic gases in contact with water, air or an acid
H13 Substances and preparations capable by any means, after disposal, of yielding another substance, e.g. a leachate, which possesses any of the characteristics listed above
H14 Ecotoxic

(Tetatogenic means harmful to fetuses, in Swedish "fosterskadande").

Secondly, ***alternative B***, a waste is classified as hazardous if it possesses one or more of the following properties

- flame point ≤ 55 ºC,
- one or more substances that is/are classified as highly toxic at a total concentration ≤ 0,1 %,
- one or more substances that is/are classified as toxic at a total concentration ≤ 3 %,
- one or more substances that is/are classified as harmful at a total concentration ≤ 25 %,
- one or more corrosive substances that is/are classified as R35 at a total concentration ≤ 1 %,
- one or more corrosive substances that is/are classified as R34 at a total concentration ≤ 5 %,
- one or more irritant substances that is/are classified as R41 at a total concentration ≤ 10 %,
- one or more irritant substances that is/are classified as R36, R37 or R38 at a total concentration ≤ 20 %,
- a substance that is known to be carcinogenic (category 1 or 2) at a concentration ≤ 0,1 %,
- a substance that is known to be carcinogenic (category 3) at a concentration ≤ 1 %,
- a substance that is tetratogenic (category 1 or 2) and that is classified as R60 or R61 at a concentration ≤ 0,5 %,

- a substance that is tetratogenic (category3) and that is classified as R62 or R63 at a concentration ≤ 5 %,
- a substance that is mutagenic (category 1 or 2) and that is classified as R46 at a concentration ≤ 0,1 %,
- a substance that is mutagenic (category 3) and that is classified as R40 at a concentration ≤ 1 %,

Reference is made to the Dangerous Substances Directive (DSD)[I] and to the Dangerous Preparations Directive (DPD)[II] as well as to their implementations into Swedish legislation through our rules for labelling of chemical products, primarily Reference [VIII]. It is mentioned that the so-called "*R-values*" above as quoted from the Ordinance of waste have the same meaning as the so-called "*risk phrases*" in Reference [VIII]. The words toxic, highly toxic and harmful also have the same meanings in the Ordinance of waste[VI] and in the The Swedish Chemicals Agency's Classification and Labelling Regulations[VIII].

However, the rules of summation are somewhat different in the two legislations. They are simpler according to the Ordinance of waste (cf above).

First, it was found that alternative A is impossible to pursue in practice. It would have involved the direct testing of all the properties on all the dissimilar streams and batches of ash. This would have been an enormous task.

Alternative B presupposes that ash be "prepared" by mixing various constituents with known classification. This "model" holds relatively well for organic compounds where the matter typically appears in the form of individual molecules, many of which appear in the data bases on hazardous properties.

The data base used is the so-called "classification list" that used to be included in the Swedish Chemicals Agency's Classification and Labelling Regulations[VIII]. However, from June 1st, this year, this Ordinance[VIII] refers to Annex VI in CLP[III].

The practical execution of the work has been carried out using the data base "*Kemiska Ämnen*" (Chemical substances) from Prevent. It contained the same information as the Swedish classification regulations as well as some additional voluntary data. It has recently been updated and upgraded with regard to the new labels to be used under CLP.

For inorganic substances, alternative B also resembles "*mission impossible*", and the reason is as follows. Ash consists mainly of reaction products between oxides and to a lesser extent chlorides of various elements. The formation of various phases is dictated primarily by the elements occurring in the highest abundances. Minor elements are typically included in these phases in the form of so-called solid solution. Solid solution means that elements foreign to the ideal, simple composition are included occasionally in the form of substitution. Elements that have the potential to give rise to hazardous properties are usually minor elements. Such solid solutions containing potentially hazardous elements do not appear in the data bases (such as "Kemiska ämnen").

The availability of the potentially hazardous trace elements to the water phase (pore water) is typically dictated by the (incongruent) dissolution properties of the phases formed. Their internal structures are dictated mainly by the abundances of the major elements. The minor elements, i e those which are potentially hazardous, do not form phases of their own, but are incorporated into these phases formed by the major elements. Since the pore water is typically saturated with regard to sparingly soluble phases of the major elements, dissolution rates are usually slow for aged ash.

It might therefore be tempting to conclude that since the relevant phases are not included in the data bases, and since the forms of occurrence are likely to have a low impact on health and environment, it would be reasonable and justifiable not to include them in any evaluation of hazardous properties. Such an approach would, however, be in breach of the precautionary principle in that no highest value is assessed for the hazard. Instead, a method is desired in which each element is regarded as included in a chemical form that represents the actual form in a cautious (conservative) manner, and in which all of each such element is included in the calculations of hazard.

This is achieved by defining reference substances for classification. This is not the same as reference substances under the REACH regulation.

A reference substance represents an element that has potentially hazardous properties (cf above) in an ash and soil environment[6]. It must exist in the data bases on hazardous properties, and must represent the actual properties in a conservative manner. It should also represent the element in question in a reasonably realistic manner in the chemical environment in question. It cannot be required, however, that it is thermodynamically stable in an ash environment, because, as just mentioned, minor elements do not usually form phases of their own.

It is not trivial how these reference substances are selected. Our environmental code[XII] requires that health and environment be protected (see Chapter 1 §1). It also states that one must conserve resources and recycle (see Chapter 1 §1), and Chapter 2 § 5 states that "*persons who pursue an activity or take a measure shall conserve raw materials and energy and reuse and recycle them wherever possible. …"*.

Thus, the easiest choice – worst case – can only be used either when the impact on recycling is small, or when it is not possible to identify a reference substance that is conservative but at the same time reasonably realistic.

In concordance, the Programme on Environmentally Friendly Use of Non-Coal Ashes has commissioned three projects to develop methodology, compile the chemical prerequisites and propose pertinent reference substances, see References[3-7,13]. A compilation of the reference substances put forward is presented in Table 4.

[6] This usually holds for slag as well although the method was not originally developed for slag.

Table 4. The relation between the reference substances, R-values and hazardous properties. H4 = Irritant, H5 = Harmful, H6 = Toxic, H7 = Carcinogenic, H8 = Corrosive, H10 = Teratogenic and H11 = Mutagenic. Y = yes.

Property	**H6**	**H6**	**H5**	**H8**	**H8**	**H4**	**H4**	**H7**	**H7**	**H10**	**H10**	**H11**	**H11**
Code†	**TT+**	**T**	**Xn**	**C**	**C**	**Xi**	**Xi**	**T**	**Xn**	**T**	**Xn**	**T**	**Xn**
Limit %	**0,1**	**3**	**25**	**1**	**5**	**10**	**20**	**0,1**	**1**	**0,5**	**5**	**0,1**	**1**
R-values*	**26** **26** **26**	**23** **24** **25**	**20** **21** **22**	**35**	**34**	**41**	**36** **37** **38**	**45** **49**	**40**	**60** **61**	**62** **63**	**46**	**68**
antimony(III) oxide									Y				
arsenic(III) oxide	Y				Y			Y					
barium(II) oxide			Y										
lead(II) oxide			Y							Y	Y		
cadmium(II) chloride	Y	Y						Y		Y		Y	
kobalt(II,III) oxide			Y						Y				
copper(II) oxide			Y										
chromium(VI) oxide	Y	Y		Y				Y			Y	Y	
mercury(II) chloride	Y	Y			Y								
lantanium(III) oxide						Y							
molybdenum(VI) oxide			Y				Y						
nickel(II) oxide								Y					
vanadium(V) oxide		Y	Y				Y				Y		Y
tungsten(VI) oxide			Y		Y								
zinc(II) oxide													
Franklinite $ZnFe_2O_4$													

† Symbols and indications of danger for dangerous substances and preparations are presented in Table B1, see Appendix B.

* The meanings of the R-values are presented in Table B2 in Appendix B.

Zinc(II) oxide and franklinite ($ZnFe_2O_4$) are relevant for the property ecotoxic, where the Programme on Environmentally Friendly Use of Non-Coal Ashes recommends its members to use a voluntary limit. There is no quantitative limit for ecotoxic in the Ordinance of waste[VI]. Consequently, it is recommended[3-7] that classification as non-hazardous is not done if the data for the waste in question exceed the limit for labeling as ecotoxic according to DSD[I] and DPD[II], and their implementation in Swedish legislation[VIII-IX].

The work on the method for classification has been carried out with support from the Swedish Environmental Protection Agency in the form of information, advice and work in a reference group.

The method has been applied successfully at more than 20 district heating sites and two steel mills.

Please note again that the method relates to the present rules for classification (Ordinance of waste[VI]) which are to be modified during the course of 2010 when the new framework Directive on waste[VII] is to be implemented into Swedish legislation.

According to the remit version of the new ordinance circulated recently by our Government, the distinction between hazardous and non-hazardous waste will be based on CLP. What renders waste hazardous under CLP is dealt with in Section 6.3.4.

4.3 Assessment of impact on health and environment from geotechnical constructions containing ash

An introduction to the impact on health and environment from geotechnical constructions containing ash was given in Section 2.2. It was mentioned that the underlying prerequisite[12,17-18] for the assessment of the impact on health is that the detriment must not be larger than one incidence in 100 000 for life-time exposure of an individual in a critical group, and that 75 % of the soil organisms should be protected. It was also mentioned that Värmeforsk, through its Programme on Environmentally Friendly Use of Non-Coal Ashes has investigated possible impacts from use of ash for the purpose of road constructions [11-13].

The model used is based on various literature data by means of which it is possible to convert content of various potentially hazardous elements in a construction to e g intake through drinking water from a local well. Other mechanisms include oral intake of soil, which is most critical for infants, and oral intake of dust through vegetables grown locally. Literature data are also available for the conversions needed. Some parameters are strongly site specific, however, such as the distances between the road and wells for drinking water as well as the distribution coefficients for contaminants between soil and water in the ground.

An illustration of how contaminants can move with groundwater from a road made of ash and to a well for drinking water is shown in Figure 1.

It is usual [28-29] to define a retardation factor, R_f, as follows:

$$R_f = \frac{rate\ of\ transport\ for\ the\ fluid}{rate\ of\ transport\ for\ the\ contaminant} \quad (1)$$

Where

$$R_f = 1 + \frac{\rho_b}{n_e} K_d \quad (2)$$

and

ρ_b = bulk density of the porous medium (kg/litre)

n_e = effective porosity for the porous medium when saturated with fluid

K_d = distribution coefficient (litre/kg), i e the ratio of the concentration of the contaminant in the soil (kg/kg) to that in the water (kg/litre).

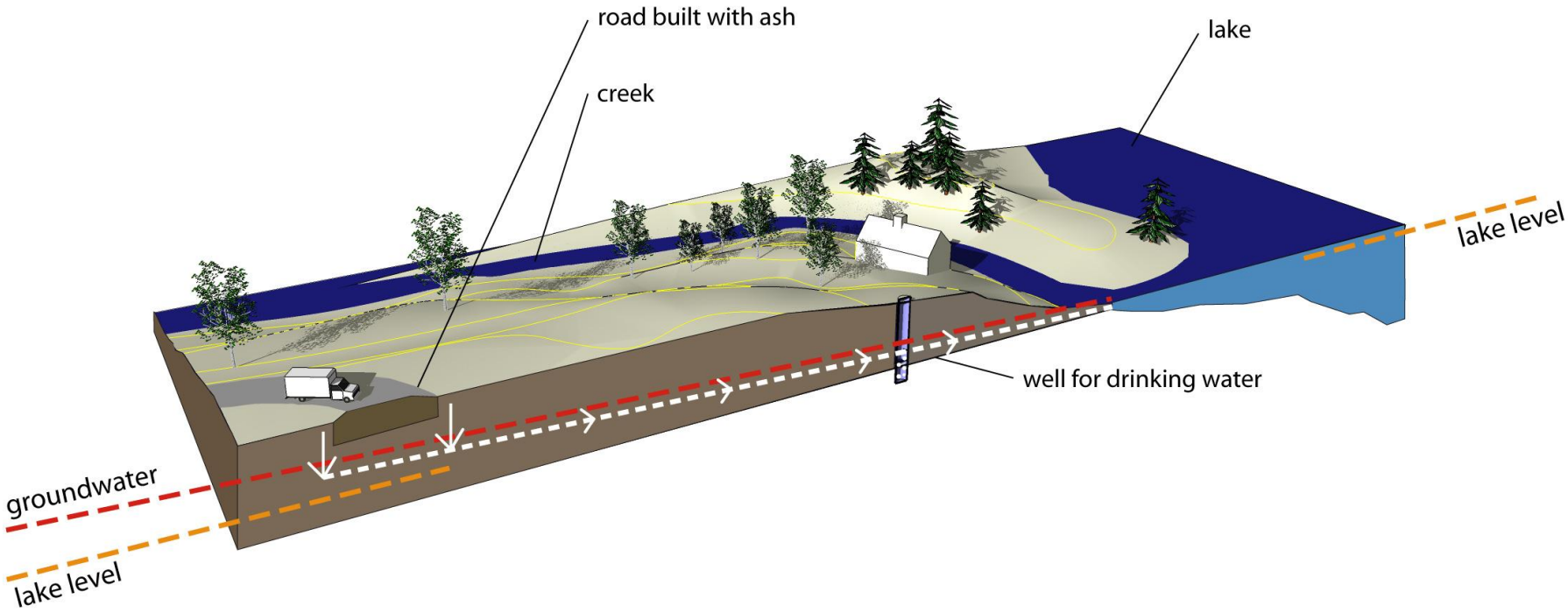

Figure 1. Path of transfer of contaminants from a road built with ash to a well for drinking water and to a small lake with fish.

In practice, the second term usually dominates in equation (2). Consequently, the rate of transport of the contaminant is approximately inversely proportional to the distribution coefficient (Kd-value). The distribution coefficient also largely dictates the concentration of the contaminant in the water in a well.

The general assumption in simple Kd-models is that the distribution coefficient is independent of concentration as well as of time of contact. Both of these assumptions are often poor or very poor. However, Kd-values determined at elevated concentrations during short contact times are usually conservative, and thus even simple Kd-modelling can be used to obtain upper limits for the impacts to health and the environment.

Distribution coefficients vary strongly with the type of soil in the surrounding of an installation. If generic impacts, applicable to just about any site, are to be sought, then the distribution coefficients will have to be chosen among the least favourable ones, i e for the poorest soils (usually sandy or silty ones).

The content of contaminants in drinking water in a well of course also depends on the concentration in the ash and on the mechanisms for release. Usually, roads are made impervious to penetration by water wherefore meteoric water drains off from the surface and dissolution of contaminants is small. Nonetheless, the work by the Programme on Environmentally Friendly Use of Non-Coal Ashes [11-13] includes scenarios in which water is allowed to penetrate through the material in a road bank and thus become equilibrated with regard to contaminants in the ash. Thus, ageing and leach properties of the ashes used are also important for the evaluation of consequences to health and the environment.

Using this and other tools, the material published by the Programme on Environmentally Friendly Use of Non-Coal Ashes [11-13] contain generic guidance values on content and leaching of various elements such that the risk criteria above are met. The models presented can also be utilized for site specific evaluations.

4.4 Qualification of slags as chemical products

Much of the material below was received during an interview with the Managing Director of SSAB Merox AB, Torbjörn Carlsson. He has been around at what is now SSAB Merox AB for about 40 years, and he also has a special interest in industrial history. The purpose of the interview was to learn about the approach and experiences with by-product utilisation.

4.4.1 Background

Sweden has rich natural resources in terms of ores and forests. Beneficiation of iron and production of steel has been a major source of income for centuries. Historically, the two have been strongly interlinked since reduction of iron ore was made using charcoal which is made from wood. In large areas of Sweden, most of the wood harvested was used for preparation of charcoal.

The by-products of the combustion of wood and manufacturing of iron, ash and blast furnace slag, respectively, were different however, since the composition of the ash related to the wood used while that of slag was dominated by non-iron elements in the ore.

Ash was used for a large number of purposes, some of them related to preparation of food and personal hygiene. It fell into disuse (other than for the purpose of fertilization) by the end of the 19th century as a result of the introduction of efficient processes to make soda (sodium carbonate) and caustic soda (sodium hydroxide).

Blast furnace slag has been used in the form of moulded blocks of glass for buildings and geotechnical constructions for centuries, and an example is shown in Figure 2. Many of them are still standing and are generally in mint condition. Blast furnace slag has also been utilised – historically as well as at the present time – as an ingredient in glassmaking.

The composition of the blast furnace slag changed when charcoal was gradually replaced by coke from coal in the blast furnaces about a hundred years ago. Somewhat later, coal combustion shifted from grate firing to powder burners. This lead to a higher firing temperature and a greater similarity in materials properties between the coal fly ash and blast furnace slag, at least in the cases where the slag had undergone rapid cooling similar to that of the particles in a coal furnace. Rapid cooling gives rise to a glass that is highly reactive when contacted with water under alkaline conditions.

In the case of SSAB Merox AB in Oxelösund there is a continuous history of utilisation of blast furnace slag for building and geotechnical construction purposes.

Generally, blast furnace slag based concrete and concrete-like materials have excellent properties in this regard, and are in several aspects superior to those of Portland cement. Thus, they have a higher resistance to various chemicals, can be moulded in large structures with less fracturing, have a lower density and a lower thermal conductivity.

Consequently, see further below, SSAB Merox AB has been very successful in marketing and selling blast furnace slag and a number of other by-products for a multitude of uses.

This success is regarded with a mixture of admiration and curiosity from the ash community, where most of the old tradition of conservation was broken a long time ago (see above) and where modern efforts of utilisation of ash are frequently met with great suspicions as well as objections from health and environment points of view.

4.4.2 The SSAB Merox AB approach

The first conclusion is that the path has not been nearly as straightforward as one might attempt and wish to reconstruct in retrospect.

In a large company like SSAB which makes various qualities of steel all the way from iron ore and scrap metal to various types of steel sheet products, there is always an internal dialogue on focus. As usual, by-products run the clear risk of being regarded as outside the main scope.

It is well known internationally that for many years, manufacturers of cement and concrete have impeded the utilisation of coal ash in spite of its in many cases superior properties. It is only recently, that most of the coal ash has been put to use, mainly for such purposes. This is true primarily for Europe and the United States, while China and India (which use huge quantities of coal) lag behind in this regard.

The obstacles have been similar in Sweden, and for many years SSAB Merox AB had to outperform alternative solutions by large margins in order to be able to sell its products.

There has not been an absence of dialogue with Authorities either, but legislation and Authority related issues have been of less significance, in comparison.

Experience and lessons learned from the example of SSAB Merox AB include the following:

- *Set long-term goals and strategies.* Acceptance among internal as well as external stake-holders does not usually come about quickly.
- *Fulfill your obligations and responsibilities with regard to health and the environment.* The Environmental Code[XII] says that it is the owner and operator of a facility that has the full responsibility for health and the environment. The role of the Authorities is to instigate such work and to control that it is being performed and executed.
- *Do your home-work.* Make sure your products are competitive and that the impact on health and environment is at least acceptable, preferably better.
- *Avoid mistakes.* Trust and confidence may well take decades to earn but can be lost overnight by a simple mistake.
- *Be open and honest.* Let everybody know how good and bad your products are and always tell the truth also to the Authorities.
- *Determine the actual impact on environment and health.* Applications and other planning documents often contain modeling of impacts on health and the environment. As explained in Section 4.3, these often – by necessity – exaggerate the impacts by orders of magnitude. Consequently, it is essential that the actual impact – that is the impact actually incurred – is accurately determined. (An example of this is the water sampling carried out from areas nearby after the motorway had been build between Nyköping and Norrköping using blast furnace slag material).
- *Be persistent and enduring*. Rationale for giving up has existed at times, but work has nevertheless progressed in accordance with the long term goals.

Figure 2. Example of historical utilisation of blast furnace slag (from iron ore reduction). House built using moulded blocks. Please note that the slag blocks were used at the most exposed parts of the building, thus indicating an excellent resistance to weathering.

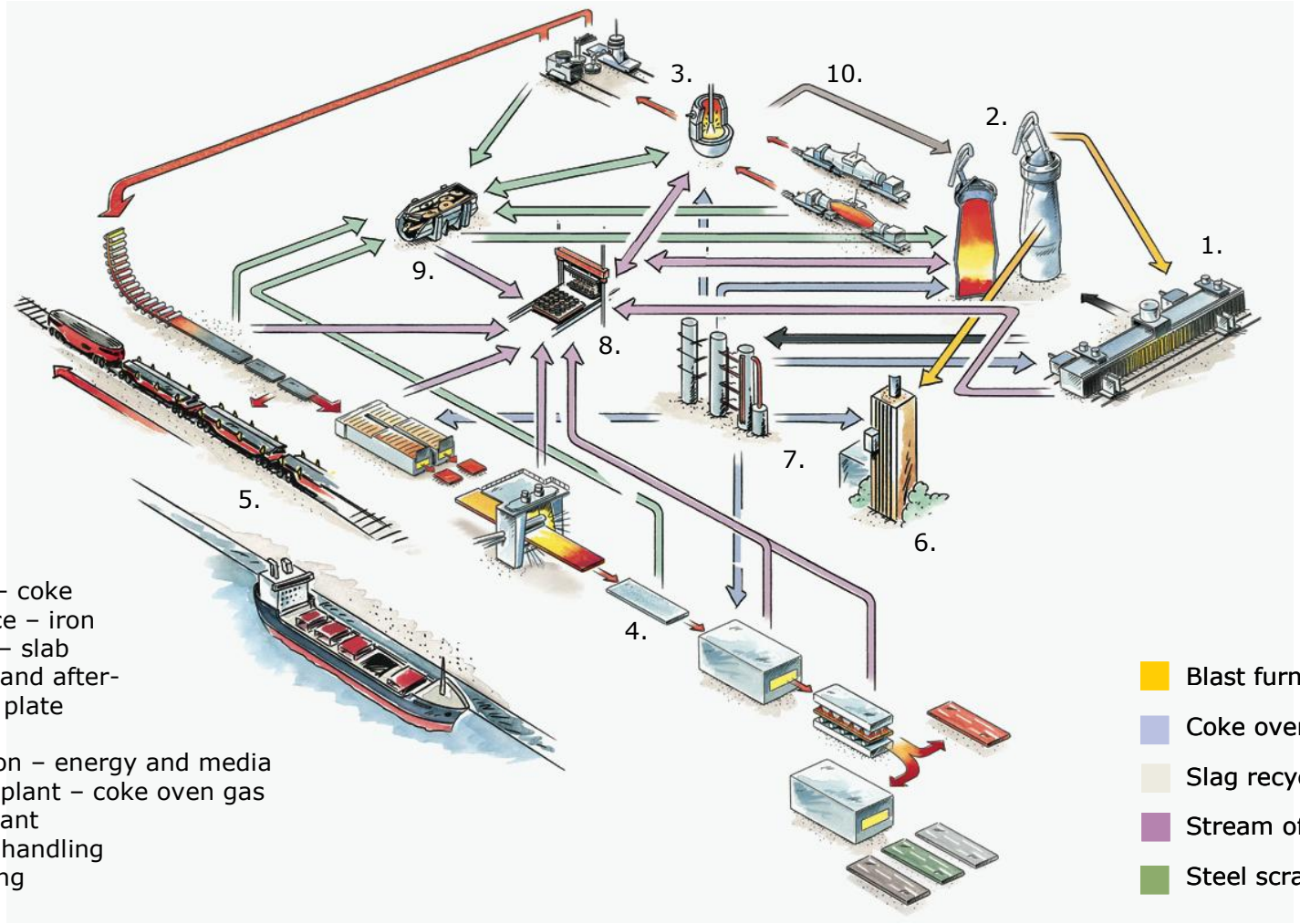

Figure 3. Iron ore reduction, conversion to steel, continuous casting, rolling of steel plates together with recycling of by-products at SSAB Oxelösund AB and SSAB Merox AB at their steel mill at Oxelösund (≈ 100 km south of Stockholm).

4.4.3 Some facts about SSAB Merox AB

SSAB Merox AB is a daughter company of SSAB AB, which is the leading manufacturer in the Nordic countries of sheet steel products. The main facilities and operations are at Oxelösund, Borlänge and Luleå.

The mission of SSAB Merox AB is to ensure a high degree of utilisation of resources by developing, processing and marketing of by-products from the blast furnace, metallurgical and other operations. The mission is also to support the recycling at SSAB Oxelösund by ensuring that as high a fraction as possible of the raw materials for the various processes is put to efficient use. In those cases where it is presently not possible to find suitable environmental and economical solutions, the residues become waste, and it is then the responsibility of SSAB Merox AB to co-ordinate the waste management and to operate landfills.

The operations at SSAB Oxelösund include coke oven plant, blast furnaces, power station, steel plant and rolling mill, see Figure 3

The total SSAB Merox AB turnover of material amounted to 900 thousand tonnes in 2006. They comprised mainly the following:

Type of by-product	**Thousand tonnes**
Briquettes for recycling	120
Blast furnace slag based products	250
Black iron oxide	50
Scrap metal e t c	400

SSAB Merox AB is certified according to the quality and environmental management standards ISO 9001 and ISO 14001, respectively.

4.4.4 Safety data sheets and similar

Initially, some of the products marketed by SSAB Merox AB were qualified according to domestic and foreign industrial standards as well as standards issued by Authorities (type approval). These were later supplemented by health and environment declarations, now safety data sheets.

Today, the products marketed by SSAB Merox AB are associated with at least a safety data sheet and a product specification sheet, and in some cases also an instruction on how it can best be used. An example of a safety data sheet is provided in Appendix A.

The key to achieve the goal of a high degree of reuse of residues is to understand the materials properties and to find the relations to the appropriate applications. Consequently, a heavy emphasis has been put on understanding not only the processes at SSAB Oxelösund's own site, but also the prerequisites for various potential applications in different industries. This is why even the early documentation focused on properties relevant for various uses as well as proper instructions for use.

The strategy has been to be proactive, and to have the relevant know-how on properties, uses and health and environment aspects beforehand.

A safety data sheet is required under REACH[IV] only for substances or preparations that are classified as hazardous according to Reference [X]. SSAB Merox AB has chosen, however, to issue safety data sheets also for other products in order to obtain additional safety and security.

Safety data sheets are intended to be used by professional customers and the purpose is to enable them to carry out precautions with regard to health and the environment.

The requirements on a safety data sheet can be found in REACH[IV], article 31 and Annex II.

5 The EU Directive on waste

It was mentioned briefly in the Background to the present report (see Section 2.1) that the new framework Directive for waste, that was issued on November 19th, 2008, will clarify the definition of waste in the European Community. This will take place when the Directive becomes implemented into the national Swedish legislation which will take place no later than during the year 2010.

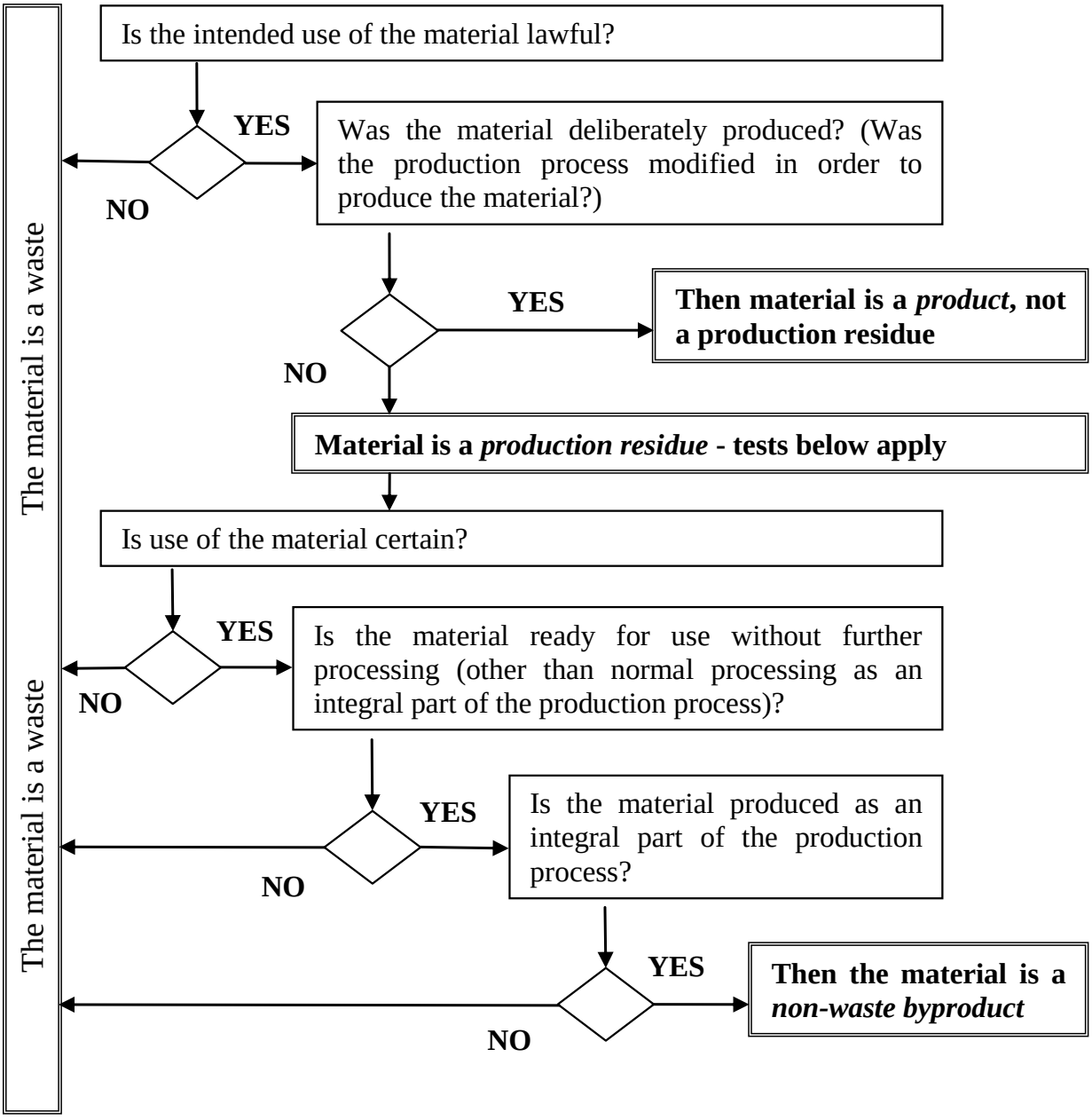

Figure 4. Scheme for determining when a residue is a by-product and when it is a waste according to the new framework Directive on waste[VII].

A residue is a by-product and not a waste if the use of the substance is certain, if it can be used directly and if it is generated as an integral part of a production process. A scheme for determining when a residue is a by-product and when it is a waste according to the new framework Directive is presented in Figure 4.

In addition to the definition in Article 5 of by-products, quoted in Section 2.4, and explained in Figure 4, criteria are given in Article 6 on "*end of waste*". They are as follows:

"1. Certain specified waste shall cease to be waste within the meaning of point (1) of Article 3 when it has undergone a recovery, including recycling, operation and complies with specific criteria to be developed in accordance with the following conditions:

(a) the substance or object is commonly used for specific purposes;

(b) a market or demand exists for such a substance or object;

(c) the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and

(d) the use of the substance or object will not lead to overall adverse environmental or human health impacts.

The criteria shall include limit values for pollutants where necessary and shall take into account any possible adverse environmental effects of the substance or object. ... "

The Directive has, furthermore, a clear focus on conservation and recycling. This is illustrated by the "waste hierarchy" presented in Article 4:

"1. The following waste hierarchy shall apply as a priority order in waste prevention and management legislation and policy:

(a) prevention;

(b) preparing for re-use;

(c) recycling;

(d) other recovery, e.g. energy recovery; and

(e) disposal."

Article 11 has the title "*re-use and recycling*", and "*recovery operations*" are listed in Annex II. Point number R 10 in the list is as follows: "*Land treatment resulting in benefit to agriculture or ecological improvement*".

The list is said not to be exhaustive, and it is assumed in this report that point R 10 covers forestry as well.

Thus, point R 10 is significant for the question of whether ash that is recycled as nutrient to the forest is to be regarded as waste or by-product. It can be concluded that the inclusion of point R 10 under the heading "*recovery operations*" is compatible with

a view that ash to be recycled to the forest can be regarded as waste. This issue is dealt with further in Section 7.3.

In the past, Authorities have recurrently maintained that an ash is a waste until it is actually utilised and put in place in its construction. At present, various Authorities analyse the new Directive in order to make interpretations and to issue recommendations and guidelines. It might be suspected that reminiscences of old arguments will be found in such upcoming documents. The risk should be moderate, however, since the Directive is very clear on these issues.

Options to regard a residue as waste or by-product, may thus be limited from an Authority point of view. But what leeway is available to a plant owner?

For a residue to be a by-product according to Article 5 (on by-products), it is required that the use of the substance is certain, and for a waste to cease being waste according to Article 6, it is required that a market or demand exists.

The certainty of use and existence of a demand does not come about by themselves. They require some sort of qualification of a residue, and in industry this relates to product specifications, quality management systems and marketing activities.

A manufacturer who wants to put his residues on a landfill could thus keep a very low profile on these issues. However, caution is warranted since the Swedish Environmental Code[XII] states (Chapter 2 § 5) that "*persons who pursue an activity or take a measure shall conserve raw materials and energy and reuse and recycle them wherever possible. ...*". Keeping too low a profile on this issue might thus not be compatible with the law. (Appropriate recycling may well be achieved also when a residue is regarded as waste).

In a sense, this issue is self-regulating, however. If utilisation becomes popular and there are many customers on a market, then marketing a product rather than a waste would just make good business sense.

Article 14 deals with "*costs*" and reads as follows:

"1. In accordance with the polluter-pays principle, the costs of waste management shall be borne by the original waste producer or by the current or previous waste holders.

2. Member States may decide that the costs of waste management are to be borne partly or wholly by the producer of the product from which the waste came and that the distributors of such product may share these costs."

The polluter pays principle is a fundamental principle of the Swedish Environmental Code[XII]. Chapter 2 § 8 states as follows:

"Persons who pursue or have pursued an activity or taken a measure that causes damage or detriment to the environment shall be responsible, until such time as the damage or detriment ceases …"

Similar legislation exists in other European countries, as is apparent from the Directive on environmental liability with regard to the prevention and remedying of environmental damage[XIII].

Point 2 above from Article 14 in the new framework Directive on waste[VII] can be interpreted to mean that a manufacturer that sells products that give rise to contamination in the ash once the products in question have become waste and are incinerated may become liable for costs associated with the problems encountered by the district heating facility in dealing with this impurity.

A similar interpretation can be made of Article 14 in the Directive on Environmental Liability[XIII].

According to the Directive on incineration of waste[XIV], "*The operator of the incineration or co-incineration plant shall take all necessary precautions concerning the delivery and reception of waste in order to prevent or to limit as far as practicable negative effects on the environment*".

This stands in sharp contrast with REACH, according to which a manufacturer may pay for keeping knowledge secret by means of which a recycler might otherwise assess the health and environment related properties of his product. It is thus possible – at least in principle – for a manufacturer to gain a competitive edge by manufacturing a product with impurities that hamper recycling.

There are many decisions on policies for recycling and sustainable development. Several of those documents refer to the so-called Brundtland report[30], in which the following can be found (underlining by the present authors):

"The chemical producer and user industries, as the source of the risks associated with chemicals and as the greatest beneficiary of their use. should bear the responsibility for ensuring (and the liability for not ensuring) that their products meet the highest standards of safety, have the fewest adverse side effects on health and the environment, and are handled with appropriate care by workers and users. <u>This will require the fullest possible disclosure of information about the properties and production processes of chemical substances and on comparative risks</u>, not only to the regulatory authorities but also to the workers, consumers., and residents of the community in which the chemical industry operates."

Obviously, this is an issue where there are contradictions, and at present one can only speculate on how this issue will be resolved.

The latest news received from ECHA on this matter is from their draft guidance document on the preparations of dossiers for harmonised classification and labelling[31]. There ECHA states the following under the heading "*use of confidential information*": "*There is an ongoing discussion on the use of confidential information in CLH dossiers, and this section will be finalised at a later stage*".

This issue is dealt with further in Section 7.4.2.

6 Labelling of chemical products

6.1 Introduction

A brief introduction to the legislation on chemical products was given in Section 1.5 and is not repeated here.

Terms used for classification and labelling are presented in Sections 1.2 – 1.4. Please note that the terms vary considerably between the old (DSD and DPD)[I-II,VIII-IX] and the new (CLP)[III] legislation. Please note also the full implications of the difference between substances and preparations / mixtures, cf Section 1.2.

It might be tempting to assume that the Dangerous Substances Directive (DSD)[I] and the Dangerous Preparations Directive (DPD)[II] have simply been replaced by REACH[IV] and CLP[III]. This is not quite the case. Actually, REACH at present (late 2009) refers to DSD and DPD many dozens of times but not at all to CLP as such. (In a few instances reference is made to such new codes that can be found only in CLP).

It is the case, however, that both CLP and REACH have come about as a result of discontent with DSD and DPD in certain respects. They focus on hazard only (actually danger in their nomenclature, cf Section 1.2), not on risk, and therefore risk is managed in REACH. Hazard / danger is an inherent property of a substance whereas risk describes the possibility of damage or detriment when the substance in question is handled and used.

There has also been discontent with DSD and DPD with regard to the slow rate of progress in determining reliable data on the various substances. The situation was worst with the substances introduced into the market before 1981, altogether 100 106 substances. This number might be compared with the number registered between 1982 and 2007 which is about 3000.[21, see also 20,22-25,32-33] While new substances had to be tested (according to DSD), there were no such requirements for those introduced early. Thus, the knowledge was insufficient, and the responsibility for the databases rested with the Authorities. There was a need to place this responsibility onto those that put the chemicals into circulation, and also to put the highest requirements on quality on those who supply the largest quantities. This is the rationale for REACH, see also Section 7.1.

CLP builds largely on DSD and DPD, and has "imported" classifications for a large number of substances from existing databases. They are referred to as "*harmonised classifications*", see further below. The codes and labels are different, however, between on one hand DSD and DPD and on the other hand CLP. The main reason for the new labels is the need to be compatible with the labelling system of the United Nations. Their system is called GHS which stands for Global Harmonized System.

It is recurrently pointed out in CLP[III] that upcoming information relevant for the classification must be considered and notified to the Authorities.

It can be foreseen that a main source for such supplementary information will be data obtained as a result of testing required under REACH.

Nonetheless, knowledge on whether a substance is dangerous / hazardous or not is required under REACH. It is also required in some other circumstances, e g in the current waste legislation, see Sections 2.1 and 5.

The testing required is actually similar between CLP and REACH since the properties of interest are largely the same. The level of proof in the testing may be higher for REACH, especially when it comes to existing chemicals.

Since DSD and DPD are to be phased out, it can be foreseen that some corresponding classification in CLP will be used as a basis in REACH in the future. This and related issues will be dealt with in Section 6.3.4.

It is therefore warranted to first deal with DSD, DPD and CLP, and then REACH so that the implications of the legislation for labelling becomes clear.

It should be remembered in this regard that CLP and REACH are separate and independent European Union regulations.

6.2 The dangerous substances and dangerous preparations directives

A brief introduction to the dangerous substances directive (DSD) [I] and the dangerous preparations directive (DPD) [II] was given in Sections 2.5 and 6.1, and is not repeated here. The issue of "dangerous substances" is dealt with further in Section 6.3.4.

According to DSD and DPD, a chemical substance or preparation must be labelled with symbols and indications of danger if it possesses dangerous properties. The properties together with their respective labels are shown in Table B1 in Appendix B.

The entity "dangerous properties" is not the same as "harmful properties", and thus the properties R52 (harmful to aquatic organisms) and R53 (may cause long-term adverse effects in the aquatic environment) do not render a substance dangerous for the environment, cf DSD Article 2 and Annex VI.

DSD and DPD also state that substances and preparations in certain cases must be labelled with risk phrases as well as safety phrases. The risk phrases used are listed in Table B2 in Appendix B. Dangerous substances and preparations associated with any of the symbols and indications of danger in Table B1 in Appendix B also carry one or more risk phrases and safety phrases. The rules in DSD and DPD may also imply that risk and safety phrases must be used for certain other substances as well.

According to DSD, the dangerous properties of a substance are determined by analysis of the results of a number of tests.

For a preparation (= mixture of substances) the dangerous properties may be determined by figuring according to certain rules using the classifications for the substances in the preparation together with their respective abundances. The latter procedure is described in DPD[II] as well as in the National Swedish legislation[XIII-IX].

A chemical product with several components (chemical compounds) can also be tested directly under DSD in order to obtain an appropriate classification. In this case, the product in question may become regarded as a substance under CLP (as well as REACH).

The properties of interest in the case of ash and slag can be determined using figuring in accordance with DPD as well as using direct measurements according to DSD.

It is beyond the scope of the present report to describe in detail how such figuring or measuring is to be carried out. They are described in Reference [VIII]. In most cases, the alternative with a weighed average is used. Here the weight in the weighing is related to the degree of danger for the respective constituent substances.

Although somewhat more complex than the summation rules used in the Ordinance of waste[V-VI], cf Section 2.1, these rules are still easy to apply for various preparations having different compositions.

This simplicity might in some cases imply that a preparation can be classified as non-hazardous (no symbol or indication of danger) in spite of the fact that a test might actually give rise to such labelling of the preparation. Such cases may e g appear when a very toxic substance is present in low abundance, in which case the danger of that substance might in fact be underestimated. This inconsistency is rectified in CLP, cf below.

6.3 CLP

6.3.1 Purpose and scope of CLP

The purpose and scope of CLP is presented in Article 1, point 1, in the regulation[III]:

"1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by:

(a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;

(b) providing an obligation for:

(i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;

(ii) suppliers to label and package substances and mixtures placed on the market;

(iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;

(c) providing an obligation for manufacturers and importers of substances to notify the Agency of such classifications and label elements if these have not been submitted to the Agency as part of a registration under Regulation (EC) No 1907/2006;

(d) establishing a list of substances with their harmonised classifications and labelling elements at Community level inPart 3 of Annex VI;

(e) establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (c) and (d).”

Substances and mixtures for scientific research are not included, and waste is not regarded as a substance or mixture under CLP, as is apparent from points 2 and 2 of Article 1 in CLP:

“2. This Regulation shall not apply to the following:
…
(d) substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under controlled conditions in accordance with Community workplace and environmental legislation.

3. Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste (2) is not a substance, mixture or article within the meaning of Article 2 of this Regulation.”

(This is further elaborated on in Article 4).

There are other exceptions, but none of them could be identified to be of relevance in conjunction with ash.

It should be noted that a “chemical product” is regarded in CLP as either a substance, a mixture or an article. Articles are included only if they fall under REACH, in which case it is intended that they release substances or mixtures, cf Section 7.3. It should also be noted that exceptions are few and distinct.

As will be elaborated on in later sections in this report, this contrasts somewhat to REACH under which there is a multitude of possibilities. This will be dealt with in Section 7, see also Section 1.4.

6.3.2 The labelling in CLP

According to Article 1 in CLP[III], it applies to substances as well as mixtures (= preparations in DSD and DPD). According to the same Article, CLP does not apply to “*substances and mixtures for scientific research and development, which are not placed on the market*”, nor does it apply to waste.

According to Article 2, hazard (=danger in DSD and DPD) e t c is expressed as follows in CLP:

- *hazard class* means the nature of the physical, health or environmental hazard
- *hazard category* means the division of criteria within each hazard class, specifying hazard severity
- *hazard pictogram* means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or color that is intended to convey specific information on the hazard concerned
- *signal word* means a word that indicates the relative level of severity of hazards to alert the reader to a potential hazard; the following two levels are distinguished:
  - a *Danger* means a signal word indicating the more severe hazard categories
  - b *Warning* means a signal word indicating the less severe hazard categories
- *hazard statement* means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard
- *precautionary statement* means a phrase that describes recommended measure(s) to minimize or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal

Substances and mixtures (and in some cases also articles) that are classified according to CLP must be labeled with regard to all hazard indicators presented in the listing above, as appropriate.

The hazard pictograms and the associated hazard classes are shown in Table B3 in Appendix B.

The actual labelling to be applied is to be found in tables in Annex I in CLP and examples are provided in Tables B4a – B4c in Appendix B in the present report.

As can be seen from Tables 4 and 5 in Appendix B, the character of the hazard is indicated primarily by the hazard class and the hazard pictogram, and the severity of the hazard is indicated primarily by the hazard category and the signal word.

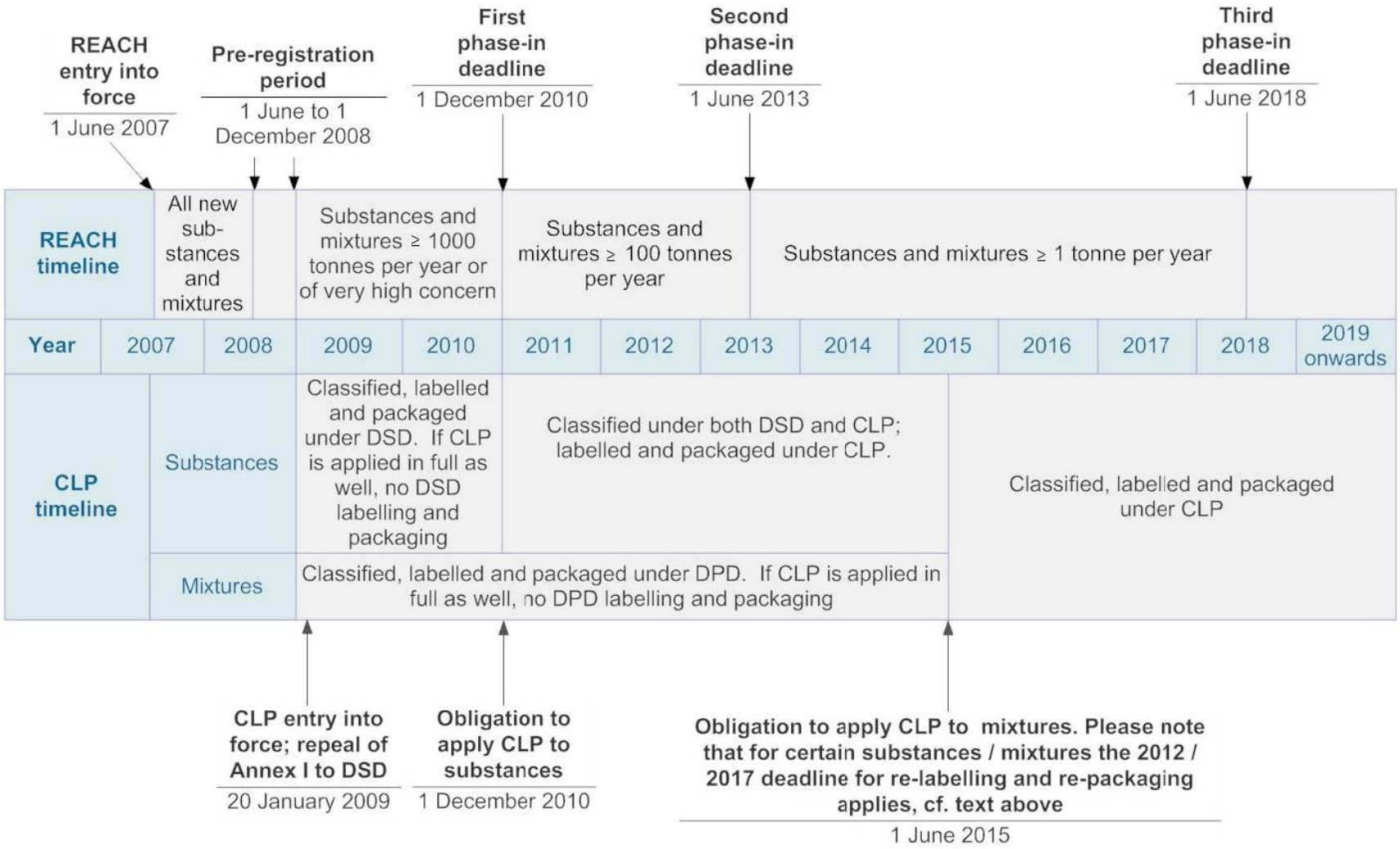

Figure 5. Timetables for REACH[IV] and CLP[III]. Illustration taken from Reference [1]

6.3.3 Conversion of a classification from DSD and DPD to CLP.

The gradual replacement of DSD and DPD with CLP is illustrated in Figure 5. As can be seen from the figure, the transition involves not only DSD and DPD on one hand and CLP on the other, but there is also a differentiation between DSD and DPD. Thus, DSD is to be phased out first, and DPD second. Thus, and for a few years, preparations (mixtures) may be classified according to DPD based on substances classified according to DSD, while at the same time the substances themselves will have to be classified according to both DSD and CLP.

There is, however, more to this conversion than what is apparent from Figure 5. Article 61, point 5, in CLP states the following "*Where a substance or mixture has been classified in accordance with Directive 67/548/EEC* [DSD] *or 1999/45/EC* [DPD] *before 1 December 2010 or 1 June 2015 respectively, manufacturers, importers and downstream users may amend the classification of the substance or mixture using the conversion table in Annex VII to this Regulation*".

The tables in Annex VII do actually convert a complete classification according to DSD and DPD intor one according to CLP, thus providing appropriate hazard classes, hazard categories, hazard pictograms, signal words, hazard statements and precautionary statements.

Such a transformation is not quite so straightforward, in general, however, as is apparent from the following taken from [34]: "*Although conceptually similar, the coverage of CLP and the DSD or DPD is different. In some places, there is a good relationship between the category of danger and corresponding R-phrases and hazard categories and corresponding hazard statements but in others, the relationship is less well defined. Additionally CLP introduces new hazard classes reflecting hazards that were not covered or only partly covered by DSD and DPD.*"

This means that since the intervals giving rise to certain classifications do not quite correspond to each other in CLP as compared to DSD and DPD, precision is lost in the translation. There are indications in the literature that the translation is precautionary, and therefore in general gives rise to a somewhat harsher result.

Please note that the following conditions apply to using the conversion tables in Annex VII:

"*When classifying in accordance with CLP, the use of the tables contained in Annex VII is optional. They can only be used to translate an existing classification provided that:*

- *the substance was classified according to the DSD before 1st December 2010 or the mixture was classified according to the DPD before 1st June 2015; and*
- *there is no data (scientific or technical information) for the substance or mixture available for an individual hazard class.*"

The second point has a direct relevance in relation to REACH. If tests are required according to REACH, and the results of those are of relevance for the classification, then the results must also be used in the classification. In this way, REACH might be proactive in relation to CLP. Relations between REACH reference, DSD classification criteria and CLP classification criteria can be found in Chapter 5 in Reference [23].

6.3.4 Conversion to CLP of the concept "dangerous" in DSD and DPD

The concept "dangerous" has a clear definition in DSD. Dangerous substances are to be labeled with symbols of danger, and no such symbol indicates that the substance in question is not dangerous.

This distinction between dangerous and non-dangerous substances is utilized in other European Union Directives such as the chemical agents directive[XV] and the old directive on hazardous waste[V] which both refer to DSD and the labeling with symbols of danger.

The new directive on hazardous waste[VII] also refers to DSD, but the remit version of the implementation into Swedish legislation of this directive refers to CLP (no detail is provided, however).

It has already been mentioned (cf Section 6.1) that REACH at present refers almost exclusively to DSD. It is intended, however, that REACH be updated in concordance with the transition from DSD and DPD to CLP. Reference [1] states the following:

"As the CLP rules for the classification of substances will be effective by 2010 and for mixtures by 2015, the relevant EU acts will have to be amended. To preserve their scope, they would have to refer explicitly to those CLP hazard classes and categories reflecting the previous scope of 'classified as dangerous' where there was previously a reference to 'classified as dangerous' under DSD/DPD. REACH has been amended in this way through CLP Article 58, with the exception of the rules for Safety Data Sheets where the concept of "hazardous" is introduced."

Thus, in order to foresee what will be required under REACH with regard to "*dangerous properties*", it is necessary to read Article 58 in CLP (and not REACH).

This might also be relevant for the division in the new ordinance of waste between hazardous and non-hazardous waste, cf Section 5.

It might have been tempting to assume that labeling with pictograms in CLP would contain the same classification as "dangerous properties" in DSD. Indeed, labeling with pictograms implies that the substances in question are hazardous in some (sometimes very minor) way.

However, the message in Article 58 in CLP is different. The text refers to a large number of combinations of hazard classes and hazard categories.

The above quotation suggests that the conversion from labeling with symbols of danger in DSD and DPD to certain hazard classes and hazard categories in CLP is intended to "preserve" the "scope" of the concept "dangerous".

A logical corollary to this is that the properties R52 (harmful to aquatic organisms) and R53 (may cause long-term adverse effects in the aquatic environment) should not render any classification corresponding to "dangerous" neither in the updated REACH, nor in the new Ordinance of waste. The reason for this is the difference between "dangerous properties" and "harmful properties", cf Section 6.2.

6.3.5 Self-classification and harmonized classification

The concepts of self-classification and harmonized classification of substances are explained in Reference [1]:

"*CLP includes provisions for two sorts of classification: self-classification and harmonised classification. If you are not familiar with these terms, 'harmonised classification' and 'self-classification' are described briefly below:*

***Self-classification**: the decision on a particular hazard classification and labelling of a substance or mixture is taken by the manufacturer, importer or downstream user of that substance or mixture, or, where applicable, by those producers of articles who have the obligation to classify, see Table 2.5 of section 2 of this document.*

The requirement to self-classify is set out both under DSD (and DPD) and CLP. Under CLP, manufacturers of substances, importers of substances or mixtures, producers or importers of explosive articles or of articles where REACH provides for registration or notification, downstream users including formulators (making mixtures) and distributors have to self-classify those substances that do not have a harmonised hazard classification, see below, or where a harmonised classification is available for selected hazards only. Mixtures must always be self-classified by downstream users or importers of mixtures. …

***Harmonised classification:** the decision on classification for a particular hazard of a substance is taken at Community level (see also section 22 of this guidance document). Harmonised classifications of substances are included in the Tables of Part 3 of Annex VI to CLP.*

The use of a harmonised classification and labelling of a substance is mandatory. It has to be applied by all suppliers of the same substance, i.e. by manufacturers of substances, importers of substances or mixtures, producers or importers of explosive articles or of articles where REACH provides for registration or notification, downstream users including formulators (making mixtures) and distributors. For around 8,000 substances harmonised classification and labelling were listed in Annex I to DSD. Upon entry into force of CLP Annex I to DSD was repealed. In order to take full account of the work and experience accumulated under DSD, all harmonised classifications as well as most of the specific concentration limits of substances listed in Annex I to DSD have been transferred to Part 3 of Annex VI to CLP: in Table 3.1 the substances are classified according to CLP while Table 3.2 contains the original classifications based on the DSD criteria.

Harmonised classification and labelling under DSD normally comprised all categories of danger. In future, harmonisation of classification will apply for CMR [Carcinogenic, Mutagenic and Reprotoxic] *properties and respiratory sensitisation. In addition, harmonisation of classification for other properties will be done on a case-by-case basis. Substances regulated under Directive 98/8/EC (BPD) on biocidal products or under Council Directive 91/414/EEC (PPPD) on plant protection products shall normally be subject to harmonised classification and labelling for all hazardous properties (CLP Article 36(2)). For further information see section 22 and section 24 of this guidance document.*"

The harmonized classification in Annex VI to CLP is related to the *classification and labeling inventory* that is administrated by ECHA. Manufacturers and importers are required to notify the ECHA of the classification and labelling of substance(s) placed on the market. ECHA will then include the information in a classification and labelling inventory in form of a database. Some of this information will be publicly available on ECHA:s website, including the substance name, the classification, labelling and any relevant specific concentration limit or M-factor (see Section 6.3.7). It will be indicated if there is a harmonised classification for the entry, or if it is an agreed entry between manufacturers or importers.

If there is no harmonized classification (and no classification given in the inventory) then self-classification will have to be made, see the next Section.

6.3.6 Self-classification of substances

How have chemical products usually been classified in the past? As substances or as preparations / mixtures? A simple search on the internet indicates that of all the classifications made, there are probably one to two orders of magnitude more classifications that have been made based on DPD (as preparations / mixtures) as compared to DSD (substances, including cases where mixtures have been tested directly and not through calculations based on the ingredients).

Preparations / mixtures have usually been evaluated mainly based on the so-called "bridging principles" (cf Section 6.3.7), i e that the danger / hazard has been evaluated based on some weighed average of the properties of the ingredient substances. The bridging principle does not apply to the evaluation of a substance. Bridging may in many cases not be sufficient for the full classification of a mixture, e g for physical properties, so other means, including tests and read across, may apply to preparations / mixtures as well as to substances.

Thus, the possibility to estimate the hazardous properties of a mixture based on the ingredients has been of paramount significance for making reasonably accurate assessments a manageable task. The specifics of classification of mixtures are presented in the next Section.

What will then apply in the case of self-classification of a substance (or a mixture) under CLP? Firstly, there is a requirement on identification and examination of substances and

mixtures, see CLP, Articles 5 and 6, respectively. Secondly, there is – when appropriate - a requirement on generation of new information, see CLP, Article 8. According to Article 7, special caution applies regarding tests on animals (see also Reference [XVI], and testing on humans is not to be conducted (results from historical testing may be used, however).

The following summation on the classification of a substance can be found in a guidance document from ECHA[34]:

"*The classification of a substance is based on the relevant information available on its hazardous properties. This information can include experimental data generated in tests for physical hazards, toxicological and ecotoxicological tests, historical human data such as accident records or epidemiological studies, or information generated in in vitro tests, (Quantitative) Structure Activity Relationships ((Q)SAR), "read across", or category approaches.*

CLP does not require new testing for the purpose of classification for health or environmental hazards; testing for physical hazards is required unless adequate and reliable information is already available. Although data may be provided through the application of REACH, it should be recognised that the data set required by REACH (particularly at lower tonnages) will not necessarily enable the comparison with the criteria for all hazard classes. Information may also be available from other EU legislation for which there are specific requirements for test data to be generated such as Directive 91/414/EEC (Plant Protection Products)29 and Directive 98/8/EC (Biocidal Products)30, or from various non-Community programmes. Finally, the supplier may decide to conduct new testing in order to fill data gaps, provided that he has exhausted all other means of generating information. Testing on animals must be avoided wherever possible and alternative methods (including in vitro testing, the use of (Q)SARs, read-across and/or category approaches) must always be considered first provided they provide adequate reliability and quality of data.

If, for the purpose of CLP, it is required or decided to generate new data, certain test methods and quality conditions must be met. Studies must be conducted in accordance with the EU test methods (Regulation 440/2008)31 or other international test methods validated according to international procedures such as those of the OECD. For physical hazards new tests shall be carried out (at least from January 2014) in compliance with relevant recognised quality system or by laboratories complying with a relevant recognised standard, and for health and environmental hazards in compliance with the principles of Good Laboratory Practice (GLP). Animal tests must comply with the Directive 86/609/EEC32. Tests on non-human primates are prohibited for the purposes of CLP. Tests on humans shall not be performed for the purpose of CLP. However, existing data obtained from other sources, such as accident records and epidemiological and clinical studies, can be used."

The EU regulation on test methods and the EU directive on good laboratory practice appear as References [XVII] and [XVIII], respectively.

Similar wordings can be found in article 8 in CLP itself (underlining by the present authors):

"*For the purposes of determining whether a substance or a mixture entails a health or environmental hazard as set out in Annex I to this Regulation, the manufacturer, importer or downstream user may, provided that he has exhausted all other means of generating information including by applying the rules provided for in section 1 of Annex XI to Regulation (EC) No 1907/ 2006, perform new tests.*"

Annex XI of the REACH regulation is provided in Appendix C. As can be seen in the Appendix, existing and available data should be interpreted and assessed using expert judgement. It is mentioned in Annex XI (see Appendix C) that ECHA will provide guidance with regard to Qualitative or Quantitative structure-activity relationship ((Q)SAR) as well as on grouping of substances and on the read-across approach. Such a document was published in May 2008[35] and excerpts from this document are presented below and in Appendix E.

QSAR stands for Quantitative Structure-Activity Relationship. It represents the relation between chemical structure and composition on one hand and the hazard to health and the environment on the other. It is mostly applied for complex organic molecules, but can just as well be used for ash.[21]

The following is presented in Section "*R.6.2.1.6 The interdependence between categories and QSARs*" in Reference [35]:

"*The chemical category and QSAR concepts are strongly connected. The concept of forming chemical categories and then using measured data on a few category members to estimate the missing values for the untested members is a common sense application of QSAR. The reason this concept is so compatible with QSAR is that this broad description of the categories concept and the historical description of QSAR are one and the same (see Figure R.6-4).*

A Quantitative Structure-Activity Relationship (QSAR) is a quantitative (mathematical) relationship between a numerical measure of chemical structure, and/or a physico-chemical property, and an effectpactivity (Figure R.6-4). QSARs often take the form of regression equations, and can make predictions of effects/activities that are either on a continuous scale or on a categorical scale. Thus, in the term QSAR, the qualifier quantitative refers to the nature of the relationship, not the nature of the endpoint being predicted. An example of a QSAR is the prediction of acute toxicity to an invertebrate species (Tetrahymena pyriformis) by means of a regression equation with the partitioning behaviour (log Kow value) of the chemical as a descriptor (Schultz et al, 2002).

Similarly, a Quantitative Activity-Activity Relationship (QAAR) is a mathematical relationship, but between two biological endpoints (Figure R.6-4), which can be in the

same or different species. QAARs are based on the assumption that knowledge about the mechanism or mode of action, obtained for one endpoint, is applicable to the same endpoint in a different species, or to a similar endpoint in the same species, since the main underlying processes are the same (e.g. partitioning, reactivity, enzyme inhibition). QAARs provide a means of performing trend analysis and filling data gaps."

The following is presented in Section "*R.6.2.2.1 Read-across*" in Reference [35] (see also Section 6.3.7 and Appendix E):

"*In the read-across technique, endpoint information for one chemical is used to predict the same endpoint for another chemical, which is considered to be similar in some way (usually on the basis of structural similarity). In principle, read-across can be applied to characterise physico-chemical properties, environmental fate, human health effects and ecotoxicity. For any of these endpoints, read-across may be performed in a qualitative or quantitative manner. In practice, read-across for basic physico-chemical properties is not generally recommended, since reliable data should normally be available or easily obtainable, does not involve the use of animals and provides key information for the assessment of a chemical. However, there may occasionally be practical problems, especially for UVCBs, when the use of these techniques will be required.*"

The following is presented in Section "*R.6.2.4 General guidance on a stepwise procedure to develop categories*" in Reference [35]:

"*Chemical categories accomplish the goal of obtaining hazard information through the evaluation of all available experimental data for the individual chemicals in the category, so that reliable estimates that are adequate for classification and labelling and/or risk assessment can be made without further testing of the individual members of the category. If there is sufficient experimental data to support the category evaluation that the chemicals in the category behave in a similar or predictable manner, then the relational features described in Table R. 6-5 can be used to assess the chemicals instead of conducting additional testing. If not, it may be necessary to: a) perform limited and targeted testing; b) revise the category hypothesis (and therefore the applicability of the category in terms of members and/or endpoints); or c) as a last resort abandon the category hypothesis.*"

The following is presented in Section "*R.6.2.5.3 Chemical reaction products and multi-constituent substances*" in Reference [35]:

"*Categories can be developed for series of chemical reaction products or multi-constituent substances (MCS) that are related in some regular fashion. As with categories based on discrete chemicals, in a category containing reaction products or MCS some, but not all, of the individual substances may require testing.*"

The following is presented in Section "*R.6.2.5.5 Complex substances (UVCB)"* in Reference [35]:

"*Complex substances include a diverse range of materials which are defined (see Guidance on substance identification) as substances of Unknown or Variable composition, Complex reaction products or Biological material (UVCB substances). The range of different types of UVCB is very wide and the specific properties may be diverse, such that the applicability of a common approach needs justification.*"

Section "*R.6.2.5.6 Metals, metal compounds and other inorganic compound*s" in Reference [35] is also of utmost interest for the appropriate and efficient classification of ashes. It is too long to be quoted here and is therefore provided in Appendix E instead.

Please note again that the guides quoted refer to Section 1 in Annex XI of the REACH regulation, and that CLP refers explicitly to the rules provided there. Thus, the material quoted applies equally and fully to REACH as well as to CLP.

It can also be seen from this material how the approach of the Programme on Environmentally Friendly Use of Non-Coal Ashes might be improved to a higher efficiency, and improved precision.

For completeness it should also be mentioned that there is also some material on "*The role and application of expert judgement and weight of evidence determination*" in Annex I, Section 1.1.1, in CLP. This material is quoted in Appendix D.

These information management strategies apply equally well to REACH and will therefore be referred to in the text on REACH, see Section 7.2.

6.3.7 Hazard evaluation and decision on classification for mixtures

Most of what was said in the previous section can be applied to mixtures as well. Mixtures can be tested for their hazardous properties in the same way as substances.

However, if the properties of the ingredient substances (or mixtures) in a mixture are known, many of the properties of the mixture can be obtained by bridging, cf Section 6.3.6. Application of bridging to a mixture may be sufficient to classify a mixture and to label it appropriately, but it can never convert a mixture to become a substance. A mixture becomes a substance only if all of the classification is based on testing of the mixture and / or read across, and no bridging is applied (cf DSD versus DPD).

It is assumed in the present section that information on the relevant substances have been obtained and derived, as appropriate, as described in the previous section.

In some cases, this information applies directly to the substances and mixtures in question. In other cases the information refers to ingredients (be they substances or mixtures). Article 9, Section 4 in CLP applies to this case:

"Where the criteria cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006."

Section 1.1.3 in Annex I tells that the bridging principles do not apply well to physical properties, but can be used in a few different ways for toxicity and ecotoxicity.

In Article 10, Sections 1 and 2, it is stated that:

"*Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.*" …"*M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by manufacturers, importers and downstream users.*"

(The term M-factors are described briefly below).

Cut-off values are presented in Table 1.1 in Annex I.

These limits and M-factors do not apply to harmonized hazard classes.

According to Article 14, the classification of a mixture shall not be affected if the mixture reacts slowly with atmospheric gases such as oxygen, carbon dioxide and water vapour to form different new chemical compounds at low concentration.

Acute toxicity is dealt with in Section 3.1 in Annex I. The simple description of the procedure there is that a weighed average over the various ingredients is used.

Special tables are provided for the management of skin corrosion/irritation and other potential detriments to man. The principles are similar to those applied in DSD and DPD, but the complexity is greater in CLP.

For ecotoxicity, a weighed average can be used as well. In cases where toxicity data is not available, so-called M-factors can be used. The supplier is obligated to supply them. Figuring using M-factors gives an approximately equivalent result as compared to that of a weighed average.

It should be noted that a weighed average will provide a considerably more correct estimate of the hazard for a mixture in cases where highly toxic substances are included. In DPD, these were given insufficient weight in relation to their hazard.

Bridging is not mentioned in REACH as it does not refer to substances, only to mixtures. Read-across resembles bridging somewhat, but applies preferentially to substances that are similar. Bridging as a principle can be assessed to be included in the expert judgement that is one of the basic elements of the Guidance on information requirements for REACH[35].

6.4 Discussion and analysis

It can be concluded that the strategies described in Reference [35] – and as quoted above and in Appendix D - concord surprisingly well[7] with those applied in the classification methodology developed by The Programme on Environmentally Friendly Use of Non-Coal Ashes that operates under the auspices of the Värmeforsk, cf Section 2.1.

The following should be particularly noted in the guidelines from ECHA[35] (as quoted more fully in Appendix D):

"*The water solubility of the metal compounds is often used as the starting point for establishing a category, as this provides a first indication of the availability of the metal ion in the different compartments of interest. For example, for inorganic nickel a number of sub- categories have been suggested, reflecting different ranges of aqueous solubility (Hart, 2007).*

The most simplistic approach to hazard evaluation is to assume that the specific metal-containing compound to be evaluated shows the same hazards as the most water-soluble compounds. This is a conservative approach, since systemic metal ion availability will normally be reduced with decreasing water-solubility and consequently reduced bioavailability.

This simplistic approach can be refined for categories containing many substances by building subcategories based on water solubility, when data is available on trends with water solubility. For example, mixed oxides with limited water solubility can be evaluated by comparison with the hazard profile for the metal oxides (where this is known) rather than for the soluble salts.

This difference in trend is clearly recognised in evaluating the environmental hazards of metals and metal compounds, where the relevant hazards can be evaluated using a transformation/dissolution protocol (OECD 2001).
…

The crystalline structure of insoluble metal compounds could influence the hazard profile. If there is reason to believe that the crystalline structure influences significantly the bioavailability and so the effects of the compound to be assessed, this must be taken into account in the evaluation. An example is the low bioavailability of spinels and rutiles."

[7] As will be apparent later in the present report, agreement is good also with REACH itself. However, the guidelines issued by ECHA extend beyond what is apparent from REACH alone, and this will be discussed in some detail.

The text cited is confirmed by the OECD report mentioned [36] as well as by the presence of iron in most ashes. For example, iron occurs in the form of spinel in municipal solid waste incinerator bottom ash at a level of around 10 %.[37] In most ashes, iron is around an order, or more, of magnitude more abundant than other transition and heavy metals.

However, these scientifically sound ideas from OECD do not appear to have disseminated appreciably into the waste classification society in Europe, see e g Reference [38], with the exception of the work by *Värmeforsk, The Programme on Environmentally Friendly Use of Non-Coal Ashes* and by *Swedish Waste Management*.[5]

7 REACH

7.1 Overview

The purpose of this overview is to provide enough background in order to make the subsequent material intelligible.

7.1.1 Background

The REACH regulation has been described as "*the most complex in EU history*"[8]. In combination with CLP, there are thousands of pages of legislation, a large part of which (not to mention the guidance literature) will have to be penetrated by anyone manufacturing or selling chemicals.

Why do we need this? The question has been answered by the European Commission in their document "*REACH in Brief. Why do we need REACH? ...* "[25] Much of the rationale for REACH is the same as for CLP, see Section 6.1, namely that "new chemicals (> the year 1981) have to be tested but there were no such provisions "existing" chemicals.

The pre-REACH allocation of responsibilities meant that it was the public Authorities that were responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import or use the substances. Since 1993, only 141 high-volume chemicals had been identified as priority substances for risk assessment.[25]

The former legislation required the manufacturers and importers of chemicals to provide information, but did not impose similar obligations on downstream users unless the substance had to be classified and a safety data sheet had to be supplied.

Moreover, the previous legislation implied that notification and testing had to be conducted for quantities down to as little as 10 kg / year. This constituted a barrier against research and innovation of new substances, and favoured us of "existing" substances over "new" ones, thus hampering the implementation of the substitution principle.

The progress of restriction of very hazardous chemicals was slow, and only an inadequately small number was restricted.

Thus, there was a need to "*improve protection of human health and the environment from the risks of chemicals while enhancing the competitiveness of the EU chemicals industry*", and this is the basic objective of REACH.[25] .

In the year 2001, the European Commission published a "*strategy for a future chemicals policy*"[26], and it constitutes the basis for the REACH (and CLP) regulations.

[8] "*EU's REACH chemicals law begins life in Helsinki*". EUobserver.com. 31 May 2007. http://euobserver.com/9/24169.

The document[25-26] puts forward seven objectives that needed to be balanced within the overall framework of sustainable. They are:

"• Protection of human health and the environment

- *Maintenance and enhancement of the competitiveness of the EU chemical industry*
- *Prevention of fragmentation of the internal market*
- *Increased transparency*
- *Integration with international efforts*
- *Promotion of non-animal testing*
- *Conformity with EU international obligations under the WTO"*
  [WTO = World Trade Organisation].

7.1.2 Basic elements of REACH

The basic elements of REACH have been described as follows[25]:

"*1. All substances are covered by the REACH Regulation unless they are explicitly exempted from its scope.*

2. Registration requires manufacturers and importers of chemicals to obtain relevant information on their substances and to use that data to manage them safely.

3. To reduce testing on vertebrate animals, data sharing is required for studies on such animals. For other tests, data sharing is required on request by other registrants.

4. Better information on hazards and risks and how to manage them safely will be passed down and up the supply chain.

5. Downstream users are brought into the system.

6. Evaluation is undertaken by the Agency for testing proposals made by industry or to check compliance with the registration requirements. The Agency co-ordinates substance evaluation by the authorities to investigate chemicals with perceived risks. This assessment may be used later to prepare proposals for restrictions or authorisation.

7. Substances with properties of very high concern will be made subject to authorisation; the Agency will publish a list containing such candidate substances. Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternative substances or technologies. If there are, they must prepare substitution plans, if not, they should provide information on research and development activities, if appropriate. The Commission may amend or withdraw any authorisation on review if suitable substitutes become available.

8. The restrictions provide a procedure to regulate that the manufacture, placing on the market or use of certain dangerous substances shall be either subject to

conditions or prohibited. Thus, restrictions act as a safety net to manage Community wide risks that are otherwise not adequately controlled.

9. *The European Chemicals Agency (ECHA) will manage the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that the legislation can be properly implemented and has credibility with all stakeholders.*
10. *A classification and labelling inventory of dangerous substances will help promote agreement within industry on the classification of a substance. For some substances of high concern there may be a Community wide harmonisation of classification by the authorities.*
11. *Rules on the access to information combine a system of publicly available information over the internet, the current system of requests for access to information and REACH-specific rules on the protection of confidential business information.*"

REACH stands for Registration, Evaluation and Authorisation of Chemicals.

Registration. Chemical substances that are imported or manufactures have to be registered. The registration is to be accompanied with compilation of existing data as well as a proposal for testing in order to determine a knowledge base for the safe and environmentally appropriate handling and use. Data sharing is required in order to reduce testing on vertebrate animals and to promote coherence in the identification of substances and in assessments of hazard and risk. Information is to flow forth and back in the supply chains. Specific obligations are put on downstream users so that risk analyses and instructions for safe use can be based on reality. Substances in articles also have to be registered if it is intended that they release substances.

Evaluation. The EU Competent Authority, the European Chemicals Agency, ECHA, also referred to as the Agency, evaluates the registration dossiers and the proposals for testing e t c received from the manufacturers and suppliers to check compliance with registration requirements on comprehensiveness as well as to prevent excessive testing on vertebrate animals. It is also the duty of the Agency to develop criteria for prioritising substances for further evaluation in cooperation with the Member States.

Authorization. For substances of very high concern, listed in Annex XIV, authorization is required before they can be placed on the market and used. Substances that may require authorization include CMR-substances (= carcinogenic, mutagenic and toxic to reproduction), PBT-substances (= persistent, bio-accumulative and toxic) as well as vPvB (= very persistent, very bio-accumulative). Such substances (included in Annex XIV) can only be used after authorization by ECHA, based on an application showing that the risks can be adequately controlled.

Restrictions. ECHA has the authority and task to define and implement restrictions on the use of chemicals as appropriate to protect human health and the environment. Substances of concern are included in Annex XVII. This is a supplement to the other prescriptions in REACH.

7.1.3 Registration

REACH applies primarily to substances. This can be found in Article 6, Point 1, which states : "*Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of one tonne or more per year shall submit a registration to the Agency.*"

This sentence may not be easy to understand. It means that unless something else is stated elsewhere in REACH, a manufacturer or importer of a substance is obligated to submit a registration to ECHA. It does not matter if the substance is traded as such or as an ingredient in a preparation (PDP) or a mixture (CLP)[9]. Quantities below one tonne per year do not need to be registered. The quantity in question is the quantity of the substance, regardless of whether the substance in question is traded as such or in a preparation or mixture. The quantity is to be counted per manufacturer or importer. According to ECHA guidance[39], these are identified to be the corresponding legal entities, e g in Sweden "aktiebolag" in a group (Swedish: "koncern") or in the Anglo-American nomenclature: limited stock company in a group.

According to Article 10, such a registration shall include the following:

"(a) a technical dossier including:

(i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;

(ii) the identity of the substance as specified in section 2 of Annex VI;

(iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;

(iv) the classification and labelling of the substance as specified in section 4 of Annex VI;

(v) guidance on safe use of the substance as specified in Section 5 of Annex VI;

(vi) study summaries of the information derived from the application of Annexes VII to XI;

(vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;

(viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;

(ix) proposals for testing where listed in Annexes IX and X;

(x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;

[9] As is specified in Section 1, a mixture of substances is called a preparation in DPD and a mixture in CLP.

(xi) a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests. Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

(b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories."

Point a(iv) refers to DSD and DPD and it can be foreseen that it will refer to CLP by the end of 2010.

In addition, safety data sheets are required for substances and/or preparations/mixtures that are dangerous / hazardous in the meaning of Article 31. Such a safety data sheet must be prepared in accordance with Annex II. It must also conform with the chemical safety report, cf point (b) in the above quotation.

The requirements on information vary considerably with annual quantity and intrinsic hazard (classification). The dependence on quantity is presented in Table 5. Annex II applies in all cases if the substance in question is dangerous / hazardous.

Table 5. Sources for information requirements for different annual quantities of the substances in concordance with Article 12 in REACH.

Annual quantity of substance, tonnes	Annex in REACH						
	I	**VI**	**VII**	**VIII**	**IX**	**X**	**XI**
1 – 10	yes	yes	yes*				yes
10 – 100	yes†	yes	yes	yes			yes
100 – 1000	yes†	yes	yes	yes	yes		yes
> 1000	yes†	yes	yes	yes	yes	yes	yes

* No information is required for substances that are not hazardous in the way defined in Annex III.

† The chemical safety assessments must also include exposure assessments and risk characterisations for substances having certain hazardous properties according to Article 14. This also applies to preparations/mixtures containing such substances.

Of these annexes, Annex I presents the general provisions for assessing substances and preparing chemical safety reports. Annex VI provides the general prescriptions on how to comply with the specific information requirements in Annexes VII – X.

7.1.4 Testing

Especially Annexes VIII – X call for what may well amount to a lot of testing. There is no direct reference to hazard as is the case for chemical safety assessment and chemical safety report. Neither is there any straight reference in all of REACH as to what test methods to apply.

The most concrete statements on what test methods to apply has been found in Article 13 point 3 which states the following:

"*Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate. The Commission shall adopt that Regulation, designed to amend the non-essential elements of this Regulation by supplementing it, in accordance with the procedure referred to in Article 133(4).*"

However, it is obvious from other sources that the tests in question are those in Reference [XVII], and at least this document (i e [XVII]) refers to REACH. (It does not refer to CLP which, however, refers to the regulation with test methods).

Strategy for testing should not be based solely on the regulation containing the test methods themselves[XVII] but also on the Directive on good laboratory practice[XVIII] and the Directive on protection of animals used for experimental and other scientific purposes[XVI].

The lists in Annexes VII – X should also be read together with the following statement which appears in the beginning of each of these annexes:

"Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q) SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated."

Annex XI states amongst other things the following:

"1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3) if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment;

(2) sufficient documentation is provided to assess the adequacy of the study; and

(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance."

In the present case of ash, the first question is whether existing data is sufficient in order for classification and labelling to be carried out, and this was dealt with in Section 6. The second question is whether the data available would support a proper risk assessment, and this is dealt with in Section 4.3. These issues are also included in the final discussions in this report.

Generally, Annex XI supplements and mitigates the long lists of tests in Annexes VII – X by pointing out different routs to obtain the data needed, e g grouping of substances and read-across. This is dealt with in Section 7.2.

It should be noted, cf above, that the registration documentation is to include what testing is proposed in accordance with Annexes IX and X. This proposal is to be reviewed by ECHA who then makes a decision on what testing is actually warranted.

7.1.5 Times for registration

Registration of a chemical substance can be carried out at any time, and such registration qualifies a manufacturer or importer to put the substance in question on the market.

Special rules apply to old substances and to the introductory stages of REACH. A general timetable for REACH and CLP is provided in Figure 5. A more detailed timetable is presented in Figure 6.

The REACH regulation provides for a special transition period during which certain substances – so-called phase-in substances - already on the market can be traded without interruption. Most of these substances can be expected to appear in the European Inventory of Existing Commercial Chemical Substances (EINECS). It comprises substances that existed on the market some time during 1971 – 1981. A detailed definition of phase-in substances can be found in Article 3.

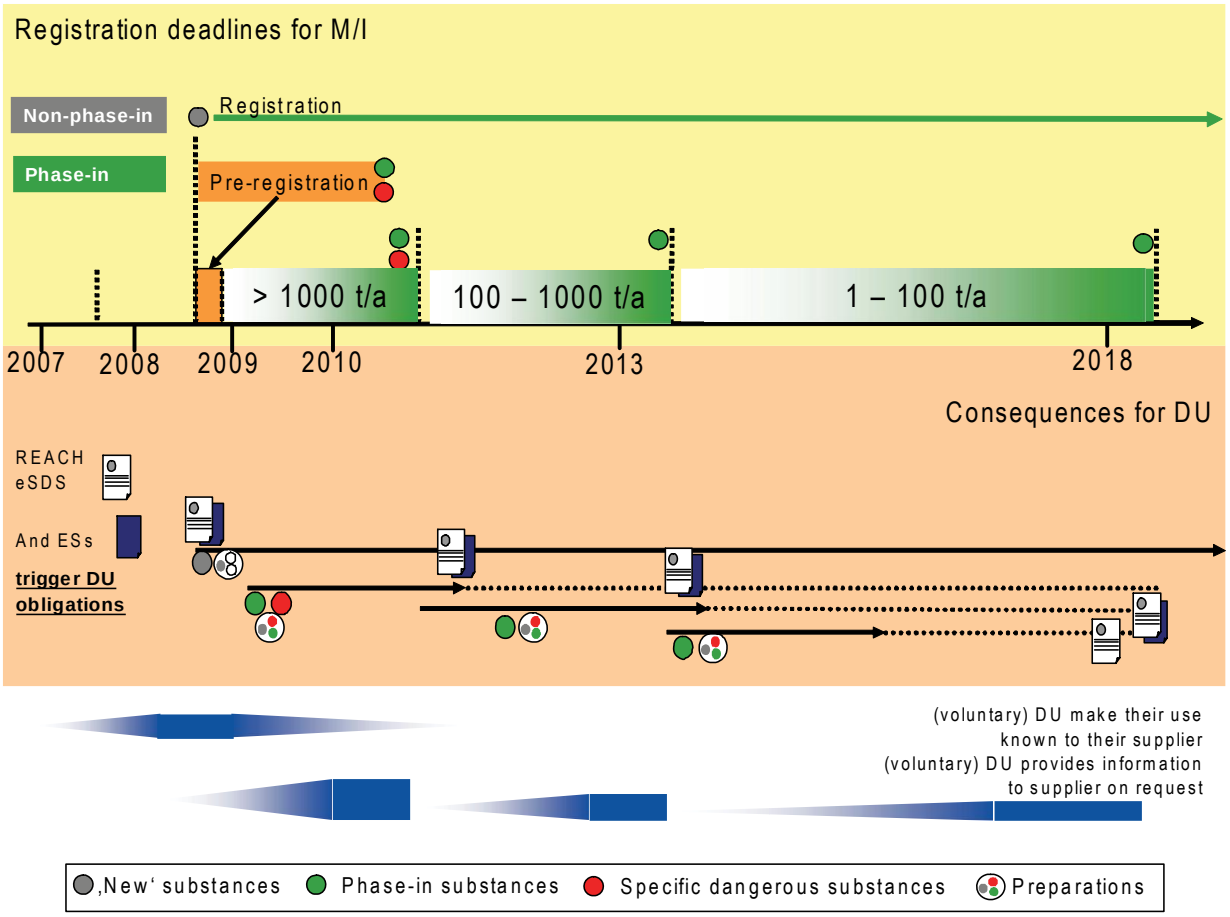

Figure 6. Detailed timetable for the introduction of REACH. Illustration taken from Reference [40]. Abbreviations: DU = Downstream User, ES = Exposure Scenario, SDS Safety Data Sheet, and t/y = Tonnes per year.

Substances notified according to DSD (after 1981) are excluded since they are considered already registered. They can be found in the data base ELINCS.

A pre-condition for the uninterrupted and smooth transition is that they were preregistered between June 1st and December 1st, 2008. A detailed definition of phase-in substances can be found in Article 3.

The timetables in Figures 4 and 5 apply to phase-in substances that have been pre-registered.

Non phase-in substances, will need a submission of an inquiry dossier (rather than a so-called technical dossier for pre-registered substances) in order for ECHA to determine whether a registration or another inquiry has already been submitted for the same substance so that data sharing mechanisms can apply. Only after the response from ECHA can a technical dossier be submitted and trade take place.

REACH has several provisions to facilitate the sharing of data between registrants. This reduces testing on vertebrate animals and costs to industry. Data collected through vertebrate animal testing must be shared, in exchange for payment. The main communication mechanism for phase-in substances is the establishment of the Substance Information Exchange Forum (SIEF) following pre-registration. For non-phase in substances the mechanism is the inquiry process.

The classifications submitted to ECHA in conjunction with the registrations will be entered into a database called the classification and labelling inventory. It shall be publically available. ECHA will oversee that the classifications of the substances in the database be harmonized.

7.1.6 Costs for registration

Fees and costs for registration can be found in the Värmeforsk report [20]. It estimates (in Table 12) that the testing required according to the list in Annex VIII (for 10 – 100 tonnes per year) amounts to a quarter of a million euro in the price level of the year 2006. The cost then goes up by a factor of two for each level, i e raises to up to half a million euro for 100 – 1000 tonnes per year and ends at around a million euro for above 1 000 tonnes per year. The cost for testing and reporting to ECHA is the dominating cost although the ECHA fees are far from negligible. See Reference [20] for further details.

Please note again that the tonnage intervals refer to substances, since that is what is registered under REACH. If multiple registrations are required in order to account for variations in composition and properties, then the strategy with regard to how substances are defined may be even more significant.

As will be discussed later in the present report, alternative substance definitions and registrations may have a large effect on the total need for testing. Since testing constitutes the dominating cost in most cases, alternative substance definitions are generally expected to have a profound effect on cost.

7.1.7 Current situation for registration of ash

The present situation with regard to preregistration and registration of ash is described in Reference [20]. The registrations are made based on EINECS numbers, and the presently considered and pursued alternatives are listed in Table 6.

The ash is registered as UVCB which is in accordance with the latest guidance from ECHA[27] It is possible that such registration of ash will suffice and that no supplementary registrations will be utilized. However, the purpose of the present work is to analyse the alternatives available for the implementation of REACH to ashes. Therefore, alternative possibilities are considered. It will become apparent later in the present report that some kind of basic registration of ash will be needed, but that it might be supplemented by other registrations in order to manage variability and impurities in an efficient manner.

Table 6. EINECS numbers for ashes. Data from Reference [20].

Substance	EINECS number	EINECS:s substance description
Ashes (residues)	268-627-4	The residuum from the burning of a combination of carbonaceous materials. The following elements may be present as oxides: aluminum, calcium, iron, magnesium, nickel, phosphorus, potassium, silicon, sulfur, titanium, and vanadium.
Ashes (residues) plant	297-049-5	The residuum from the burning of a combination of plants.
Slags, coal	270-708-4	Inorganic residuum from the combustion of coal.
SDA, Residues, calcium sulfate-contg., flue gas wet desulfurization neutralization	302-652-4	Residue rich in calcium sulfate obtained during the desulfurization of flue gases of bituminous coal or oil-fired boilers of power plants. Composed primarily of calcium sulfate with chlorides, fluorides, trace element oxides as well as pure gas dust components from the combustion process.

7.2 Substances and preparations / mixtures

7.2.1 Introduction

REACH is about substances, and it is substances that are to be registered under REACH.

According to Article 3 in REACH "*substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition*".

REACH relates to preparations / mixtures only in conjunction with downstream communication where the use of a substance is to be specified. In such cases the use often implies that a substance is incorporated into a preparation / mixture, in which case the use of that entity will have to be analysed and reported.

According to Article 3 in REACH, a "*preparation means a mixture or solution composed of two or more substances*"

As was mentioned in Section 1.2, preparation means (about) the same as mixture. The word preparation is used in DPD while the word mixture is used in CLP. The present version of REACH refers to DPD and DSD and thereby also to preparations. By the end of the year 2010, REACH will instead relate to CLP, at which time it can be expected that the word preparation in the text will somehow be replaced with mixture.

7.2.2 The difference between substances and preparations / mixtures

It was mentioned already in Section 1.2 and 1.4 (see also Sections 6.3.6 and 6.3.7) that it is important to fully realize the difference between substances and preparations. It is even more important to keep this difference in mind when REACH is to be implemented to ash.

A preparation / mixture can be classified and labelled according to DPD and CLP, respectively, but this does not convert any preparation or a mixture into a new substance.

Thus, the "bridging principles" in CLP (cf Sections 1.4, 6.3.6 and 6.3.7) cannot be applied to a blend of chemical compounds in order to obtain the data related to hazardous properties needed for registration as a substance under REACH. This is the case even if the chemical compounds in the blend are registered as substances and classified as such according to CLP.

However, a blend of various substances might be characterized through testing and read across (cf Sections 1.4, 6.3.6 and 6.3.7) such that the classification is made based on the results obtained. Then the blend is no longer just a mixture of various substances but can actually be considered to have become a substance.

A certain type of ash can thus be regarded as either a substance, in which case test results on the material itself[10] will have to be available for the classification as well as for the risk analysis. In this case it is the ash that has to be registered as a substance.

A certain type of ash can also be regarded as a preparation / mixture, in which case the constituent substances will have to be registered. An example of such a mixture would be a basic ash with no impurities together with a few oxides of elements that are of concern with regard to health and environment (see further below).

Since testing is costly and since unnecessary testing on certain animals is forbidden, it is essential that multiple testing on the same substance be avoided as far as possible. This is the basis for the statements in REACH on SIEF:s (SIEF = Substance Information Exchange Forum). A number of rules apply to SIEF-related work (cf Article 29 in REACH), but that is outside the scope of the present report.

Avoidance of multiple testing presupposes that sameness of substances can be assessed in a harmonized manner. Sameness of substances is also essential for the classification and labelling register that is being instituted by ECHA. Cf Section 7.2.4.

The concept of substance is discussed in detail in the ECHA *Guidance for identification and naming of substances under REACH*, see Reference [41].

[10] Possibly, data of constituents might be used as well, but only if the test results apply to the ash as a whole, and without applying the bridging principles in CLP. Read across is appropriate, however.

This guidance brings to mind the struggle that the contemporary scientists and "chemical engineers" in the metal beneficiation industry had in the mid-eighteenth century on what are the basic elements of chemistry, see e g Reference [42] which covers the general areas of chemistry without any chemical formulas (that the metals were elements was discovered during the first decade of the 19th century)[43].

It actually helps for an inveterate chemist to attempt to distance himself somewhat from some of the basics of chemistry because REACH is legislation and not science, at least not primarily science.

But first a few words about the relation to science, see the next section.

7.2.3 Science and mixed oxide preparations

REACH makes statements such as "*without affecting the stability of the substance or changing its composition*", cf the quotation from the definition on substance above. It can also be concluded from REACH that an alloy can be regarded as a preparation and the constituent metals as substances. This can be concluded from Annex I where it is stated as follows:

"When assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account."

This raises the fundamental question as to when chemical bonding takes place and when interaction is merely some kind of association distinguishable from chemical bonding.

It is at least sometimes assumed that the rate of reaction is closely related to the bonding energy. In general, there is probably also some co-variation between rate of reaction and bonding energy. But there are very many examples of rapid reaction with little or no energy difference between the initial and end states, and with essentially no reaction even where the energy difference is considerable.[11] Actually it is the energies associated with the so-called reaction co-ordinate, which can be summarised to an activation energy, that (together with the relevant parts of the phonon spectrum) dictate the rate of a reaction.

Similar arguments apply to types of bonding. Generally, covalent bonding is considered less susceptible to reactions than ionic bonds. This is however, strongly related to the medium or solvent, where our most common solvent water favours ionic and dipolar reactions.

No fundamental chemical reason can be found for differentiating between on one hand alloys, which can be preparations, and on the other hand mixed oxides, which are not

[11] If thermodynamics alone would dictate labelling, then moist air would be dangerous since nitrogen, oxygen and water are unstable in relation to nitric acid.

explicitly mentioned as preparations in REACH. They are mentioned, however, in the documents associated with CLP, as mentioned in Section 6.4.

The most credible and irreproachable partitioning of any piece of matter - as presented first by Berzelius and others[43] – is that into the elements (those that appear in the periodic table). This is not mentioned in REACH, however. Nonetheless, for inorganic substances (chemical compounds), analysis of risk based on the constituent elements is not only scientifically sound but also constitutes the generally accepted route for reliable and cautious estimate of the associated risk. This is dealt with in Section 7.7.

The issue of whether metal oxides in solid solution can be regarded as separate substances is also dealt with in the ECHA draft *Guidance on waste and recovered substances*[27] that was published at the final stages of editing of the present report. It states the following in its Section 2.4.2 (see Appendix G for context): "*However, in case glass is specifically selected for the presence of certain pigments, those pigments should also be considered as separate substances for which the exemption according to Article 2(7)(d) has to be checked, even if they are present in smaller quantities than 20%(w/w).*" It is also mentioned in the same paragraph that glass frit is an UVCB substance.

The quotation means that the pigment substance, which is a recovered substance, will have to be registered under REACH unless it has been registered before and the following applies (quote from Article 2 in REACH:

"(d) substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery."

Obviously, ECHA[27] in the above statement views the glass frit as a mixture / preparation comprising two substances: the glass frit without the pigment oxide and the pigment oxide (typically a transition metal oxide). Again according to ECHA[27], glass frit with or without the pigment oxide can be regarded as a UVCB substance. Thus, the glass frit consists of oxides in solid solution, where – according to ECHA - different oxides or mixtures of oxides can be regarded as different substances. No constraints are mentioned in the ECHA draft guideline[27] regarding the previous history of the glass frit, and it is therefore reasonable to assume that such history is irrelevant. This contradicts other statements by ECHS where a reaction product containing different chemical compounds must be regarded as a substance, cf Section 7.2.6.

It is mentioned in Section 7.5.3, that the glass frit itself is exempted from REACH.

Of all the examples encountered in the present work, this case is the one that most closely resembles and reflects the situation in ash.

It is concluded that no reason can be found not to regard mixed oxides of metals as preparations / mixtures just as metals in an alloy (which is explicitly mentioned in REACH) and as auxiliary oxides in a glass frit (as in the just mentioned example). Moreover, it was found in Section 6.4 that there is "official" support for regarding mixed metal oxides as preparations. This is therefore assessed to be valid in the following. This conclusion is in concordance with the regulations REACH[IV] and CLP[III], while the guidance from ECHA may be inconsistent.

However, the same precautions apply as those already cited above from what was said about alloys in Annex I, namely that *"the way the constituent substances are bonded in the chemical matrix shall be taken into account."* This has been considered throughout in the work conducted in the Programme on Environmentally Friendly Use of Non-Coal Ashes carried out under the auspices of Värmeforsk, as is apparent from References [2-7,11-12].

7.2.4 Sameness

A substance is frequently thought of as consisting of organic molecules of one kind with covalent bonds within the molecules, and dipolar and van der Waals bonds between the molecules. Indeed, most substances registered in the data bases EINECS and ELINCS are of this nature. When chemistry has become more complex, substances with less simple chemical composition have also been registered as substances, e g oxides with mixed oxidation numbers and mixed oxides.

A first prerequisite for assessment of sameness is to define the unique characteristics of a substance. This is presented[12] in REACH, Annes VI, point 2:

"2. IDENTIFICATION OF THE SUBSTANCE

For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCs number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

[12] This text from REACH, Annex VI is quoted in the Guideline in which reference is made alternatively to Annex VI (correct) and Annex IV (incorrect). Annex IV deals solely with certain exemptions from registration and has nothing to do with how a substance is to be specified and identified under REACH.

2.2.1. Molecular and structural formula (including SMILES notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

2.3. Composition of each substance

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (… ppm, … %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced."

In practice, variability plays a very important role. The variability is most likely very different among different substances that are registered. Furthermore, the significance of the variability for the potential harm to man and environment is highly variable depending on the precise nature of the variation.

Consequently, ECHA has issued some guidelines for "*identification and labelling of substances under REACH*"[41] and some important elements are presented in the subsequent Section.

7.2.5 Well defined substances and UVCB:s

According to Reference [41], a substance can in most cases be identified by its chemical composition, chemical identity and the content of each constituent (cf items 2.1, 2.2 and 2.3, respectively, in the listing above). For other substances, additional identification is required.

Reference [41] thus divides substances into the following two groups:

"1. 'Well defined substances': Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex IV item 2.

2. 'UVCB substances': Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified by the above parameters.

Variability of composition for well defined substances is specified by the upper and lower limit of the concentration range(s) of the main constituent(s). For UVCB substances the variability is relatively large and/or unpredictable.

It is recognised that there will be borderline cases between well-defined substances (reaction products with many constituents, each within a broad range) and UVCB substances (reaction products with variable and poorly predictable composition). It is the responsibility of the registrant to identify a substance in the most appropriate way.

Rules for identification and naming differ for "well defined substances" with one main constituent and for substances with more than one main constituent. And for the various substance types under the umbrella of "UVCB", different identification and naming rules are described."

Further detail is provided in e g Tables 4.1 and 4.2 in Reference [41]. The following is of special interest to ash:

Well defined substances typically fall into one of the following categories:

1. *Mono-constituent substances.* Main constituent ≥ 80 %, maximum level of impurities 20 %.
2. *Multi-constituent substances*. A mixture of main constituents each ≥ 10 % and < 80 %.
3. *Substances defined by more than the chemical composition* (e g graphite and diamond). Chemical composition as mono- or multi-constituent substance AND other physical or characterisation parameters: e.g. crystallomorphology, (geological) mineral composition, e t c. Important parameters for identification include name, source and process.

UVCB substances include "*Chemical and mineral substances with poorly defined, complex or variable composition (UVC)*" under which heading "*Concentrates or melts, e.g. metallic minerals, or residues of various melting or metallurgic processes, e.g. slags*" can be found. ECHA also recognizes that there will be borderline cases between well-defined substances and UVCB substances and that it is the responsibility of the registrant to identify the most appropriate substance group.

In its guidance [41], ECHA points out that "*This grouping of substances with identification and naming rules should not be considered as an official categorization system for substances, but as a practical help to apply the specific rules suitably and to find the appropriate guidance in this TGD*".

This is interpreted to imply the following for ash. If the implementer has no reason to categorize otherwise, then the ECHA structuring ought to be followed. However, the need for efficiency in the registration and risk assessment may warrant other structuring. That should also be acceptable to ECHA provided that the reasons are explained.

The ECHA guidance [41] states the following on the requirements on identification:

"All constituents (except additives) which are not the main constituent(s) in the mono-constituent substance or a multi-constituent substance are considered to be impurities. Although in some sectors it is general practice to use the term 'traces', only the term 'impurities' is used in this TGD.
The different constituents have different identification requirements:

- *Main constituents contribute to the naming of the substance and each main constituent shall be completely specified by all relevant identifiers;*
- *Impurities do not contribute to the naming of the substance and need only to be specified by name, CAS-number and EC-number and/or molecular formula.*
- *Additives contribute to the substance composition (but not to the naming) and should always be fully identified."*

ECHA[41] is also aware of and open for the possibility to refer to registrations of individual constituents:

"In general, recording the identity of substances for the purpose of (pre)registration should follow the multi-constituent substances approach (i.e. registration of the multi-constituent substance). As a deviation from that approach, individual constituents can be registered, if justifiable. The possibility to deviate from the standard case to identify (and potentially register) substances by their individual constituents is given, when

- *there is no reduction in information requirements;*
- *there is sufficient existing data to justify the approach of registering the individual constituents i.e. the approach should normally not instigate additional (vertebrate animal) testing compared to the standard approach;*
- *registering the individual constituents leads to a more efficient situation (i.e. avoiding numerous registrations of substances which are composed of the same constituents);*
- *the information on the composition of the individual reaction masses is given."*

The difference between the alternatives can be illustrated with the following example. Assume that a district heating facility has combusted wood having a contamination with Cuprinol. Cuprinol was a commonly used agent for protecting wood against attack by microorganisms. It comprises a solvent together with a copper salt of certain organic acids that are generated as bi-products in the refinement of crude oil. When wood from demolition of buildings and other structures is sorted before it is used as a fuel it is very difficult to avoid the last traces of contaminants. Thus, the ash from the facility in question is assumed to be contaminated with copper. The element copper appears in an oxide form of valence II. Since the abundance is low, copper does not form any phases of its own but is included in other oxide phases in the form of solid solution. As concluded above, this is equivalent to an alloy, and a decision has to be made by the implementer as to how this material is best reported to ECHA.

(It is further assumed that the ash in question has attractive properties such that the district heating facility is recurrently approached by various firms urging them to make this product commercially available to them through registration under REACH).

So far, the following alternatives can be identified for the district heating facility:

a To register the ash as a UVCB

b To register the ash as a mono-constituent substance[13]

c To consider the ash as a preparation / mixture and to register

   1 ash from the same source but with such sorting that no copper is present in the ash, and

   2 to register copper oxide

In a simple interpretation, all tests have to be made in cases a and b, and double registrations and associated tests have to be made in case c. However, if new ash is generated during the subsequent season, registration according to c may prove most efficient since it may be applied also if the composition of the ash is different. Furthermore, data on copper oxide may be openly available in the literature or possible to share from someone else at moderate cost. Alternatives a and b also contain possibilities for improved efficiency in comparison with measuring everything in that existing literature data or data from a SIEF might be used.

This interpretation might be disputed based on some wordings in Reference [41], and this is dealt with in the next Section.

It might be added here that, again according to Reference [41], the following applies regarding the information on chemical composition:

"For multi-constituent substances, the chemical composition is known and more than one main constituent is relevant for the identification of the substance. Furthermore, the chemical composition of the substance is predictable, as typical values and ranges. The main constituents shall be specified completely by all relevant parameters. The sum of typical concentrations for main constituents (≥ 10%) and impurities (< 10%) shall be 100%.

Impurities present in a concentration ≥ 1% should be specified by at least one of the following identifiers: chemical name, CAS-number and EC-number and/or molecular formula. Impurities that are relevant for the classification and/or PBT assessment shall always be specified by the same identifiers, independently from their concentration.
…

For a UVCB substance, all known constituents, present at concentrations ≥ 10% should be specified by at least English IUPAC name and preferably a CAS number; the typical

[13] Since the pure ash constituent amounts to more than 80 %. The copper oxide is a minor constituent or an impurity.

concentrations and concentrations ranges of the known constituents should be given as well. Constituents that are relevant for the classification and/or PBT assessment of the substance shall always be identified by the same identifiers, independently from their concentration."

7.2.6 Can a chemical process generate more than one substance?

The very vast majority of chemists would regard the question in the title above as at best redundant, but more likely as unenlightened. Of course, a chemical reaction in general can generate a multitude of substances. However, this is another example of when knowledge about chemistry might lead astray, or at least impede proper attention to an important issue. Remember, REACH is legislation, cf Section 1.5.

The ECHA *Guidance for identification and naming of substances under REACH* [41], under the heading "7.3 MIXTURE OF ISOMERS" maintains the following (on the example of a *"methanolic solution that contains 'zolimidine' (EC 214-947-4; CAS 1222-57-7, $C_{14}H_{12}N_2O_2S$) and 'imidazole'(EC 206-019-2; CAS 288-32-4, $C_3H_4N_2$)"*.:

"*The substance in question is a mixture (reaction mass) of two isomers formed during the manufacturing reaction. The individual isomers were reported for EINECS. Directive 67/548/EEC regulated the placing of substances on the market. As the production manner of the substance was not significant, the mixture was covered by the EINECS entries of the two individual isomers. REACH requires the registration of manufactured substances. It is a case by case decision to establish to what extent the different steps conducted while producing the substance are covered by the definition of 'manufacturing'. If the isomer mixture is registered as a multi-constituent substance (following the guidance of Chapter 4.2.2), there is no need to test the substance as such, if the hazard profile of the substance can be sufficiently described by the information of the individual constituents. However, reference should be made to the EINECS entries of the individual isomers to demonstrate the phase-in status.*"

As is apparent from the text, ECHA may decide on "*a case by case*" basis whether products from a reaction may or may not be regarded as consisting of more than one substance.

The recently published ECHA "*Guidance on waste and recovered substances"* states the following in its present draft form[31]: "*The term 'mixture' is limited to blends which are not the result of a chemical reaction*". This quote is taken from Section 2.2.3 under the heading "*Substances on its own or in mixtures*". The context can be found in Appendix G in which much of the material in Reference [31] is quoted.

The same view is put forward in Sections 7.16 – 7.18 in Reference [23]. (The opposite view is put forward by ECHA in Section 2.2.3 in [31], see Section 7.2.3).

How would this apply to the case of the Cuprinol mentioned in the previous section? A possible scenario would be that the solvent in the Cuprinol vaporized soon after the application of it. With time, the organic constituents in the Cuprinol degraded to mainly

carbon dioxide and water, and the copper was left behind in an oxide form. Then the wood with its content of copper in its oxide form was combusted and the copper – still in oxide form – went into solid solution with the other oxide components in the ash. If the above quotation was to be interpreted draconically, the ash together with the copper in oxide form in solid solution must be regarded as one substance.

If enforced in a general way, the statement would have a paramount influence on the chemical industry. It would lead to probably several or maybe even many times more registrations than otherwise judging from the fact that there are at present 10 – 100 times more classifications based on DPD as compared those based on DSD.

The issue has not been left unobserved by the chemical industry that has responded openheartedly. Thus the internet magazine Chemicalwatch[14] has pointed out the consequences of a draconic application of the statement quoted above.

In Chemicalwatch[15] Rolf Schneider, Consultant, formerly at Siemens, concludes that *"This* {the above quoted interpretation by ECHA[41][16]} *would mean that according to the guidance, a mixture of substances (in this case of isomers) would have to be named differently and registered, depending on the manufacturing process. Irrespective of the fact that both are identical mixtures of substances (and both are called "mixture" in the guidance), only the latter mixture of previously separate isomers could be seen as a preparation, while the other mixture, formed from a chemical reaction, would be regarded as one substance - namely a "multiconstituent substance*.

In this exclusivity and absoluteness, this is certainly an overly narrow interpretation of the REACH Regulation. As expounded above, the REACH Regulation contains no restrictions concerning the type of manufacturing process in which substances and preparations can be obtained and no restrictions concerning the number of substances resulting from a manufacturing process.

According to the definition in Article 3 no. 2, all mixtures of substances (i.a. also mixtures of isomers) can be regarded as preparations.

Practically, the ECHA guidance also denies the manufacture of substances directly in preparations, even though this is expressly provided for by the REACH Regulation in Articles 5, 6 and 86. Moreover, the rule of the guidance that substances occurring in mixed form (e.g. after the manufacturing process) are not preparations ignores the fact that Article 3 no. 2 does not require intentional blending for a mixture to be a preparation.

For this reason, the rules of the ECHA guidance would considerably restrict the flexibility given in the REACH Regulation."

[14] See http://chemicalwatch.com/dr_reach

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[16] The draft guidance on waste and recovered substances was not available at that time.

Further material from Chemicalwatch is provided in Appendix F.

It can be added that the ECHA interpretation quoted early in this Section also is (at least potentially, depending on how it is generalized) in conflict with what is said in Annex XI about grouping of substances and read-across approach which is incapacitated and nullified if substances cannot be defined in accordance with their individual properties. In addition, article 25 in REACH states that "*In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort*".

If any difference is detected between the REACH regulation itself and the guidance offered by ECHA, it is always the regulation that one must follow.

It is therefore assumed in the following that the quotation in the beginning of the current Section is not applicable to ashes. Thus for the purpose of the present report, a chemical process, including combustion, incineration and metals beneficiation, can generate one or more substances. These substances can be registered under REACH and classified as such under DSD and CLP. In the case that the implementer considers that several substances are formed in a process, bridging can be used to determine the classification (according to DPD and CLP) of the corresponding blend (i e the blend can in this case be regarded as a preparation / mixture).

The definition of the substances is to be made in such a manner that the goals of REACH - a high level of protection of human health and the environment – can be reached as fully and as efficiently as possible.

For the case of the ash containing copper, see the previous section, it is up to the implementer to determine which alternative best serves the purpose of REACH, one substance of ash containing copper or two substances, one with ash without copper and the other with copper oxide. In the second case the implementer has to show that this representation is cautious in relation to the first case.

It might be added that Reference [41] makes no mentioning of ash. The word slag appears a few times, but in a confusing manner since it is mentioned as "containing varying amounts of metals that may be extracted by metallurgical processing". The common perception in metals industry is that slag is a by-product obtained when a metal is being isolated.

7.3 Articles

Articles in conjunction with recycled material is also dealt with in Section 7.4.

According to REACH, Article 3, the word article "*means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*".

Article 7 in REACH states the following:
"1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use."

The only application of ash known to the authors where release is intended is when ash is recycled to the forest. As described in Section 5, this clearly is a recycling of waste under the new directive of waste[VII].

In this case, the ash is waste until it reaches the ground in the forest. After that the ash is recycled to form part of the soil. Soil is exempt under REACH.

It is clear from the citation above (and with the exception of recycling of ash to the forest) that if an ash would be considered to be an article it would not have to be registered under REACH.

Materials intended for geotechnical construction purposes should by the very meaning of the word "geotechnical construction" often be considered to be articles. Functioning could include mechanical strength in a specific shape, filtering, drainage and tightening against water flow.

In order to illuminate this issue, the ECHA *Guidance on requirements for substances in articles*[44-45] have been consulted, both the official version from May 2008[44] and a draft new version[45]. The draft new version states the following:

"2.3.1 Sets of objects

According to Article 3(3) of the REACH Regulation an article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. This implies that the shape, surface or design must be deliberately determined and given during a production step. In this sense, the "production step" of an article can also be understood to include the assembly of the components (which can themselves be articles) of a complex article (e.g. a car). A set of objects that are merely put (or "collected") together to be supplied does not have a particular production step during which a specific shape, surface or design is given to the set. Therefore a set of objects (e.g. a cookware set consisting of different casseroles and pans) cannot be regarded as one article, but has to be regarded as many articles.

2.3.2 Small and 'simple' objects

Media for sandblasting, milling media, toner beads and other products can consist of relatively small and 'simple' objects. These small and 'simple' objects have in common

that they are not used individually (i.e. as one object) but in larger numbers to fulfil their function. A counterexample would be a microchip or a miniature screw which are used as single objects to fulfil their respective function.

The REACH Regulation defines an article as an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. Hence the definition stipulates that to be considered as an article an object needs to have a particular function that it can fulfil as a single object. Furthermore it can be concluded that the article definition is not based on a size limit or minimum degree of complexity below which an object could no longer be regarded as an article."

A consequent application of the "simple objects" principle announced above in this draft guidance document would indeed exclude many of the items that we use in everyday life and that we certainly do not regard as substances. For instance, according to the principle minted, balls intended to be used in a bearing would have to be considered as a substance eligible for registration under REACH even though the chemical composition is not important for the function.

The conclusion in the present report is therefore that many ashes must be considered to be articles according to the definitions in the REACH regulation itself.

However, the phrasing in the draft guidance documents indicates that it may be difficult to foresee how such an approach would be regarded by the Authorities.

Another conclusion is that since the REACH regulation is so recent, it may take some time before the various details are in place and results of Authority reviews of material submitted can be foreseen with ordinary precision.

Somewhat different views have been put forward by the European Commission[19] as well as by ECHA[27] in conjunction with articles and recycled material, see Section 7.4.3. This information does not change the above conclusions, however.

7.4 Residues, by-products and waste

7.4.1 Is recovery a manufacturing process?

Substances, preparations and articles that fall under the waste directives[V-VII] are exempt from the REACH legislation. As described in Section 5, the new waste directive implies that much of what has been regarded as waste in the past will now be regarded as products, many of which will fall under REACH.

The bulk of the present work was carried out before ECHA published its "*Guidance on waste and recovered substances*"[27], and its content become available to the present authors only during the final stages of the editing of the report. This document has therefore been read and analyzed somewhat in retrospect. However, content of interest

has been incorporated in the text of the present report. Also, much of its content has been quoted in Appendix G.

Nonetheless, much of the text in the present report builds on older documents, notably the draft "staff position"[19] document circulated by the European Commission. Many of the thoughts expressed there have been reiterated in the very recent ECHA guidance.

The document discusses whether or not recovered substances need new registrations, and concludes that this may not be required if a substance recovered is the same as that put into circulation. In such cases the organisation that carries out the recovery is requested to obtain safety data sheets, registration number and other information from a registrant. The information need not come from the same supply chain.

In other cases, the substances have been modified during the recovery process. Reference [19] refers here to Article 3 in REACH where manufacturing is defined as "*production or extraction of substances in the natural state*", and concludes that "*substances that have undergone a chemical modification during the waste and recovery process (e.g. certain slags, fly ash, creation of methane during 'feedstock recycling' of polymers) clearly fulfil this definition*".

Although cases can be found where a substance initially registered under REACH progresses essentially intact (in oxide and mixed oxide forms) all the way from manufacturing and to the ash, this is not always the case.

Moreover, wood-based fuel, consisting almost exclusively of wood and other cellulose fiber based material such as paper is assessed to be exempt from REACH according to Annex V, point 8 and Annex IV (cellulose pulp). Since substances of interest from a health and environment point of view only occur as trace impurities in the fuel (but enriched albeit still at low levels in the ash), their presence is not expected to alter the exemption for the fuel. Thus, the "chain of custody" under REACH is assumed to be lost in the case of impurities in the ash originating from e g paint and impregnation residues in the fuel.

The conclusion is that combustion and incineration are manufacturing processes and that the products are to be regarded as substances (unless they are waste or exempt, see below). Since these substances are new substances, it is the duty of the manufacturer / recycler to do all the work associated with the obligations under REACH.

This conclusion is in concordance with Section 2.2.1 in the "*Guidance on waste and recovered substances*"[27], see Appendix G.

7.4.2 Transfer of information on hazardous properties

This last conclusion in the previous Section ought to be discussed together with what was said in Section 5 on transfer of information to a recycler. It was found there that on one hand, under REACH, a producer of a substance might be allowed to keep certain test documentation secret whilst legislation in accordance with the polluter pays and

sustainable development principles may require that such information be forwarded to recyclers.

Various transition and heavy metals are included in various products and constructions. Sooner or later most of them end up in the waste. Swedish legislation does not allow landfilling of organic (i e combustable) waste which is instead recycled either through digestion or composting (or both), or through combustion or incineration. More than 50 % of the domestic waste in Sweden is incinerated, and the very most of wood-based waste is recycled as fuel for combustion. Sludge from reprocessing of paper is also combusted.

It is generally acknowledged that the best way to avoid hazardous substances in the waste is to avoid them at the source, and the waste management society is probably very grateful for REACH in this regard.

The issue of responsibility for hazardous substances in waste is dealt with also in other legislations. The Swedish Environmental code[XII] states that everyone is required to possess the appropriate knowledge in order to protect health and environment. It also states that it is the polluter that must pay for all costs associated with remedial actions and waste management. This principle is substantiated in the Directive on environmental liability[XIII] with regard to the prevention and remediation of environmental damage. In addition, one of the cornerstones of REACH is that information should be forwarded down the chain of custody of a batch of a substance.

Altogether, this implies that it is those who produce heavy metal compounds and put them on the market that also ought to supply at least the data needed in order to use simple oxides as reference substances. [17] This is somewhat in conflict with statements in REACH which allow registrants to keep test reports secret, thus making it impossible (or at least difficult) for others to use their results.

Combustion and incineration of recycle fuels is not only a realisation of the principle of conservation, but also implies that most of any hazardous components in the fuel become destroyed. Any potentially harmful biological or organic compounds in the fuel are typically completely converted to harmless reaction products. Thus, a great service is provided – from a polluter pays principle perspective - to those that put such potentially harmful substances in circulation. Only heavy metals remain in the ash, and often in a form such that they are relatively inaccessible to man and the environment. The heavy metals in recycled fuels do no good for the combustion process and provide no benefit in conjunction with utilisation of ash. Their only effect is that they add complexity to the qualification process and may be potentially harmful to man and the environment.

It therefore appears appropriate that - unless information on e g simple oxides of elements in question is already openly available - data needed be requested from either

[17] This thought is also in concordance with the various EU Directives on producer's responsibility (94/62/EC about packages, 2000/53/EC about vehicles, 2002/96/EC on electrical equipment, and 2006/66/EC on batteries; see also Swedish regulation on radiation sources, SFS 2007:193).

the manufacturers or ECHA. Recycling should not be regarded as something that competes with practices including exhaustion of natural resources, but rather is a natural element of closing the cycles.

Reference [19] also brings up the important question of impurities in recycled material as well as their variations, and puts forward the following:

"Recovered substances may contain impurities which may distinguish them from corresponding materials not deriving from recovery processes. This is in particular the case when recovered materials contain unintended constituents which have no function for the recovered material and the only reason for their presence in the recovered material is that they were part of the input waste for the recovery process. The content and nature of such unintended constituents may vary significantly from batch to batch (e.g. in time and location). Full knowledge of the exact composition in each such case may require substantial analytical efforts. While such constituents may have originally been intentionally added as substances to form a preparation, their presence in the recovered material may be unintended (depending on whether these constituents have a specific function or not) and therefore, they can be considered as impurities, which do not require separate registration.

Constituents present in quantities above 20%(w/w) should, however, in general not be considered as impurities but as separate substances in a preparation. However, in the case that recovered material is intentionally selected for the presence of certain constituent(s), those constituents should also be considered to be separate substances, even if they are present in smaller quantities than 20%(w/w) (e.g. if PVC is selected for the presence of softeners, it may be necessary to register these softeners, unless they have been registered before)."

It is important in this regard that sameness can be maintained even if the classification of different sources and batches may differ, as apparent from the following:

"It should be noted that variations in the composition and the impurity profile, including a variation in the percentage of impurities, do not necessarily mean that substances are different. According to the guidance on data sharing, 'for substances with a well-defined composition (i.e. mono-constituent and multi-constituents substances) the sameness of the naming is in principle sufficient to be able to share data even though certain impurities might lead to a different classification/hazard profile. Only in cases where all data is clearly not suitable for the other substance these substances can be regarded as different (e.g. in case of very different physical properties which have essential impact on the hazard properties, like water solubility).

For UVCB substances also – in general - the name is leading to determine the 'sameness'. If the name is the same, the substance is regarded the same, unless available data shows the contrary.' "

The above messages are reiterated in the just published ECHA *Guidance on waste and recovered substances*[27], see long quotations in Appendix G.

7.4.3 Recovered aggregates

Articles for which release of substances is not intended fall outside REACH. In Section 7.3, the invention by ECHA of "simple objects" (which does not exist in the REACH regulation) was presented and it was concluded that although the ECHA advice would hardly hold in a court, it nonetheless creates uncertainty and prompts unjustified caution.

However, the view put forward by ECHA in Section7.3 is obviously not shared by the staff at the European Commission, as is apparent from section 3.1.5.2 on "*Recovered aggregates"* in their draft memorandum[19]. The memorandum has been received by ECHA who have used it as a basis for their recently published draft *Guidance on waste and recovered substances*[27]. The texts on "*Recovered aggregates*" are very similar and the ECHA version can be found in Section 2.4.4 in Appendix G.

In its draft guideline, ECHA regards aggregates from construction as articles. Obviously, ECHA has to stretch itself here since they motivate their obligingness as follows: "*This exceptional application of the article definition is justified by the fact that a large fraction of the recovered aggregates originating from construction contain mainly stones and reacted concrete that do not require a registration*".

The text also says the following:

"Recovered aggregates from construction consist of concrete, natural stones, masonry and/or asphalt, either alone or in certain cases mixed. They can have diverse applications, such as in civil engineering works, in roads and as railway ballast. The main function of this application is to provide stability and resistance to degradation/fragmentation. If for this function the shape, surface or design is more important than the chemical composition, the recovered aggregates would in line with one of the decisive elements to be considered as articles."

The conclusion here is that no reason has been found to modify the conclusion in Section 7.3.

7.5 Exemptions from REACH

7.5.1 Introduction

The main exemption of interest in conjunction with ash and ash utilization is if an ash is considered to be waste under the Hazardous Waste Directive.[VII] This is dealt with in Section 5. It is assumed in the following (as well as in all of Sections 6 and 7) that the ash is not exempt under this directive.

Materials exempt from registration under REACH are listed in Annexes IV and V.

It has already been concluded in Section 7.4.1 that fuel comprising wood, paper and paper sludge is exempt since wood is a substance that occurs in nature according to Annex V and cellulose pulp is listed in Annex IV.

The issue of whether or not ash can be regarded as exempted will be dealt with in the following.

7.5.2 Naturally occurring substances

According to Annex V in REACH, substances are exempt from registration if they are "*substances which occur in nature*" provided that they are not hazardous.

No formal guidance document has been found on exemption, but here exists a draft guidance document on Annex V[46] and it provides the following examples that relate to this issue:

"Note that the exemptions in points 7 and 8 do not apply to synthetic versions of the substances described in the relevant sections as such substances do not meet the definition of substances which occur in nature.

The following examples illustrate circumstances under which a substance does or does not meet the requirement of substances which occur in nature, if they are not chemically modified.

Example 1:
A substance is obtained in accordance with a steam distillation process of the leaves from Mentha arvensis. The chemical analysis of the Mentha arvensis extract thus manufactured indicates that this substance consists of several stereo-isomers including the constituent (-)-menthol (i.e. (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexanol). All the constituents in the substance were originally present in the leaves. This substance fulfils the requirements for substances which occur in nature, if they are not chemically modified.

Example 2:
The substance isolated in example 1 is further processed by crystallisation in water and ethanol to isolate (-)-menthol. Although the process did not result in the chemical modification of the substance within the meaning of Article 3(40), the isolated substance is not a substance which occurs in nature any longer and therefore does not fulfil the requirements for substances which occur in nature, if they are not chemically modified.

Example 3:
The substance isolated in example 1 is heated solely to remove water. Upon heating, a fraction of the (-)-menthol constituent decomposes. Although the isolated substance fulfils the definition of a substance which occurs in nature, it has been chemically modified and therefore does not fulfil the requirements for substances which occur in nature, if they are not chemically modified.

Example 4:
A multi-step synthesis is used for the manufacturing of (-)-menthol. Although this substance consists of the same constituent as the one found in the leaves of Mentha arvensis, it is not a substance which occurs in nature and does therefore not fulfil the requirements for substances which occur in nature, if they are not chemically modified."

It is obvious from the above that ECHA in its draft document maintains that sameness of the substances is not sufficient for a substance manufactured to be exempted even if its chemical composition is identical to that of a substance actually excavated from e g a mine.

The issue of naturally occurring substances is of paramount importance in industry in general. For instance, the tens of millions of tonnes of iron ore that are mined each year in northern Sweden by LKAB comprise magnetite. During the process of converting the dressed ore into pellets, the magnetite is oxidized to hematite. Both magnetite and hematite occur in nature.

Not surprisingly, the issue has been identified by Eurometaux, the European Association of Metals, who write the following in one of their fact sheets[47]:

"4. An Apparent Mismatch – Synthetic Minerals

- *The ECHA Guidance for the identification and naming of substances (RIP3.10) states that minerals that are produced through a manufacturing process can – for the purpose of identification - be regarded to be the same as their naturally occurring equivalent, provided the composition is similar and the toxicity profile identical. An example would be the synthesis of haematite from magnetite ore.*
- *This implies that the legal requirements (e.g. exemptions from registration) for minerals produced through a manufacturing process and fulfilling the above mentioned conditions are also the same as those for their naturally occurring equivalent. However, no confirmation of this is currently available."*

In the case of ash it can be concluded that it would be exempted if it were generated by uncontrolled processes in nature. However, the process by which ash is generated in a furnace is identical to that in a forest fire. The only difference is that the fire in a furnace is better controlled which leads to less partially combusted matter and consequently less PAH (PolyAromatic Hydrocarbons) and better for health and environment. Thus, there are reasons to regard combustion and incineration as natural processes giving rise to the natural material ash.

There is no statement in REACH that would contradict an interpretation to the nature that sameness of substances as well as processes is sufficient for exemption. It is concluded that ash from combustion and incineration is the same substance as the ash from a forest fire. It is also concluded that ash in both cases is generated by identical processes. No technical or scientific reason can therefore be found to exempt one and not the other. Therefore, ash from combustion and incineration should be exempted from registration in accordance with Annex V.

This position does not appear to be accepted by the Authorities, however.

This raises the question as to how a material might need to be characterized order to qualify for exemption under Annex V in REACH. No information has been found on this issue, however.

7.5.3 Clinker and glass frit e t c

Annex V in REACH mentions a modest number of substances that are exempted from registration under REACH. No rationale is provided regarding the basis of the selection of just this small number of substances out of the many hundreds that might appear just as warranted from a chemical and engineering perspective.

Thus, cement clinker and glass frit are exempted while ash and slag are not mentioned.

A close resemblance exists between cement clinker and blast furnace slag in that the temperatures are comparable and the major elements are the same. The main difference is that the content of calcium is significantly higher in cement clinker which renders contact water much more alkaline and corrosive as compared to blast furnace slag. A similar comparison can be made between wood ash and clinker although the temperatures during generation are somewhat different and the difference in alkalinity is somewhat less. Both blast furnace slag and many ashes comprise high levels of glassy components, thus showing sameness with glass frit.

No support has been found in REACH to the nature that exemption can be assessed based on the same principles that apply to QSAR, grouping of substances and read across, cf Annex XI. If that had been the case, ash and slag might be considered exempt.

The lack of mentioning of ash together with the views on the nature of slag maintained in Reference [41] contrasting to that established in the metals industry, cf Section 7.3.5, might suggest that the very limited number of substances mentioned as exempted in Annex V might be related to insufficient information exchange on the significance of e g ash and slag.

The conclusion in this report is that ash can not be regarded as exempt from the REACH regulation on grounds of similarity with clinker and glass frit, at least not at the present time.

It is important that exemption of substances under REACH be made in such a way that the principles are understandable for chemists and engineers, and so that compliance with European Union regulations can remain trusted and unquestioned.

See Section 7.2.3 regarding whether glass frit can be more than one substance.

7.6 Product and Process Orientated Research and Development

Article 9 in the REACH regulation has the title: "*Exemption from the general obligation to register for product and process orientated research and development (PPORD)*". It states amongst other things the following:

"*1. Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.*

2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:

(a) the identity of the manufacturer or importer or producer of articlesas specified in section 1 of Annex VI;

(b) the identity of the substance, as specified in section 2 of Annex VI;

(c) the classification of the substance as specified in section 4 of Annex VI, if any;

(d) the estimated quantity as specified in section 3.1 of Annex VI;

(e) the list of customers referred to in paragraph 1, including their names and addresses.

The notification shall be accompanied by the fee required in accordance with Title IX. The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3. The Agency shall check the completeness of the information supplied by the notifier and Article 20(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned. The Agency shall also communicate this information to the competent authority of the Member State(s) concerned.

4. The Agency may decide to impose conditions with the aim of ensuring that the substance or the preparation or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a preparation or article and that remaining quantities will be re-collected for disposal after the exemption period. In such cases, the Agency may ask the notifier to provide additional necessary information."

The regulation in itself is quite clear, and no interpretation appears to be needed.

One question is, of course, to what extent utilisation of wood-based ash should be regarded as *product and process orientated research and development.* It is very obvious for anyone that has been involved in the Programme on Environmentally Friendly Use of Non-Coal Ashes executed under the auspices of Värmeforsk that any geotechnical construction project in Sweden that involves the utilization of ash also includes considerable research and development work. Not least is it imperative not only to predict the impact on health and environment but also to determine the actual impact once the geotechnical installations are completed, cf Sections 4.4.

PPORD is therefore assessed as fitting excellently into what in many cases is the current situation for utilization of ash for geotechnical purposes (and regardless of REACH). However, UVCB may be more appropriate in cases where the pertinent methodologies have already been fully developed.

Support for selection of the PPORD alternative also arises from the fact that REACH is a large and new legislation where a number of important aspects are not yet fully resolved. It can be expected that the ash community should take part in and contribute to such a process, but there should be some proportionality of such engagements in relation to the quantities of material in question and their hazardous properties. PPORD would allow time for such research and development activities to take place that are needed for the appropriate implementation with regard to ash of REACH[IV] as well as CLP[III] and the new directive on waste[VII].

7.7 Approach on hazard estimation

The general idea in REACH is that the hazardous properties for the various substances in a preparation must be evaluated, the use of the preparation is described, scenarios for exposure to man and the environment identified and risk assessment carried out. Such risk assessments should then be utilised to provide appropriate safety data sheets.

Corresponding analyses have already been carried out for ash, see Section 4.3. It was found that the properties of the ash (be it regarded as a substance or a preparation) itself might be directly influencing the consequences for the case of oral intake.

For oral intake – including intake as a result of dusting - it was assumed that all of the transition elements as well as the heavy elements in the ash were available and taken up by the organism in question (human).

This is a generic, but quite a pessimistic approach, and precision might be improved using batch-specific data on properly aged ash.

Most of the scenarios dealt with leaching from a geotechnical installation through soil and into a nearby well from which members of a critical group took water for domestic purposes including their gardening. (The garden was also exposed to dust from the installation). In this case, the initial release was related to the leaching properties of the aged ash. The transport to the well had little to do with the chemistry of the ash, and this

was then of course also the case for the uptake from the water. This part of the analysis dealt with the respective elements and their speciation in a soil environment.

The analysis was generic with cautiously selected transport parameters. Thus, substantial improvement in precision can be obtained by using site specific data, or even better, empirical data from a similar installation.

Annex XI states amongst other things that existing data shall be considered to be equivalent to new data if the following conditions are met: :

> *"(1) adequacy for the purpose of classification and labelling and/or risk assessment;*
>
> *(2) sufficient documentation is provided to assess the adequacy of the study; and*
>
> *(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance."*

From the above and from the description in Section 4.3, the conclusion is drawn that best available methodology has been used and that this is in concordance with the quotation above from Annex XI.

8 General discussion and conclusions

8.1 Proportionality principle aspects

The analyses so far have dealt with the actual content of REACH and related European Union legislation as well as associated guidance documents. But it is also warranted to look for what might be missing or dealt with inadequately.

It might be tempting to identify considerations regarding costs as missing, judging e g from the way in which ECHA sometimes puts forward that a reaction product must be regarded as a substance (see Section 7.2.6).

The Swedish constitution[XIX] as well as the Swedish ordinance governing public administrations including competent authorities[XX] clearly state that there must be a proportionality between requirements in the legislation and the anticipated effected.

The same applies in the European Union, where there are agreements between the member states on certain basic principles that are to be followed in all work including lawmaking and issuing of guidance documents. It is outside the scope of the present work to go into this in any detail. The European Union has, however, published a glossary at one of their websites[18], and some of the brief explanations of basic principles are quoted in Appendix H.

In concordance with the principle of proportionality, the European Commission as well as ECHA have carried out a number of related analyses, and the reports can be downloaded from their respective webb sites. The overall conclusion from these studies is that the benefits to health are larger than the costs for implementation.[21]

A brief search in this material has unveiled little cost/benefit related analysis of recycled material, and none on such material in conjunction with the idea of viewing all chemically modified recycled batches as new substances under REACH. Instead, the following reservation has been found regarding the applicability of the proportionality principle analyses to at least certain types of recycled materials, see Section 6.5 in Reference [48]) The study was monitored by a multi-stakeholder group that included trade unions, environmental and consumer NGOs and that was chaired by the European Commission.

"Energy recovery and materials recycling in cement production. Due to the limited expected price increase (due to direct costs of REACH), fly-ash and blast-furnace slag is still likely to be used as a secondary raw material. However, the potential impacts can be considerably more important given that companies generally use different alternative raw materials from several suppliers.

[18] See http://europa.eu/legislation_summaries/glossary/index_en.htm.

It is unclear to the participating companies in the (in)organics study and the companies participating of the sector workshop whether all secondary raw materials/fuels are exempt from the scope of REACH or whether they are totally or partly included in the scope of REACH.

Under the precondition that waste is assumed not to be exempt from REACH, strict REACH requirements could limit the European trend of high-quality recycling and recovery.*

**The broken information chain (the link between the material/substances used in the first-time production of an article is lost once the final consumer discards the article and the article is collected for recycling/recovery) in the recycling/recovery of secondary raw materials/fuels complicates registration."*

No statement that directly relates to the issue of proportionality has been found in the ECHA draft *Guidance on waste and recovered substances*[27].

It is therefore concluded, that although the issue of proportionality has received considerable attention in general, no incidence of consideration has been found in conjunction with such recovered material that undergoes modification of its chemical structure during recovery. ECHA considers that such changes occur for ash[27].

According to some of the statements made by ECHA (cf Section 7.2.6) this view implies that any ash would have to be registered as a substance. Since different ashes have different properties, and precision is needed for adequate utilization, registration costs may well be prohibitive. The alternative of registering the constituents of ash may offer a far superior efficiency, thus promoting health and environment as well as economy and recycling.

It is obvious, cf Section 7.2.6, that regarding a chemical reaction product as a single substance will be of paramount importance for a highly variable by-product such as ash from combustion and incineration. It will require testing that may well be an order of magnitude or more higher than otherwise, i e when the rules for preparations / mixtures are applied.

If any difference in precision is to be identified with regard to health and environment in the present report it is that the preparation / mixture alternative is better since it is much more adaptable with regard to the variations.

As elaborated on above, no justification has been found for the highly increased cost and inefficiency for solely applying the substance only alternative. Thus, attempts to uncritically implement the principle that any reaction product must be regarded as a substance is a breach not only of the statements in REACH (cf Section 7.2.6), but also against one of the cornerstones of European Union as well as Swedish national legislation, namely the proportionality principle.

It will be left to the reader to judge for her- or himself regarding the compatibility with some of the other principles, e g the principle of simplification of legislation, c f Appendix H.

8.2 Summary of conclusions

It was found in Section 5 that the new European Union framework directive on waste has clear definitions to the nature that much of what presently is regarded as waste may in the future be regarded as by-products and fall under REACH (waste is exempt from REACH). However, it is presently unclear how the Directive will be implemented into Swedish legislation. Since it is also unclear how REACH will apply in the case of ash (see below), it is concluded in the present report that generators of ash and their branch organizations ought to keep both alternatives open.

Prerequisites for regarding ash as a by-product include that the ash can be used in the form that it is generated and that there exists a market.

Using waste for land treatment is regarded as a recovery operation. It is assessed that using ash as a fertilizer to forest falls in this category.

It was found in Section 6 that according to DSD and DPD, the classification of a substance as dangerous is related to the substance in question having dangerous properties. Consequently, a substance having only harmful properties is not dangerous according to these directives.

For substances, there is, in principle, always the possibility to test according to certain requirements. However, restrictions apply in CLP as well as REACH to testing on humans and animals, and a number of techniques are available for making appropriate assessments without new testing, including read across. Much of the requirements on knowledge is the same in CLP and REACH.

For the case of preparations / mixtures, bridging can be applied. It is based on knowledge about the substances in the preparation / mixture and constitutes a very efficient way in which danger / hazard can be evaluated.

Application of bridging does not “convert” a preparation / mixture to a substance. It only implies that the preparation / mixture in question can be evaluated with regard to the various dangerous / hazardous properties that are relevant for the labelling.

Neither of DSD, DPD and CLP puts any restrictions on what may be regarded as a preparation other than it must comprise two or more substances. For instance, a manufacturer is free to regard a reaction product as either a preparation or a substance. This flexibility is very important for the efficiency of the classification, and thus enhances substantially the possibilities for compliance. However, the ECHA draft guidance is ambiguous on this issue.

In Section 6.4, reference is made to OECD work, referenced by ECHA, in which the properties of metal oxides in solid solution were modelled using simple oxides. This corresponds closely to the approach taken since many years by Värmeforsk through the Programme on Environmentally Friendly Use of Non-Coal Ashes.

The REACH regulation (cf Section 7) differs from other European Union regulations, e g CLP, in that it is not only a regulation, but also a negotiation protocol and an experiment. Consequently, ECHA has issued a number of guidance documents in order to clarify what may be requested. In some cases these guides go beyond what is actually requested in REACH and there are also occurrences of contradictions in these guidance documents.

The most important issue for the registration of ash under REACH is whether an ash – if viewed as a reaction product – can be regarded as either one or several substances, as most appropriate with regard to the efficiency and precision in the evaluations and assessments of danger / hazards. The various ECHA guides have been scrutinized with regard to this issue and it has been found that ECHA is ambiguous. Nothing has been found in the REACH regulation itself that might question this interpretation, and it is instead supported by REACH in that various methodologies should be applied in order to avoid unnecessary testing of humans and vertebrate animals.

A related question concerns whether ash in which the various elements of interest appear as oxides in solid solution can be regarded as a preparation / mixture. Comparison with alloys and glass frit, as well as the above mentioned OECD report on mixed oxides, indicates that it is indeed compatible with REACH as well as the ECHA guidance to regard ash as a preparation / mixture also from this point of view.

Since fuel consisting of virgin wood, recycled wood or waste does not fall under REACH, the chain of custody is lost for the heavy elements and transition elements in ash. REACH endorses forwarding of information down the chain of users but it is also possible in some cases for a supplier or importer to keep data secret. At the same time, basic principles for sustainable development as well as the polluter pays principle and the principle of equity between generations indicate that necessary information should be forwarded. Part of the rationale for such forwarding is also that the impurities in the ash have no positive role, neither at the combustion / incineration facility nor for the ash recycler.

If the shape is more important than the chemical properties, then the entity in question is an article. Articles for which it is not intended that they release substances are exempt from REACH. Crushed debris from cement and brick structures are articles according to ECHA, but it cannot be taken for granted that e g sand from fluidized beds or crushed bottom slag will be regarded in the same way.

Naturally occurring substances as well as a few other substances are also exempt from REACH. The exact meaning of “substance that occur in nature” is not defined in

REACH. It appears that ECHA interprets this to mean that the material in question must actually have been generated totally without any influence by man. Ash occurs in Nature where it is formed by recurrent forest fires. In addition, ash in a furnace is produced in exactly the same process. Nonetheless, it cannot be taken for granted that ash is a natural substance.

Other exemptions include cement clinker and glass frit, but not ash. No information has been found as to on what grounds a certain type of substance can become exempt. From general considerations based on what may contribute to dangerous / hazardous properties, as well as on other examples on what apparently warrants exemption, no reason has been found why ash should not be exempt. A prerequisite for such exemption would of course be that the ash in question is not dangerous / hazardous. It might be added that REACH does not state that exemptions may be granted on a case by case basis, only that certain types of material are exempt.

According to ECHA[19], substances can be registered under REACH as well defined substances or as UVCB's. UVCB stands for s*ubstances of Unknown or Variable composition, Complex reaction products or Biological materials)*

Well defined substances typically fall into one of the following categories:

1. *Mono-constituent substances.* Main constituent ≥ 80 %, maximum level of impurities 20 %.
2. *Multi-constituent substances*. A mixture of main constituents each ≥ 10 % and < 80 %.
3. *Substances defined by more than the chemical composition* (e g graphite and diamond). Chemical composition as mono- or multi-constituent substance AND other physical or characterisation parameters: e.g. crystallomorphology, (geological) mineral composition, e t c. Important parameters for identification include name, source and process.

UVCB substances include "*Chemical and mineral substances with poorly defined, complex or variable composition (UVC)*" under which heading "*Concentrates or melts, e.g. metallic minerals, or residues of various melting or metallurgic processes, e.g. slags*" can be found.

ECHA puts forward in its advice that it is appropriate to consider ash as UVCB. The preregistrations of ash made so far follow this guidance.

It is important in this context to consider what features and variations may influence hazards and precautions. In a typical case for a bulk chemical, it is the "active substance" that is of main interest, and impurities are less important. In the case of ash, it is the other way around, namely that the ash itself (e g from virgin wood) is essentially harmless for health and environment, but that it is the impurities that may be of interest.

[19] REACH itself makes no mentioning of well defined substances, mono-constituent substances or multi-constituent substances. UVCB is mentioned only once in REACH.

The impurities in the ash originate from impurities in the fuel (e g paint) and show very large variations in character and abundance.

Consequently, any potentially dangerous / hazardous properties of an ash may be best described by the impurities, preferably accounted for as separate substances. Thus, none of the ECHA distinctions is tailored to fit the profile of ash.

Perhaps mono-constituent substance is most suitable if ash (the real ash, with impurities) is regarded as a substance with a main constituent in the form of a (hypothetical) pure ash, and the impurities of interest are included as separate oxide type of compounds (simple oxides in the least complicated cases). The pure ash constituent (without impurities) could also be regarded as a substance, either a UVCB or a multi-constituent substance. (Alternatively, ash with impurities could be regarded as a substance, either a UVCB or a multi-constituent substance.)

Alternatively, ash with its content of impurities could be registered as a UVCB, and divisions be made depending on the levels of the various impurities.

What really matters is how many substances that need to be qualified and perhaps also tested extensively, because it is such qualification that is associated with the highest costs. It is absolutely essential in this regard that variations in impurity content in the ash can be dealt with also by bridging. Thus, it must be possible to regard the ash as a preparation / mixture.

REACH recognises that it may not be practical to provide all the data on such chemical products that are under development. It is understood that this is not only needed for laboratory scale synthesis and similar, but also for development and testing on a large scale. The alternative in question is called PPORD which stands for "Product and Process Oriented Research and Development". PPORD's are exempt from REACH on a case by case basis, after application and as decided by ECHA. The longest period possible is two times five years for substances placed on the market.

At present, many geotechnical projects of any significance in which ash is used are associated with substantial research and development work. Exceptions to this include but are not limited to geotechnical applications at landfills, in which cases ash may be regarded as waste anyway.

Moreover, it can be hoped that uncertainties regarding how REACH is to be applied to recycled materials will decrease with time. The alternative PPORD will thus serve the double purpose of allowing for research and development work on ash applications, including how best to comply with the REACH legislation, as well as for regulatory development to take place.

The development work associated with large projects includes making measurements to understand transport and environmental impact. It is recognized since long that the appropriate approach for inorganic substances such as ash is to regard the elements

involved. This approach is well in concordance with using the approach of solid solution and to regard the impurity elements as simple oxides. It is imperative in this regard, however, to check the chemistry such that it can be shown that the approach applied is indeed cautious.

One of the main principles underlying any legislation is the proportionality principle. No advantage has been identified in the approach of regarding any ash as one substance. Draconic implementation of such a principle may easily cost an order of magnitude more as compared to a situation where the generator of the ash can decide on whether a particular ash is one substance or a mixture of substances.

It is concluded that the methodologies developed by Värmeforsk through the Programme on Environmentally Friendly Use of Non-Coal Ashes regarding impact on health and environment as well as on assessment of dangerous / hazardous properties are suitable to pursue when qualification of ash under REACH is to be achieved. No discriminating factors have been identified, but there exists a substantial uncertainty as to how REACH and CLP are and will be interpreted by the Authorities.

9 Suggestions for further work

9.1 A conceivable scenario

Since the purpose of the present work is to provide a basis for the decision makers in defining a strategy for the implementation of REACH with regard to ash, it would be presumptuous to put forward any such possible decisions on strategy and associated work in the present report. However, it is the policy of Värmeforsk to request that suggestions for further work be included in their reports. This is interpreted by the present authors to imply that the Institute wishes to receive suggestions on what research may be carried out together with what might reasonably be achieved using the corresponding results. In order for such suggestions to appropriately serve their purpose, they should cover at least the amount of work that Värmeforsk may wish to consider to finance. Such a quantity is typically considerably larger than what actually becomes financed.

Consequently, a scenario is presented in the following for which the associated work provides such a basis for decision on direction as well as on ambition. **It is strongly emphasized that the sole purpose of presenting this scenario is to provide a decision base for Värmeforsk, and not in any way to disavow its bodies for decision-making or prejudice any of their rulings.**

The work suggested in the next section thus corresponds to the following scenario.

Värmeforsk through its Programme on Environmentally Friendly Use of Non-Coal Ashes wishes to continue to use its method for classification of ash according the Ordinance of waste. Based on the plans for chemical products, it can be anticipated that it is a good idea for the members of Värmeforsk to have their present classifications well updated because then, such a classification might be accepted during some transition period. Such an approach might receive a higher acceptance if it is obvious that efforts are made at the same time to implement the new rules in a timely and ambitious manner. It is the ambition to develop and use the method also in accordance with the upcoming legislation on classification according to the ordinance of waste. The quality should be sufficient to warrant acceptance with a reasonably high probability.

Since neither the implications of the new legislation on waste, nor that of products can be foreseen, the knowledge base required for both is to be developed. Thus, ash utilization is to be qualified also under REACH. Since a number of issues important for the utilization of ash as a product are obscure at present, the PPORD option can be selected by ash producers who still develop their products and the associated applications. This permits less drastic schedules for the development work.

The aim of the development work is to obtain a methodology for supplying ash qualified under REACH but with highly efficient schemes for utilization of measurements, whilst at the same time differentiating efficiently with regard to the varying properties among

ashes with regard to environment and health related properties. Thus, each batch of ash can be directed to an appropriate purpose with the support of REACH.

It is assumed that ash may be regarded as a mixture, but that the validity of this approach will have to be proven.

9.2 Suggestions

The following further work is proposed based on the scenario described in the previous section.

- Communicate the classification methodology and its possible use under the new waste directive as well as under REACH among domestic ash producers, authorities and internationally (including consortia). Exchange of information and search for potentials for co-operation.
- A special dialogue with the authorities concerned (The Swedish Chemicals Agency, The Swedish Environmental Protection Agency and the European Chemicals Agency) on what approaches are suitable.
- Compile information material for Authorities and associated scientists and consultants so that they get ample access to what they might need in order to e g extend the list of exemptions from REACH and to be able to follow the principle of proportionality e g regarding when a blend can be regarded as a mixture.
- On condition that support is obtained from the above contacts, a compilation of the prerequisites for exemption from REACH and an analysis of whether ash may or may not correspond to the requirements for exemption. It is assumed that the present exemptions are issued based on certain generic and impartial prerequisites. It is also assumed that exemption may not be applicable to all ashes suitable for use as products.
- Update the present methodology for classification of ash according to the ordinance of waste with regard to the implementation of the new waste directive. (It has been announced by the Swedish Government that the corresponding new ordinance of waste will be based on CLP, and that it is expected to come into force at around the summer of 2010). The updating should include actual measurements on ash.
- On condition that support is obtained from the above contacts, an analysis of how REACH may best be implemented in practice, especially with regard to variability among different ashes. How many registrations are needed, and how many of these may be available from other sources (including other consortia)? Which registrations would be for reference ash and for reference heavy metal oxides, respectively? To what extent can read across and bridging be used? What test results can be found from various sources, and what supplementary testing is needed? How can such a system be maintained? Estimation of costs for access to information for registration. This work will probably have to be carried out in stages. The goal is to obtain a methodology for implementation of REACH to ash.

- A methodology for efficient but cautious implementation of REACH will probably have to be supplemented after having been taken into use, e g by adding new applications.
- Review and update of the environmental guidelines / risk assessments (cf [11-12]) to conform fully with REACH. It is assumed that this is generally the case already, but this needs to be analyzed and verified. Also, selection of reference ash for registration under REACH may prompt supplementary work on environmental guidelines.
- Analyze marketing prerequisites and give recommendations on qualifying ashes as products.
- Mitigate the detriment of lack of continuity with historical use of ash as a product by publishing a popular book on historical use of ash. Alternatively, or as a supplement, the continuity with other similar products (e g slag or coal ash / volcanic ash) may be described.
- Uncertainties in hazard evaluations imply that caution must be applied. This leads to sub-optimization in comparison with sure hazards. Research is therefore needed to reduce uncertainty, e g by measuring the actual environmental impact for completed projects. Such information will help saving resources as well as help direct resources to such areas for which the improvement for health and environment are the greatest.

10 References

ECHA advice and other key documents have been published continuously throughout the course of this work. None of the references are published after the year 2009. The coverage towards the end of the year 2009 may be less comprehensive than earlier.

In a few cases, ECHA has issued draft documents. ECHA has the following text of warning for at least some of the draft guidances:

"Please note that this document is a draft guidance document which the European Chemicals Agency (ECHA) is further elaborating in cooperation with Member States and relevant stakeholders in accordance with ECHA's Consultation Procedure on Guidance. It does not constitute or represent a formal view of ECHA and may still be subject to amendments.

ECHA does not accept any liability with regard to the contents of this document."

Please note that draft documents can appear after the corresponding formally issued document has been published.

10.1 Legislation

"SFS" stands for "svensk författningssamling" which translates to *Swedish code of statutes*. It is the series that the Government has for its ordinances (as well as certain other documents).

KIFS is the series of regulations issued by the Swedish Chemicals Agency.

[I] *Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances as amended taking account of changes up to 1/08/2008.* It is commonly called the Dangerous Substances Directive, or DSD.

[II] *DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations* It is commonly called the Dangerous Preparations Directive, or DPD.

[III] *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.* This regulation is commonly referred to as CLP.

[IV] *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.* This regulation is commonly referred to as REACH.

[V] *Council Directive 91/689/EEC of 12 December 1991 on hazardous waste.*

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[VII] *DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives.*

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[XIV] Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste.

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Names of Swedish organisations are given in English translation. For corresponding Swedish names, see Section 1.2.

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APPENDICES

A An example of a safety data sheet from SSAB Merox

MEROX
- Ett företag i SSAB-koncernen -

Produktnamn
M-Kalk

Utförande datum: 2009-05-19
Omarbetad, version: 4

SÄKERHETSDATABLAD

1. NAMNET PÅ ÄMNET/BEREDNINGEN OCH BOLAGET/FÖRETAGET

Tillverkare/Leverantör:	SSAB MEROX AB, 613 80 OXELÖSUND
Tel:	0155 - 25 44 00
Fax:	0155 - 25 52 21
Utfärdare:	Katarina Jakobsson Tel. 0155-25 41 19 katarina.jakobsson@merox.se

Handelsnamn:	Kemisk/teknisk produktbenämning:	Produkttyp/användning:
M-Kalk	Luftkyld masugnsslagg	M-Kalk används som jordförbättringsmedel

Nödtelefon nummer:	Giftinformationscentralen	08-33 12 31 112 (begär giftinformation)

2. FARLIGA EGENSKAPER

Damm av M-Kalk kan verka irriterande på slemhinnor och ögon.
Hudkontakt kan ge irritationer på grund av uttorkning. Damm i ögonen irriterar främst genom mekanisk retning.

R-fraser, riskfraser: R32 – Utvecklar mycket giftig gas i kontakt med syra
R66 – Upprepad kontakt kan ge torr hud eller hudsprickor
S-fraser, skyddsfras: S22 – Undvik inandning av damm
S13 – Förvaras åtskilt från livsmedel och djurfoder

3. SAMMANSÄTTNING/INFORMATION OM BESTÅNDSDELAR

Ämnesnamn	Element	EG nr	CAS-nr	Halt vikt-% (Torr Substans)	Farosymbol/ R-fraser
Luftsvalnad, kristallin masugnsslagg	*Se nedan*	266-002-0	65996-69-2	100	Ej märkningspliktig produkt.

SAMMANSÄTTNINGSKOMMENTARER:
M-kalk har normalt en fukthalt på 5-8 %. M-kalk innehåller ingen fri kvarts, kristobalit, tridymit.
M-kalk består av följande element i olika ternera eller andra stabila föreningar.

Element		Riktvärden [TS]	Kommentar
$Oxid_{balanserat}$	[O]	≈ 43	Samtliga ämnen föreligger i oxidform. Den kemiska analysen till vänster är en grundämnesanalys. M-kalk kan liknas vid ett mineral i mald form. Spårämnen av ytterligare element i masugns-slagg redovisas särskilt när sådana krav finns. Se även produktspecifikationen.
Kalcium	Ca	≈ 24	
Kisel	Si	≈ 17	
Magnesium	Mg	≈ 9	
Aluminium	Al	≈ 6	
Svavel	S	≈ 1,4	
Järn	Fe	≈ 0,3	

Masugnsslagg framställs vid tillverkning av råjärn i en så kallad masugn. Råvarorna består av järnrik malm och slaggbildare. Dessa upphettas i en reducerande miljö, med hjälp av koks och kolpulver. Ur

SÄKERHETSDATABLAD

masugnen tappas flytande slagg och järn. Masugnsslaggen kan sägas bestå av sammansmälta naturliga råvaror från olika bergarter. Den smälta slaggen kyls långsamt därefter mals den till M-kalk.

4. ÅTGÄRDER VID FÖRSTA HJÄLPEN

Inandning:	Frisk luft
Hudkontakt:	Tvätta med tvål och vatten.
Kontakt med ögon:	Skölj rikligt med vatten. Kvarstannar partikel kontakta läkare eller sjukhus.
Förtäring:	Drick rikligt med vatten.

5. BRANDBEKÄMPNINGSÅTGÄRDER

Ej brännbart ämne.

6. ÅTGÄRDER VID OAVSIKTLIGA UTSLÄPP

Saneringsmetoder:	Medelfuktig produkt: Samla upp mekaniskt. Skyffel och borste. Uttorkad dammande produkt: Dammsugare, eller fukta och låt härda för att sedan bryta loss i klumpar.

7. HANTERING OCH LAGRING

Minimera dammbildning.

8. BEGRÄNSNING AV EXPONERINGEN / PERSONLIGT SKYDD

Begränsning av exponering:	Använd normala oömma kläder och vanliga tyg/läder-handskar vid behov.
Personliga skyddsåtgärder:	Vid blåsigt väder eller andra ogynnsamma förhållanden bör skyddsglasögon användas och vid behov även andningsfilter mot damm (typ P2).

9. FYSIKALISKA OCH KEMISKA EGENSKAPER

Utseende:	Ljusgrått pulver
Kornstorlek:	0-3 mm
Bulkdensitet	≈ 1,35 kg/dm^3
Specifik vikt:	≈ 3 kg/dm^3 (korndensitet)
Smältpunkt:	≈ 1300-1500°C

10. STABILITET OCH REAKTIVITET

Stabilitet:	Stabilt ämne.

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Material och kemiska produkter som bör undvikas:	Reagerar med stark syra och bildar då svavelväte som är mycket giftigt vid inandning.

11. TOXIKOLOGISK INFORMATION

Inandning:	Inandning av damm kan verka irriterande på slemhinnor.
Hudkontakt:	Kan verka uttorkande.
Stänk i ögonen:	Mekanisk retning kan orsaka irritation.
Förtäring:	Förtäring kan ge svavelväte i magsäck, som är giftig vid inandning.

12. EKOLOGISK INFORMATION

Höjer pH-värden i mark och vatten. Används såsom jordförbättring och är KRAV-godkänt.

13. AVFALLSHANTERING

Kan efter fuktning deponeras på tipp som byggavfall. Se lokala föreskrifter.

14. TRANSPORTINFORMATION

Alla transportsätt kan utnyttjas. M-kalk är inte farligt gods. Vid transport av M-kalk som bulkvara, måste bilarna täckas för att undvika damm på övriga trafikanter.

15. GÄLLANDE FÖRESKRIFTER

Klassificering/märkning:

Faroklass:	ingen
Farosymbol:	ingen
Riskfraser:	R32 – Utvecklar mycket giftig gas i kontakt med syra R66 – Upprepad kontakt kan ge torr hud eller hudsprickor
Skyddsfraser:	S22 – Undvik inandning av damm S13 – Förvaras åtskilt från livsmedel och djurfoder

16. ANNAN INFORMATION

Informationen i detta säkerhetsdatablad har utarbetats med stöd av bästa tillgängliga information vid detta tillfälle (om hur denna produkt normalt bör hanteras).
Den tidigare klassningen MÅTTLIGT HÄLSOSKADLIG är ej längre tillämplig enligt gällande regler för kemiska produkter, därför har denna tagits bort. Farosymbolen LÄS VARNINGSTEXTEN har dock sparats för att uppmärksamma läsaren. Ingen ändring eller omvärdering av produkten har gjorts, det är enbart regelverket som ändrats.

Referenser: Kemanalyser, testning av produkten med avseende på lakning och dermal resp oral exposition. KRAV-certifikat nr 229175.

B Labelling of chemical products – large tables

Table B1. Symbols and indications of danger for dangerous substances and preparations according to DSD and DPD.[I-II,VIII-IX]. Cf text in Section 6.

E	Explosive	
O	Oxidizing	
F	Highly flammable	
F+	Extremely flammable	
T	Toxic	
T+	Very toxicd	
C	Corrosive	
Xn	Harmful	
Xn	Irritant	
N	Dangerous for the environment	

Table B2. The risk phrases used in DSD and DPD (cf text in Section 6).

R1	Explosive when dry
R2	Risk of explosion by shock, friction, fire or other sources of ignition
R3	Extreme risk of explosion by shock, friction, fire or other sources of ignition
R4	Forms very sensitive explosive metallic compounds
R5	Heating may cause an explosion
R6	Explosive with or without contact with air
R7	May cause fire
R8	Contact with combustible material may cause fire
R9	Explosive when mixed with combustible material
R10	Flammable
R11	Highly flammable
R12	Extremely flammable
R14	Reacts violently with water
R14/15	Reacts violently with water, liberating extremely flammable gases
R15	Contact with water liberates extremely flammable gases
R15/29	Contact with water liberates toxic, extremely flammable gases
R16	Explosive when mixed with oxidising substances
R17	Spontaneously flammable in air
R18	In use, may form flammable/explosive vapour-air mixture
R19	May form explosive peroxides
R20	Harmful by inhalation
R20/21	Harmful by inhalation and in contact with skin
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R20/22	Harmful by inhalation and if swallowed
R21	Harmful in contact with skin
R21/22	Harmful in contact with skin and if swallowed
R22	Harmful if swallowed
R23	Toxic by inhalation
R23/24	Toxic by inhalation and in contact with skin
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R23/25	Toxic by inhalation and if swallowed
R24	Toxic in contact with skin
R24/25	Toxic in contact with skin and if swallowed
R25	Toxic if swallowed
R26	Very toxic by inhalation
R26/27	Very toxic by inhalation and in contact with skin
R26/27/28	Very toxic by inhalation, in contact with skin and if swallowed
R26/28	Very toxic by inhalation and if swallowed
R27	Very toxic in contact with skin
R27/28	Very toxic in contact with skin and if swallowed
R28	Very toxic if swallowed
R29	Contact with water liberates toxic gas

R30	Can become highly flammable in use
R31	Contact with acids liberates toxic gas
R32	Contact with acids liberates very toxic gas
R33	Danger of cumulative effects
R34	Causes burns
R35	Causes severe burns
R36	Irritating to eyes
R36/37	Irritating to eyes and respiratory system
R36/37/38	Irritating to eyes, respiratory system and skin
R36/38	Irritating to eyes and skin
R37	Irritating to respiratory system
R37/38	Irritating to respiratory system and skin
R38	Irritating to skin
R39	Danger of very serious irreversible effects
R39/23	Toxic: danger of very serious irreversible effects through inhalation
R39/23/24	Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/23/25	Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/24	Toxic: danger of very serious irreversible effects in contact with skin
R39/24/25	Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/25	Toxic: danger of very serious irreversible effects if swallowed
R39/26	Very Toxic: danger of very serious irreversible effects through inhalation
R39/26/27	Very Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/26/27/28	Very Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/26/28	Very Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/27	Very Toxic: danger of very serious irreversible effects in contact with skin
R39/27/28	Very Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/28	Very Toxic: danger of very serious irreversible effects if swallowed
R40	Limited evidence of a carcinogenic effect
R41	Risk of serious damage to eyes
R42	May cause sensitisation by inhalation
R43	May cause sensitisation by skin contact
R42/43	May cause sensitisation by inhalation and skin contact
R44	Risk of explosion if heated under confinement
R45	May cause cancer

R46	May cause heritable genetic damage
R48	Danger of serious damage to health by prolonged exposure
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation
R48/20/21	Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/20/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/21	Harmful: danger of serious damage to health by prolonged exposure in contact with skin
R48/21/22	Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed
R48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation
R48/23/24	Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/23/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/24	Toxic: danger of serious damage to health by prolonged exposure in contact with skin
R48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed
R49	May cause cancer by inhalation
R50	Very toxic to aquatic organisms
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R51	Toxic to aquatic organisms
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R52	Harmful to aquatic organisms
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R53	May cause long-term adverse effects in the aquatic environment
R54	Toxic to flora
R55	Toxic to fauna
R56	Toxic to soil organisms
R57	Toxic to bees

R58	May cause long-term adverse effects in the environment
R59	Dangerous for the ozone layer
R60	May impair fertility
R61	May cause harm to the unborn child
R62	Possible risk of impaired fertility
R63	Possible risk of harm to the unborn child
R64	May cause harm to breast-fed babies
R65	Harmful: may cause lung damage if swallowed
R66	Repeated exposure may cause skin dryness or cracking
R67	Vapours may cause drowsiness and dizziness
R68	Possible risk of irreversible effects
R68/20	Harmful: possible risk of irreversible effects through inhalation
R68/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin
R68/20/21/22	Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed
R68/20/22	Harmful: possible risk of irreversible effects through inhalation and if swallowed
R68/21	Harmful: possible risk of irreversible effects in contact with skin
R68/21/22	Harmful: possible risk of irreversible effects in contact with skin and if swallowed
R68/22	Harmful: possible risk of irreversible effects if swallowed

Table B3. The hazard pictograms for each hazard class according to CLP.[III] Cf text in Section 6.

Hazard class	**Hazard pictogram**
• Unstable explosives • Explosives of Divisions 1.1, 1.2, 1.3, 1.4 • Self reactive substances and mixtures, Types A, B • Organic peroxides, Types A, B	
• Flammable gases, hazard category 1 • Flammable aerosols, hazard categories 1, 2 • Flammable liquids, hazard categories 1, 2, 3 • Flammable solids, hazard categories 1, 2 • Self-reactive substances and mixtures, Types B, C, D, E, F • Pyrophoric liquids, hazard category 1 • Pyrophoric solids, hazard category 1 • Self-heating substances and mixtures, hazard categories 1, 2 • Substances and mixtures, which in contact with water, emit flammable gases, hazard categories 1, 2, 3 • Organic peroxides, Types B, C, D, E, F	
• Oxidising gases, hazard category 1 • Oxidising liquids, hazard categories 1, 2, 3 • Oxidising solids, hazard categories 1, 2, 3	
• Gases under pressure: • Compressed gases; • Liquefied gases; • Refrigerated liquefied gases; • Dissolved gases	
• Corrosive to metals, hazard category 1	
• Acute toxicity (oral, dermal, inhalation), hazard categories 1, 2, 3	

• Skin corrosion, hazard categories 1A, 1B, 1C • Serious eye damage, hazard category 1	
• Acute toxicity (oral, dermal, inhalation), hazard category 4 • Skin irritation, hazard category 2 • Eye irritation, hazard category 2 • Skin sensitisation, hazard category 1 • Specific Target Organ Toxicity — Single exposure, hazard category 3 • Respiratory tract irritation • Narcotic effects	
• Respiratory sensitisation, hazard category 1 • Germ cell mutagenicity, hazard categories 1A, 1B, 2 • Carcinogenicity, hazard categories 1A, 1B, 2 • Reproductive toxicity, hazard categories 1A, 1B, 2 • Specific Target Organ Toxicity — Single exposure, hazard categories 1, 2 • Specific Target Organ Toxicity — Repeated exposure, hazard categories 1, 2 • Aspiration hazard, hazard category 1	
Hazardous to the aquatic environment • — Acute hazard category 1 • — Chronic hazard categories 1, 2	

Table B4a. Acute toxicity label elements. From table 3.1.3 in Reference [III]. Cf text in Section 6.

Classification	Category 1	Category 2	Category 3	Category 4
GHS Pictograms				
Signal Word	Danger	Danger	Danger	Warning
Hazard Statement: — Oral	H300: Fatal if swallowed	H300: Fatal if swallowed	H301: Toxic if swallowed	H302: Harmful if swallowed
— Dermal	H310:Fatal in contact with skin	H310:Fatal in contact with skin	H311: Toxic in contact with skin	H312: Harmful in contact with skin
— Inhalation (see Note 1)	H330:Fatal if inhaled	H330: Fatal if inhaled	H331: Toxic if inhaled	H332: Harmful if inhaled
Precautionary Statement Prevention (oral)	P264 P270	P264 P270	P264 P270	P264 P270
Precautionary Statement Response (oral)	P301 + P310 P321 P330	P301 + P310 P321 P330	P301 + P310 P321 P330	P301 + P312 P330
Precautionary Statement Storage (oral)	P405	P405	P405	
Precautionary Statement Disposal (oral)	P501	P501	P501	P501
Precautionary Statement Prevention (dermal)	P262 P264 P270 P280	P262 P264 P270 P280	P280	P280
Precautionary Statement Response (dermal)	P302 + P350 P310 P322 P361 P363	P302 + P350 P310 P322 P361 P363	P302 + P352 P312 P322 P361 P363	P302 + P352 P312 P322 P363
Precautionary Statement Storage (dermal)	P405	P405	P405	
Precautionary Statement Disposal (dermal)	P501	P501	P501	P501
Precautionary Statement Prevention (inhalation)	P260 P271 P284	P260 P271 P284	P261 P271	P261 P271
Precautionary Statement Response (inhalation)	P304 + P340 P310 P320	P304 + P340 P310 P320	P304 + P340 P311 P321	P304 + P340 P312
Precautionary Statement Storage (inhalation)	P403 + P233 P405	P403 + P233 P405	P403 + P233 P405	
Precautionary Statement Disposal (inhalation)	P501	P501	P501	

Table B4b. Label elements for skin corrosion/irritation. From table 3.2.5 in Reference [III]. Cf text in Section 6.

Classification	Category 1 A/1 B/1 C	Category 2
GHS Pictograms		
Signal Word	Danger	Warning
Hazard Statement	H314: Causes severe skin burns and eye damage	H315: Causes skin irritation
Precautionary Statement Prevention	P260 P264 P280	P264 P280
Precautionary Statement Response	P301 + P330 + P331 P303 + P361 + P353 P363 P304 + P340 P310 P321 P305 + P351 + P338	P302 + P352 P321 P332 + P313 P362
Precautionary Statement Storage	P405	
Precautionary Statement Disposal	P501	

Table B4c. Label elements for specific target organ toxicity after single exposure From table 3.8.4 in Reference [III].

Classification	Category 1	Category 2	Category 3
GHS Pictograms			
Signal Word	Danger	Warning	Warning
Hazard Statement	H370: Causes damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H371: May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H335: May cause respiratory irritation; or H336: May cause drowsiness or dizziness
Precautionary Statement Prevention	P260 P264 P270	P260 P264 P270	P261 P271
Precautionary Statement Response	P307 + P311 P321	P309 + P311	P304 + P340 P312
Precautionary Statement Storage	P405	P405	P403 + P233 P405
Precautionary Statement Disposal	P501	P501	P501

Table B5. The hazard statements in CLP[III]. Data taken from Annex III, Tables 1.1 – 2.3 and 3. part 3. Cf text in Section 6.

Hazard statement number	Type of hazard	Hazard statement
Hazard statements for physical hazards. Data from CLP Annex III, Table 1.1.		
H200	2.1 — Explosives, Unstable explosives	Unstable explosives.
H201	2.1 — Explosives, Division 1.1	Explosive; mass explosion hazard.
H202	2.1 — Explosives, Division 1.2	Explosive, severe projection hazard.
H203	2.1 — Explosives, Division 1.3	Explosive; fire, blast or projection hazard.
H204	2.1 — Explosives, Division 1.4	Fire or projection hazard.
H205	2.1 — Explosives, Division 1.5	May mass explode in fire.
H220	2.2 — Flammable gases, Hazard Category 1	Extremely flammable gas.
H221	2.2 — Flammable gases, Hazard Category 2	Flammable gas.
H222	2.3 — Flammable aerosols, Hazard Category 1	Extremely flammable aerosol.
H223	2.3 — Flammable aerosols, Hazard Category 2	Flammable aerosol.
H224	2.6 — Flammable liquids, Hazard Category 1	Extremely flammable liquid and vapour.
H225	2.6 — Flammable liquids, Hazard Category 2	Highly flammable liquid and vapour.
H226	2.6 — Flammable liquids, Hazard Category 3	Flammable liquid and vapour.
H228	2.7 — Flammable solids, Hazard Category 1, 2	Flammable solid.
H240	2.8 — Self-Reactive Substances and Mixtures, Type A 2.1.5 — Organic Peroxides, Type A	Heating may cause an explosion.
H241	2.8 — Self-Reactive Substances and Mixtures, Type B 2.1.5 — Organic Peroxides, Type B	Heating may cause a fire or explosion.
H242	2.8 — Self-Reactive Substances and Mixtures, Types C, D, E, F 2.1.5 — Organic Peroxides, Types C, D, E, F	Heating may cause a fire.

H250	2.9 — Pyrophoric Liquids, Hazard Category 1 2.10 — Pyorphoric Solids, Hazard Category 1	Catches fire spontaneously if exposed to air.
H251	2.11 — Self-Heating Substances and Mixtures, Hazard Category 1	Self-heating: may catch fire.
H252	2.11 — Self-Heating Substances and Mixtures, Hazard Category 2	Self-heating in large quantities; may catch fire.
H260	2.12 — Substances and Mixtures which, in contact with water, emit flammable gases, Hazard Category 1	In contact with water releases flammable gases which may ignite spontaneously.
H261	2.12 — Substances and Mixtures which, in contact with water, emit flammable gases, Hazard Category 2	In contact with water releases flammable gases.
H270	2.4 — Oxidising Gases, Hazard Category 1	May cause or intensify fire; oxidiser.
H271	2.13 — Oxidising Liquids, Hazard Category 1 2.14 — Oxidising Solids, Hazard Category 1	May cause fire or explosion; strong oxidiser.
H272	2.13 — Oxidising Liquids, Hazard Category 2, 3 2.14 — Oxidising Solids, Hazard Category 2, 3	May intensify fire; oxidiser.
H280	2.5 — Gases under pressure: Compressed gas, Liquefied gas, Dissolved gas	Contains gas under pressure; may explode if heated
H281	2.5 — Gases under pressure: Refrigerated liquefied gas	Contains refrigerated gas; may cause cryogenic burns or injury.
H290	2.16 — Corrosive to metals, Hazard Category 1	May be corrosive to metals.
Hazard statements for health hazards. Data from CLP Annex III, Table 1.2.		
H300	3.1 — Acute toxicity (oral), Hazard Category 1, 2	Fatal if swallowed.
H301	3.1 — Acute toxicity (oral), Hazard Category 3	Toxic if swallowed.
H302	3.1 — Acute toxicity (oral), Hazard Category 4	Harmful if swallowed.
H304	3.10 — Aspiration hazard, Hazard Category 1	May be fatal if swallowed and enters airways.
H310	3.1 — Acute toxicity (dermal), Hazard Category 1, 2	Fatal in contact with skin.
H311	3.1 — Acute toxicity (dermal), Hazard Category 3	Toxic in contact with skin.
H312	3.1 — Acute toxicity (dermal), Hazard Category 4	Harmful in contact with skin.

H314	3.2 — Skin corrosion/irritation, Hazard Category 1A, 1B, 1C	Causes severe skin burns and eye damage.
H315	3.2 — Skin corrosion/irritation, Hazard Category 2	Causes skin irritation.
H317	3.4 — Sensitisation — Skin, Hazard Category 1	May cause an allergic skin reaction.
H318	3.3 — Serious eye damage/eye irritation, Hazard Category 1	Causes serious eye damage.
H319	3.3 — Serious eye damage/eye irritation, Hazard Category 2	Causes serious eye irritation.
H330	3.1 — Acute toxicity (inhal.), Hazard Category 1, 2	Fatal if inhaled.
H331	3.1 — Acute toxicity (inhal.), Hazard Category 3	Toxic if inhaled.
H332	3.1 — Acute toxicity (inhal.), Hazard Category 4	Harmful if inhaled.
H334	3.4 — Sensitisation — Respirat., Hazard Category 1	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	3.8 — Specific target organ toxicity — Single exposure, Hazard Category 3, Respiratory tract irritation	May cause respiratory irritation.
H336	3.8 — Specific target organ toxicity — Single exposure, Hazard Category 3, Narcosis	May cause drowsiness or dizziness.
H340	3.5 — Germ cell mutagenicity, Hazard Category 1A, 1B	May cause genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H341	3.5 — Germ cell mutagenicity, Hazard Category 2	Suspected of causing genetic defects <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H350	3.6 — Carcinogenicity, Hazard Category 1A, 1B	May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H351	3.6 — Carcinogenicity, Hazard Category 2	Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routs of exposure cause the hazard>.

H360	3.7 — Reproductive toxicity, Hazard Category 1A, 1B	May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H361	3.7 — Reproductive toxicity, Hazard Category 2	Suspected of damaging fertility or the unborn child <state specific effect if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H362	3.7 — Reproductive toxicity, Additional category, Effects on or via lactation	May cause harm to breast-fed children.
H370	3.8 — Specific target organ toxicity — single exposure, Hazard Category 1	Causes damage to organs <or state all organs affected, if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H371	3.8 — Specific target organ toxicity — Single exposure, Hazard Category 2	May cause damage to organs <or state all organs affected, if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H372	3.9 — Specific target organ toxicity — Repeated exposure, Hazard Category 1	Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H373	3.9 — Specific target organ toxicity — Repeated exposure, Hazard Category 2	May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
Hazard statements for environmental hazards. Data from CLP Annex III, Table 1.3.		
H400	4.1 — Hazardous to the aquatic environment — AcuteHazard, Category 1	Very toxic to aquatic life.
H410	4.1 — Hazardous to the aquatic environment — Chronic Hazard, Category 1	Very toxic to aquatic life with long lasting effects.

H411	4.1 — Hazardous to the aquatic environment — Chronic Hazard, Category 2	Toxic to aquatic life with long lasting effects.
H412	4.1 — Hazardous to the aquatic environment — Chronic Hazard, Category 3	Harmful to aquatic life with long lasting effects.
H413	4.1 — Hazardous to the aquatic environment — Chronic Hazard, Category 4	May cause long lasting harmful effects to aquatic life.
Physical properties. Data from CLP Annex III, Table 2.1.		
EUH 001		Explosive when dry.
EUH 006		Explosive with or without contact with air.
EUH 014		Reacts violently with water.
EUH 018		In use may form flammable/explosive vapour-air mixture.
EUH 019		May form explosive peroxides.
EUH 044		Risk of explosion if heated under confinement.
Health properties. Data from CLP Annex III, Table 2.2.		
EUH 029		Contact with water liberates toxic gas.
EUH 031		Contact with acids liberates toxic gas.
EUH 032		Contact with acids liberates very toxic gas.
EUH 066		Repeated exposure may cause skin dryness or cracking.
EUH 070		Toxic by eye contact.
EUH 071		Corrosive to the respiratory tract.
Environmental properties. Data from CLP Annex III, Table 2.3.		
EUH 059	Additional EU Hazard Class	Hazardous to the ozone layer.
Supplemental label elements/information on certain substances and mixtures. Data from CLP Annex III, Section 3. Part 3.		
EUH 201/201A	Contains lead. Should not be used on surfaces liable to be chewed or sucked by children.	Warning! Contains lead.
EUH 202		Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children.

EUH 203		Contains chromium (VI). May produce an allergic reaction.
EUH 204		Contains isocyanates. May produce an allergic reaction.
EUH 205		Contains epoxy constituents. May produce an allergic reaction.
EUH 206		Warning! Do not use together with other products. May release dangerous gases (chlorine).
EUH 207		Warning! Contains cadmium. Dangerous fumes are formed during use. See information supplied by the manufacturer. Comply with the safety instructions.
EUH 208		Contains <name of sensitising substance>. May produce an allergic reaction.
EUH 209		Can become highly flammable in use.
EUH 209A		Can become flammable in use.
EUH 210		Safety data sheet available on request.
EUH 401		To avoid risks to human health and the environment, comply with the instructions for use.

C General rules for adaptation of standard testing

Rules for adaptation of standard testing can be found in Annex XI in REACH. It is also referred to in CLP and is equally valid for that regulation (refers to section 1 below). Annex XI is presented *in extenso* in the following:

ANNEX XI
GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES VII TO X

Annexes VII to X set out the information requirements for all substances manufactured or imported in quantities of:

— one tonne or more in accordance with Article 12(1)(a),

— 10 tonnes or more in accordance with Article 12(1)(c),

— 100 tonnes or more in accordance with Article 12(1)(d), and

— 1 000 tonnes or more in accordance with Article 12(1)(e).

In addition to the specific rules set out in column 2 of Annexes VII to X, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of this Annex. Under dossier evaluation the Agency may assess these adaptations to the standard testing regime.

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3) if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment;

(2) sufficient documentation is provided to assess the adequacy of the study; and

(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3) if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment;

(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);

(3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and

(4) adequate and reliable documentation of the study is provided.

1.1.3. Historical human data

Historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data and clinical studies, shall be considered.
The strength of the data for a specific human health effect depends, among other things, on the type of analysis and on the parameters covered and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

(1) the proper selection and characterisation of the exposed and control groups;

(2) adequate characterisation of exposure;

(3) sufficient length of follow-up for disease occurrence;

(4) valid method for observing an effect;

(5) proper consideration of bias and confounding factors; and

(6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

1.2. Weight of evidence

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3) or from an international test method recognised by the Commission or the Agency as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.
Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

— further testing on vertebrate animals for that property shall be omitted,

— further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

— results are derived from a (Q)SAR model whose scientific validity has been established,

— the substance falls within the applicability domain of the (Q)SAR model,

— results are adequate for the purpose of classification and labelling and/ or risk assessment, and

— adequate and reliable documentation of the applied method is provided.

The Agency in collaboration with the Commission, Member States and interested parties shall develop and provide guidance in assessing which (Q)SARs will meet these conditions and provide examples.

1.4. *In vitro* methods

Results obtained from suitable in vitro methods may indicate the presence of a certain dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, 'suitable' means sufficiently well developed according to internationally agreed test development criteria (e.g. the European Centre for the Validation of Alternative Methods (ECVAM)) criteria for the entry of a test into the prevalidation process). Depending on the potential risk, immediate confirmation requiring testing beyond the information foreseen in Annexes VII or VIII or proposed confirmation requiring testing beyond the information foreseen in Annexes IX or X for the respective tonnage level may be necessary.

If the results obtained from the use of such in vitro methods do not indicate a certain dangerous property, the relevant test shall nevertheless be carried out at the appropriate tonnage level to confirm the negative result, unless testing is not required in accordance with Annexes VII to X or the other rules in this Annex.

Such confirmation may be waived, if the following conditions are met:

(1) results are derived from anin vitro method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;

(2) results are adequate for the purpose of classification and labelling and/ or risk assessment; and

(3) adequateand reliable documentation of the applied method is provided.

1.5. Grouping of substances and read-across approach

Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. The Agency, after consulting with relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances sufficiently in advance of the first registration deadline for phase-in substances.

The similarities may be based on:

(1) a common functional group;

(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or

(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis. In all cases results should:

— be adequate for the purpose of classification and labelling and/or risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3),

— cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and

— adequate and reliable documentation of the applied method shall be provided.

2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the test methods referred to in Article 13(3), more specifically on the technical limitations of a specific method, shall always be respected.

3 SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING

3.1. Testing in accordance with Sections 8.6 and 8.7 of Annex VIII, Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment in accordance with Section 5 of Annex I and be consistent with the criteria adopted pursuant to Section 3.3, and the specific conditions of use must be communicated through the chemical supply chain in accordance with Articles 31 or 32.

3.3. The Commission shall adopt the measures designed to amend nonessential elements of this Regulation by supplementing it, in accordance with the procedure referred to in Article 133(4), to set the criteria defining what constitutes adequate justification under Section 3.2 by 1 December 2008.

D The role and application of expert judgement in CLP

Excerpt from Annex I in CLP[III].

ANNEX I
CLASSIFICATION AND LABELLING REQUIREMENTS FOR HAZARDOUS SUBSTANCES AND MIXTURES

…

1.1.1. The role and application of expert judgement and weight of evidence determination

1.1.1.1. Where the criteria cannot be applied directly to available identified information, or where only the information referred to in Article 6(5) is available, the weight of evidence determination using expert judgment shall be applied in accordance with Article 9(3) or 9(4) respectively.

1.1.1.2. The approach to classifying mixtures may include the application of expert judgement in a number of areas in order to ensure existing information can be used for as many mixtures as possible in order to provide protection for human health and the environment. Expert judgement may also be required in interpreting data for hazard classification of substances, especially where weight of evidence determinations are needed.

1.1.1.3. A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. Information on substances or mixtures related to the substance or mixture being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be assembled together in a single weight of evidence determination.

1.1.1.4. For the purpose of classification for health hazards (Part 3) established hazardous effects seen in appropriate animal studies or from human experience that are consistent with the criteria for classification shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Generally, adequate, reliable and

representative data on humans (including epidemiological studies, scientifically valid case studies as specified in this Annex or statistically backed experience) shall have precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, to assess potentially confounding factors. Therefore, positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness, quality and statistical power of both the human and animal data.

1.1.1.5. For the purpose of classification for health hazards (Part 3) route of exposure, mechanistic information and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information, as far as there is reassurance about the robustness and quality of the data, raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified.

…

E ECHA guidance on "metals, metal compounds and other inorganic compounds"

Excerpt from Reference [35]:

Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals. ECHA Guidance for the implementation of REACH. May 2008.

R.6.2.5.6 Metals, metal compounds and other inorganic compounds

The concept of chemical categories has traditionally been widely used for hazard assessment for certain endpoints and risk assessment of inorganic substances. The approaches have generally been based on the occurrence of a common metal ion or anion and the use of read-across to fill data gaps.

For example, the chemical category approach based on the metal ion has been extensively used for the classification and labelling of metal compounds in the EU[21]. Other category entries are based on certain anions of concern such as oxalates and thiocyanates. For these EU classifications the category approach has often been applied to certain endpoints of particular concern for the compounds under consideration, and has not necessarily been applied to all endpoints of each individual compound in the category of substances. A category approach has also been used during the categorisation of existing chemicals on Canada's domestic substances list (Environment Canada, 2003).

This approach has also been used for estimating the potency of the effects as well as for their identification. NOAEL(s), NOEC(s) and comparable quantitative estimates have been read-across from data obtained from water-soluble compounds to other water-soluble compounds, including, in the absence of specific data, to compounds of substantially lower water-solubility. One example is the EU risk assessments on nickel (Tsakovska and Worth, 2007).

The application of these concepts has been useful[22]

- to evaluate hazards for substances for which data are limited rather than relying exclusively on conducting tests.

[21] The EU terminology for this type of entry is a "group entry" rather than a category.

[22] The approach of grouping metals and metal compounds in risk assessments has also been applied because it allows addressing together all compounds which potentially lead to exposure to the same metal moiety.

- to evaluate hazards for a range of compounds regarded as difficult substances, as they can present technical difficulties when carrying out standard test protocols (see Section R.6.2.4).
- to evaluate hazards for a number of metal compounds, for which animal models do not always reliably predict effects on humans. Where the hazard has been identified on the basis of human data the use of read-across provides a method to avoid these difficulties.

The guidance below is based largely on the practice of the EU Technical Committee on Classification and Labelling, the EU Technical Committee on New and Existing Substances and experience gained in other fora (see also Hart, 2007; Schoeters and Verougstraete, 2007). This guidance is intended to supplement the general guidance in the previous chapters with issues specific to metals and inorganic compounds.

Assumptions underlying the grouping of metal compounds

There are a number of assumptions underlying any grouping of metal compounds for estimating their biological properties.

The hypothesis is that properties are likely to be similar or follow a similar pattern as a result of the presence of a common metal ion (or ion complex including a hydrated metal ion). This is a reasonable assumption for the majority of inorganic compounds and some organic compounds (e.g. metal salts of some organic acids). However, it is the bioavailability of the metal ion (or a redox form of this ion) at target sites that in most cases determines the occurrence and severity of the effects to be assessed for the read-across of metal substances. Supporting information to assess the bioavailability of the metal ion at the target site can include information on a number of different factors (e.g. physico-chemical properties such as water solubility, degree of dissociation of the metal –containing compound, particle size and structure30, in vitro solubility, in vivo data on systemic effects, toxicokinetics).

Basis for the development of categories or read-across approach of metal compounds

Hazard data is available for some primary metals and some key (high production volume) inorganic compounds. However, for a wide range of inorganic and organic compounds of the same metal, data is usually very limited. Data availability will play an important role in the selection of source chemicals.

As metals occur in a wide and heterogeneous range of substances, including inorganic metal compounds, organic metal salts, organometallic compounds, metals, metal-metal compounds (i.e. compounds containing more than one type of metal), alloys[23] and

[23] Alloys are regarded as special preparations (mixtures) in REACH, and are as such not covered by this guidance. However, some alloys are listed in EINECS and are therefore considered as substances, where this advice may be applicable.

complex substances, care is needed in order to select those metal compounds for which a category approach is relevant from those where read-across is not applicable.

The following points could alter the assumption of commonality and should be considered:

- Chemical speciation and valency
  When selecting the appropriate source substance, the valence state and its influence on the assumption of commonality should be checked. For some metals (predominantly transition elements), the chemical speciation and in particular the different valencies may result in differences in mechanism of action and a variation in toxicological properties. For example, differences in hazards are seen with Cr3+ and Cr6+ compounds. In some cases, species may be interconvertible, in other cases there is little interconversion between the species.
- Organometallic compounds
  Organometallic compounds will generally have a different mode of action since the metal ion is not likely to be present in the same form as for inorganic compounds. In such cases, read-across between inorganic and organometallic compounds is not recommended, although read-across may well be appropriate between different organometallic compounds. On the other hand, especially for environmental risk assessment, if an organometallic compound degrades rapidly to its inorganic metal moiety, it can be assessed together with the inorganic metal moiety.
- Metals
  Particular difficulties have been seen in evaluating the properties of metals on the basis of data for metal compounds. In some cases, read-across of properties from the metal compounds to the metal itself (metallic, zero-valent form) has been agreed (e.g. cadmium oxide to cadmium metal, EC 2007a,b,c, EC 2008), whilst for others it has not (e.g. soluble nickel salts to nickel metal, EC 2006). These need to be evaluated on a case-by-case basis.
- Metal containing UVCBs
  Some metal containing UVCB compounds may not be appropriate for consideration in a category approach, as their effects will not be expected to be adequately described by their metal content. These include compounds such as asphalt, frits and drosses. In cases where read-across is not considered appropriate, clear arguments should be put forward as to why the known hazard profile of the metal is not expected to be relevant (for example very low bioavailability).
- Crystalline structure
  The crystalline structure of insoluble metal compounds could influence the hazard profile. If there is reason to believe that the crystalline structure influences significantly the effects of the compound to be assessed, this must be taken into account in the evaluation. An example is silica of which the crystalline and non-crystalline forms have a different hazard profile (see category for synthetic amorphous silicas assessed within the OECD HPV Chemicals Programme; Silicon dioxide [CAS Nos 7631-86-9, 112945-52-5, 112926-00-8] Silicic acid, aluminum sodium salt [CAS No 1344-00-9] Silicic acid, calcium salt [CAS No 1344-95-2]).

Preliminary evaluation of the category and read-across

The water solubility of the metal compounds is often used as the starting point for establishing a category, as this provides a first indication of the availability of the metal ion in the different compartments of interest. For example, for inorganic nickel a number of sub- categories have been suggested, reflecting different ranges of aqueous solubility (Hart, 2007).

The most simplistic approach to hazard evaluation is to assume that the specific metal-containing compound to be evaluated shows the same hazards as the most water-soluble compounds. This is a conservative approach, since systemic metal ion availability will normally be reduced with decreasing water-solubility and consequently reduced bioavailability.

This simplistic approach can be refined for categories containing many substances by building subcategories based on water solubility, when data is available on trends with water solubility. For example, mixed oxides with limited water solubility can be evaluated by comparison with the hazard profile for the metal oxides (where this is known) rather than for the soluble salts.

This difference in trend is clearly recognised in evaluating the environmental hazards of metals and metal compounds, where the relevant hazards can be evaluated using a transformation/dissolution protocol (OECD 2001).

Information from other endpoints could further support the systemic bioavailability assumptions. For example, the LD50 values for the semi-soluble nickel compounds was used to demonstrate systemic uptake to justify classification for reproductive toxicity for these compounds, but not for the less soluble oxides and sulfides (Hart, 2007). For endpoints where a threshold occurs, estimates of the systemic bioavailability (i.e. toxicokinetics) of the metal ion can be ascertained for representative members of each category in order to ascertain whether the bioavailability exceeds the threshold for the compounds.

In addition to water solubility, phagocytosis, bioaccessibility in synthetic biological fluids, and organ deposition and clearance rates are relevant parameters to be considered (Schoeters and Verougstraete, 2007).

Where toxicokinetic data is available, this should be used as this provides relevant information on whether the source and target chemicals in question behave similarly as expected from read-across or whether there are biologically differences that would bring into question the validity of the category hypothesis.

Other factors may also need to be taken into account.

Counter ions and other metal ions: The assumption that the metal ion is responsible for the common property or effect implies that the toxicity of the counter ion or of other metals present in the compound will be largely irrelevant in producing the effects to be assessed. This assumption could be affected by interactions between the metal ion and other parts of the substance e.g. the counter ion. It is noted that in certain cases the effect of the counter ion in acute toxicity studies exert another effect than in repeated dose studies using lower dose levels. This could obscure the role of the metal ion in either the acute or repeated dose studies. The influence of the counter ion should be checked for each endpoint. If there is reason to believe that the counter-ion (such as cyanates, oxalates) or other metal ions present in the compound influence significantly the effects of the compound to be assessed and alter the assumption of commonality, this must be taken into account in the evaluation. One option may be to use the additive approach described in the foreword to Annex I, Directive 67/548/EEC, in the guidance to Note A. (see also Section R.6.2.5.6).

Crystalline structure:
The crystalline structure of insoluble metal compounds could influence the hazard profile. If there is reason to believe that the crystalline structure influences significantly the bioavailability and so the effects of the compound to be assessed, this must be taken into account in the evaluation. An example is the low bioavailability of spinels and rutiles.

Particle size information:
Particle size information of the substance influences the deposition behaviour in the respiratory tract and potential toxic effects. Based on particle size distribution data, trends in deposition and potency of effects can be assessed for locally acting substances.

If there is evidence that the crystalline structure and particle size influence significantly the bioavailability and so the severity of the effects of the compound to be assessed, this must be taken into account in a Weight of Evidence approach considering all available information (e.g. toxicokinetics).

<u>Considerations of the need for further refinement</u>

As described previously, a preliminary assessment of the read-across or category should be carried out to determine whether the rationale is supported and whether the approach is sufficiently robust for the assessment purpose. If these criteria are satisfied for a particular endpoint, the data gaps can be filled according to the guidance in Section R.6.2.2.

If these criteria are not satisfied (there is uncertainty or contradictory information), the registrant should consider what additional information may be required. Additional data could include demonstrating a difference in bioavailability/bio accessibility between the substances in a proposed read-across or category.

The following options could be considered:

In vitro data:
In vitro information may be obtained by determining relative solubilities in physiological media (e.g. synthetic gastric juice, synthetic sweat) or by the use of the transformation/dissolution protocol (OECD, 2001) for the endpoints of sparingly soluble metal compounds related to the aquatic environment.

The solubility in alveolar liquids, lysosomal liquid, mucous liquids may provide more relevant information than simple water solubility for argumentation of the extent of availability of the soluble fraction of material during its dwelling time in various regions of the respiratory tract. To test whether slightly soluble, particulate metal compounds are taken up into mammalian cells and release metal ions intracellularly as free metal ions or bound to cellular macromolecules and whether the metal ions reach the cell nuclei, tests in vitro can be carried out using phagocytosing mammalian cells in culture.

In vivo data:
In some cases, in vivo testing may be considered, especially for endpoints where there is uncertainty about the role of the counter-ion. In planning the testing, a starting point for the studies should be confirmation of the effects expected on the basis of a read-across. As an example, if read-across would indicate the skin irritation is expected, an initial test could be carried out in vitro to confirm this effect before in vivo testing is considered.

Toxicokinetic data:
Animal model systems (using rats and mini-pigs) have been successfully used to characterise the speciation-dependent bioavailability differential for metals such as lead, arsenic and cadmium (US Environmental Protection Agency, 2004). Alternative strategies using rare stable isotopes of metals such as lead and zinc have been successfully used for the ascertainment of bioavailability of these metals in humans and animals. These types of studies are not requested in most review programmes and therefore would require a registrant to do additional work beyond what is normally considered necessary. However, where such information is not available, information could be collected for representative members of the category.

<u>General guidance for other compounds</u>

Similar considerations are expected to apply to salts in which the anion is associated with the toxic effects (e.g. cyanides, oxalates, thiocyanates). For categories that cover reactive chemicals, the reaction/degradation products must be of a similar nature for each member of the category to be plausible (Caley et al, 2007). One example is the Methanolates category assessed under the OECD HPV programme (http://cs3-hq.oecd.org/scripts/hpv). This consists of 17 potassium and sodium methanolate and both react rapidly in water to form the corresponding hydroxide.

When comparing acids and their salts, differences arising from pH effects should be considered (Caley et al, 2007). For example, skin and eye irritation are likely to be

different for an acid compared with its salt. This is illustrated by the Phosphonic Acid Compound (Groups 1, 2, 3) categories assessed under the OECD HPV programme (http://cs3-hq.oecd.org/scripts/hpv). For these categories, dermal and irritation studies are considered separately for the acid and salts.

For the Gluconates category assessed under the OECD HPV programme (http://cs3-hq.oecd.org/scripts/hpv), it was found that for categories including ionisable compounds, the effect of the counter-ion needs to be considered (Caley et al, 2007). It is possible that the counter-ion(s) may pose hazards of greater concern than the common cation or anion on which the category is based (e.g. metal counter-ions that are inherently hazardous on their own).

Under such circumstances, it may be of limited utility to group and assess substances by the component which is expected to have the least effect. In other cases, it may be concluded that effects of the counter-ion are insignificant and therefore need not be taken into account in the assessment.

F Reaction mass registration, material from Chemical Watch

From "Chemical Watch, Briefing business on REACH and chemical risks.

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http://chemicalwatch.com/1925

Dr Reach - Common sense needed for reaction mass registration

CW Briefing March 2009

As a result of pre-registration, some companies are caught between previous legislation and REACH. But it would be a mistake to think the issue is a question of compliance versus non-compliance.

Under previous chemical legislation, substances had to be EINECS reported or ELINCS notified, but only if placed on the market. Under REACH, pre-registration and registration now apply to the point of manufacture that is, before the product is placed on the market.

What to pre-register?

Therefore, if you manufacture a mixture of ethanol and methanol... what do you pre-register and register?

The official REACH guidance suggests that generally a company should pre-register a single substance and name it a "reaction mass of ethanol and methanol". Similarly, if you make salt, it is a 'reaction mass of sodium chloride and potassium chloride'.

For EINECS, ethanol and methanol were reported separately because the components of mixtures could be reported in terms of the separate chemical species present within. As the ingredients of the mixture were covered on EINECS, there was also no need to notify ethanol, methanol or a 'reaction mass' of the two for ELINCS.

Now, under REACH, if you register "reaction mass of ethanol and methanol", the safety data sheet supplied would no longer have separate entries for ethanol and methanol. Strangely, the CAS numbers 64-17-5 and 67-56-1 would not appear.

The European Chemicals Agency (ECHA) guidance document on substance identification and naming performed a fantastic job of covering practically every type of substance under one short guidance document, complete with references and examples. Apart from omitting a couple of substance types, such as nanomaterials and certain alloys, the guidance is comprehensive and clear except for this issue of 'reaction masses'. It states that it is for each company to identify when manufacturing starts and ends. Also, it allows for the individual constituents of a reaction mass to be registered separately if certain rules are obeyed.

However, this is where the guidance becomes difficult to follow, especially when you take into account REACH-IT functionalities and other guidance from ECHA. The guidance on naming and identification says that a "reaction mass of ethanol and methanol" is different to a "reaction mass of methanol and ethanol" but other guidance and REACH-IT do not necessarily make the distinction. This becomes complicated when there are many constituents presents, each with a range of concentrations.

Data requirements

Then there is the challenge of generating data. If there is a range of concentrations of constituents of a reaction mass, which should be tested and what data should be entered into a registration dossier for the substance? For instance, a 50/50 ethanol/ methanol mixture versus 60/40 and 70/30.

In practice, charts and formulae from physical chemistry would need to be submitted to cover the range of concentrations - minimum and maximum values alone would not be useful. The same approaches may apply for toxicological data, which is not easy to do. The resulting IUCLID5 files are difficult to create and manage, especially when interlinking with other programmes, such as those for chemical safety assessments.

Of course, current quantitative structure-activity relationship (QSAR) techniques cannot be performed for the mixture, limiting potential applications.

Based on information from Germany alone, it is estimated that blind adherence to the guidance on naming and identification will result in at least an additional 14,000 substances being 'created' for registration. Of course, one could say that this is an indication that REACH is spurring innovation!

Based on the guidance it remains unclear exactly what a company is supposed to do if it produces a 'reaction mass of ethanol and methanol' and a 'reaction mass of methanol and ethanol' and also produces ethanol and methanol separately. For instance, if ethanol and methanol are being produced from the "reaction mass of methanol and ethanol" then this

implies that the "reaction mass of methanol and ethanol" could be considered as an intermediate.

According to the guidance, in this case, a review of existing data must be performed - on both ethanol and methanol. This is already quite a workload to document, for a simple two-component substance and there are no examples in the guidance document to help firms. Doing this for a multi-constituent substance with perhaps ten chemical species that can have read-across and QSARs applied to the constituents is a real challenge!

Common sense

Unfortunately, REACH is not as all embracing as many hoped it would be - but this must be respected in order for REACH to work. Many other pieces of legislation co-exist, such as the recent classification, labelling and packaging (CLP) Regulation. Therefore, rules and boundaries must be defined. For instance, the testing of mixtures should not be governed by two different laws.

Registration is complicated enough without having to go over such theoretically stimulating but practically stifling exercises. Let's hope that common sense rules of thumb will always suffice as a justification for any sensible approach.

Discussion in the October issue

Discussion of the above article in the October issue.

ECHA guidance on identification and naming of substances gives little help on how to register reaction masses. With current confusion on the most appropriate approach, Dr Reach hopes for pragmatism on the part of companies and enforcement authorities. What are your views?

Comment from Rolf Schneider, Consultant, formerly at Siemens.

There are some issues where I have an understanding of the REACH text which differs from the ones expressed in guidance the ECHA documents. One example concerns the substance identity.

However, at the end each company has to make its decision based on their own interpretation of the regulation thus providing and laying the groundwork for its legal defense if challenged by the authorities.

Definitions in the REACH Regulation
In Article 3.1 the term "substance" is defined as follows in the REACH Regulation:

"*Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.*"

The REACH Regulation does not make any further statements regarding the type of manufacturing process (e.g. chemical reaction or extraction), or the possible or permitted number, composition or identification of manufactured substances or products. The term "manufacturing" is defined in Article 3 no. 8 solely as:

"*Manufacturing: means production or extraction of substances in the natural state*"

From this follows that also several substances can form in manufacture or in a manufacturing process. In this case, a mixture of two or more substances would be the outcome of the manufacturing process.

Article 3.2 gives the definition of the term "preparation":

"*Preparation: means a mixture or solution composed of two or more substances*"

Practically, this means that the terms "mixture" and "preparation" are used as synonyms under REACH. The term "preparation" comprises all types of substance mixtures.

The REACH Regulation makes no distinction between the different origins or production methods of preparations. Consequently, a preparation can be manufactured in many different ways, e.g. by mixing substances, or in a chemical reaction where several substances form and lead to a mixture of substances (= preparation), or by extracting substances from natural materials. Moreover, the definition does not stipulate that only intentional mixtures can be deemed as preparations.

According to Article 6 (1), which was quoted earlier in the Introduction,

"*any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 ton or more per year shall submit a registration to the Agency.*"

Thus the registration requirement applies both for substances on its own which are manufactured in or imported into the EU, and for substances which are manufactured in preparations or imported in preparations into the EU. Furthermore, in Recital 45 the REACH Regulation points to "complex reaction products":

"*The European Inventory of Existing Commercial Chemical Substances (EINECS) included certain complex substances in a single entry. UVCB substances (substances of unknown or variable composition, complex reaction products or biological materials) may be registered as a single substance under this Regulation, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification.*"

This Recital is not legally binding, but it indicates that complex reaction products can be seen - but do not necessary need to be seen - as one substance.

II.2 ECHA "guidance for identification and naming of substances under REACH"

The guidance additionally introduces, inter alia, the term "constituent":

"*Constituent: Any single species present in a substance that can be characterized by its unique chemical identity" and the term "multi-constituent substance*":

"*Multi-constituent substance: As a general rule, a substance, defined by its composition, in which more than one main constituent is present in a concentration 10% (w/w) and < 80% (w/w).*"

The REACH Regulation does not include these terms. The term "compound" is not explained more closely in the Guidance, even though this could have been expected, because it is an essential element of the substance definition in the REACH Regulation. The first part of the definition of the term "preparation" is correctly repeated in the guidance, reflecting Article 3 no. 2 of the REACH Regulation:

"*Preparation: Mixture or solution composed of two or more substances*"

But then the guidance, in a comparison with the REACH Regulation, surprisingly makes severe limitations. Initially the following is stated, in a by-the-way manner, in a footnote on page 13:

"*Note: Mixtures/preparations are not the same as multi-constituents substances. Multi-constituent substances are named as "reaction mass of ...". Multiconstituents substances are the result of a chemical reaction, while no intentional chemical reaction occurs when making a preparation." This introduces the new term "reaction mass"*.

Moreover, elsewhere in the text (page 23) the definition of the term "preparation" is limited:

"*Preparations, as defined in REACH, are intentional mixtures of substances and are consequently not to be considered as multi-constituent substances.*"

In a further footnote (page 24) it is stated that:

"*The difference between preparation and multi-constituent substance is that a preparation is gained by blending of two or more substances without chemical reactions, a multi-constituent substance is the result of a chemical reaction*"

Then on page 25 it is said that:

"*REACH requires the registration of a substance as produced. If a multiconstituent substance is manufactured, the multi-constituent substance needs to be registered. It is a case by case decision to establish to what extent the different steps in producing the substance are covered by the definition "manufacturing.*"

All substances covered previously by EINECS (e.g. multi-constituent substances were covered if all individual constituents were listed on EINECS) would qualify as phase-in substances."

Finally, an example on page 49 of the guidance explains what precisely is meant:

"*REACH instead requires the registration of the manufactured substance. It is a case by case decision to establish to what extent the different steps while producing the substance are covered by the definition "manufacturing" (e.g. different purification or distillation steps). If a multi-constituent substance is produced it has to be registered (and is not covered by a registration of the individual constituents); e.g. the isomeric mixture diflurobenzene is produced, thus "diflurobenzene", as an isomeric mixture, has to be registered. However, for multiconstituent substances, there is no need to test the substance as such, if the hazard profile of the substance can be sufficiently described by the information of the individual constituents. If the individual isomers 1,2-Difluorobenzene, 1,3-Difluorobenzene and 1,4-Difluorobenzene are produced and mixed afterwards, the individual isomers have to be registered and the isomeric mixture would be regarded as a preparation.*"

This would mean that according to the guidance, a mixture of substances (in this case of isomers) would have to be named differently and registered, depending on the manufacturing process. Irrespective of the fact that both are identical mixtures of substances (and both are called "mixture" in the guidance), only the latter mixture of previously separate isomers could be seen as a preparation, while the other mixture, formed from a chemical reaction, would be regarded as one substance - namely a "multiconstituent substance".

In this exclusivity and absoluteness, this is certainly an overly narrow interpretation of the REACH Regulation. As expounded above, the REACH Regulation contains no restrictions concerning the type of manufacturing process in which substances and preparations can be obtained and no restrictions concerning the number of substances resulting from a manufacturing process.

According to the definition in Article 3 no. 2, all mixtures of substances (i.a. also mixtures of isomers) can be regarded as preparations.

Practically, the ECHA guidance also denies the manufacture of substances directly in preparations, even though this is expressly provided for by the REACH Regulation in Articles 5, 6 and 86. Moreover, the rule of the guidance that substances occurring in mixed form (e.g. after the manufacturing process) are not preparations ignores the fact that Article 3 no. 2 does not require intentional blending for a mixture to be a preparation.

For this reason, the rules of the ECHA guidance would considerably restrict the flexibility given in the REACH Regulation.

Note: The ECHA guidance allows, in "justified cases", the pre-registration or registration of individual "constituents" of a reaction product as separate substances. In the data requirements for individual "constituents", however, the total "reaction mass" and not the really manufactured quantity of the "constituent" - is to be taken into account (see example below). Again the question arises how this requirement is reconcilable with the REACH Regulation. In the REACH Regulation no points are found which would justify this requirement.

It is also worth stating that users of the guidance will barely understand the importance and the consequence that these rules of the guidance might have in practice, e.g. for pre-registration and registration at a later stage - due to the unclear and unsystematic picture given of the connections between the terms "substance", "compound", "constituent", "preparation", "mixture" and "multi-constituent substance" (where important aspects are mentioned only in footnotes; see above comments). It is almost bound to happen that companies do not become aware of the alleged borderline between "multiconstituent substances" and preparations, which is newly introduced in the Guidance.

General conclusions The REACH Regulation makes no restrictions as to the type of manufacturing process for obtaining substances and preparations. Consequently, the ECHA guidance inadmissibly reduces the flexibility given by the REACH Regulation. The above-described restrictions through the ECHA guidance would practically lead to a situation where the result of a chemical reaction - i.e. the reaction product - could not be seen as a preparation but would have to be generally viewed as a so-called "multi-constituent substance", i.e. one single substance. In other words, in all cases the guidance allows one to obtain only one single substance as product of a chemical reaction, with this product requiring pre-registration or registration. The possibility of

several substances forming in one reaction and of viewing the thus obtained mixture as a preparation is not permitted. The guidance fails to explain how these interpretations can be reconciled with the REACH Regulation.

Comment from Dr. Joseph Plamondon of Bergeson & Campbell

First, I would think that the authors of the regulation addressing this issue had in mind what are called UVCB or Unknown or Variable compositions, Complex reaction products, and Biological materials in the U.S. In these cases, one might be able to define clearly what one starts within terms of reactants, but not in terms of products. Thus, the designation of A, reaction product, with B would be used. In the cases you cite, however, the products are discrete chemical substances that are well defined and existing chemicals.

The basic principle of One Substance One Registration would seem to be violated by requiring duplicate registrations of substances depending on whether they exist alone and in mixtures or are the result of a reaction product. One might ask whether there is any possible risk associated with the substances produced through a reaction process as opposed to a simple mixing of the two, and I would be hard pressed to think of a good reason. On the other hand, it is possible that a mixture or preparation of two substances which are inherently safe on their own could produce toxic properties when mixed together. Because this possibility is ignored by not requiring the registration of mixtures, it should also not be required that components of a mixture simultaneously present due to a reaction be separately registered.

As a final comment, nearly all chemicals are synthesized by reacting two precursor chemicals together, with the resulting chemical accompanied by byproducts, such as water in the cases you present. This would lead to an unmanageable (and unnecessary) situation in which so many substances would have to be registered that it would be akin to having to register all mixtures or preparations.

G ECHA "guidance on waste and recovered substances"

Excerpt from Reference [27]:

Guidance on waste and recovered substances. Guidance for the implementation of REACH. ECHA. Draft version 2.0, 2010. (The file on the ECHA website was created 2009-12-22).

2.1 Pre-registration

If applicable, the exemption from registration for recovered substances in Article 2(7)(d) of REACH relies on the condition that the same substance has been registered before. Although it is likely that for most recovered substances this will be the case by the time registration obligations for phase-in substances apply, there is no certainty that registrations would have already been made by the end of the pre-registration phase8.

As long as the substance has not yet been registered by another actor, the conditions of Article 2(7)(d) of REACH are not fulfilled and, therefore, recovery operators manufacturing such a substance will be subject to registration obligations. This means that recovery operators that have not pre-registered their substance cannot lawfully manufacture or place on the market their substance until either they or any other actor has registered the substance and that a downstream user of the recovery operator cannot legally use the substance.

…

Moreover, pre-registration may open communication with other manufacturers of the same substance. This gives recovery operators access to the contacts information of other manufacturers of the substance and, if they so wish, a possibility to contribute to the SIEF discussions. Pre-registration will also allow recovery operators to participate in the discussion on the sameness of substances. Moreover, the SIEF may also be an opportunity to discuss access to safety information that recovery operators may need to benefit from the registration exemption and also for other obligations they may have under REACH Registration status of substances (section 2.6) and availability of information (section 2.3.2). It should be noted that pre-registering a recovered material as a UVCB (instead of single substances with impurities) may make it more difficult to benefit from the exemption from article 2(7)(d) at a later stage (section 2.2.3).

2.2.1 Is recovery a manufacturing process under REACH?

As already discussed above, after ceasing to be waste in a recovery chain, the recovered matter can be considered as a substance on its own, as a mixture containing two or more substances, or as an article. Consequently, it needs to be clarified whether recovery is a continuation of the use of the originally registered substance and if this is not the case, then, secondly, whether it is "manufacturing" that transforms waste into substances, mixtures or articles again.

Article 3(8) of REACH defines manufacturing as "production or extraction of substances in the natural state". Substances that have undergone a chemical modification during the waste and recovery process (e.g. certain slags, fly ash, creation of methane during "feedstock recycling" of polymers) clearly fulfil this definition.

Some recovery processes resulting in recovered substances do not modify the chemical composition of substances (in particular mechanical processing or recycling, e.g. sorting and crushing materials, re-melting them without chemical modification).

The life cycle and supply chain of the original substance ends with the waste stage. If waste ceases to be waste, a new life cycle of the substances in the waste starts. The recovery process focuses on recovery of the substance from that waste. Therefore, in any event and by definition, recovery cannot be a use11[24].

In order to ensure a consistent approach, all forms of recovery are considered as a manufacturing process whenever, after having undergone one or several recovery steps, they result in the generation of one or several substances that have ceased to be waste.

2.2.2 Identification of the recovered substance

To benefit from the exemption contained in Article 2(7)(d) of REACH, an identity needs to be assigned to the recovered substances. In the same way as for other substances subject to registration under REACH, the name and corresponding data that sufficiently identify the recovered substance need to be available. Section 2 "identification of the substance" of Annex VI to the REACH Regulation lists the information considered to be sufficient for correct identification and naming of the substance[1225]. This information includes in principle the IUPAC name and/or any other

[24] Article 3(24) defines "use" as "*any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation*".

[25] Guidance for identification and naming of substances under REACH is available at: http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.htm.

chemical identifier, the molecular and structural formula, the composition and analytical data (including normally spectral and chromatographic data) of the substance.

Due to the variable input of the composition of the waste stream from which the substances are recovered, or due to the fact that often mixtures and not substances as such are recovered from waste, it might not always be possible to produce such analytical data for each recovered substance. Whenever this is the case, it shall be clearly stated and argued which other data are sufficient to justify the identity of the recovered substance(s). Information that is specifically relevant to the recovered substance (origin of waste, control of input material, if available spectral data, process steps that ensure that certain impurities are not present in the recovered substance or mixture) have to be documented in order to compare the identity of the recovered substance with the original substance that was registered under Title II of the REACH Regulation.

2.2.3 Distinction between substance, mixture and article

…

Substance on its own or in mixtures

According to Article 3(1) of REACH, a substance is defined as "*a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.*"

Substances can be divided into two main groups:

1. 'Well defined substances': Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI section 2. Rules for identification and naming differ
   - 'well defined substances' with one main constituent (in principle >80%) (mono-constituent substances)
   - for substances with more than one main constituent (in principle each constituent >10% and <80 %) ('multi-constituent' substances)
2. 'UVCB substances': "*Substances of Unknown or Variable composition, Complex reaction products or Biological materials, also called UVCB substances cannot be sufficiently identified by their chemical composition, because:*
   - *The number of constituents is relatively large and/or*
   - *The composition is, to a significant part, unknown and/or*

- *The variability of composition is relatively large or poorly predictable.*"[26]

For such substances, further identifiers have to be considered such as sources of origin or type of production processes.
In particular the approaches to identify a substance as a mono-constituent or as a UVCB substance are relevant for recovered substances. In contrast, the concept of "multi-constituent substances" refers to a category of substances resulting from a specific manufacturing process[27] and applies to recovered substances only in special circumstances. Whenever materials are listed in EINECS, this is an indication that they are regarded as substances, although in many cases a refinement of substance identity may be necessary[28].

According to Article 3(2) of REACH, a mixture is defined as "*a mixture or solution composed of two or more substances.*" Thus, a recovered material may also be considered a mixture, containing a number of recovered substances.

In general, it has to be borne in mind that there is a clear distinction to be made between mixtures and substances, a result of which is that both terms are not interchangeable on a discretionary basis. The definitions of 'mixtures' and 'substances' need to be interpreted in a way that the term 'substance' includes reaction mixtures resulting from a chemical reaction. The term 'mixture' is limited to blends which are not the result of a chemical reaction.

{Underlining done by present authors – no underlining in the original text. As is explained in Sections 7.2.3 and 7.2.6, there is no support in REACH for this interpretation by ECHA}.

As many recovery operations do not produce substances on their own, but rather substances in mixtures (e.g. plastics, rubber etc), the distinction between a mixture and a UVCB substance of variable composition is described hereafter.

Many recovered materials consist of two or more substances but also have typical characteristics of UVCB substances. For this reason, the alternatives to characterise the substance(s) are to a certain degree interchangeable. It is up to the manufacturer or importer to decide which of the two options best fits the characteristics of the material.

On the one hand, it will be easier to register substances with a very complex composition as UVCB substances. On the other hand, recovered materials with a complex composition will often not have corresponding original substances that have been registered as UVCB substances before. Therefore, such substances might not be able to benefit from phase-in status as there is no corresponding EINECS entry.

[26] Guidance for identification and naming of substances under REACH, p. 29.
[27] See example in section 2.4.3.
[28] See guidance documents on substance identification and on data sharing.

Nevertheless, the individual constituents of the material may already have been registered (or are exempted from registration), thus enabling the use of the exemption in Article 2(7)(d) of REACH provided that the relevant safety information is available.

While both options are in principle applicable, it may often be easier for the recovery operator to consider the material as a mixture in which the individual constitiuents/substances have been registered before and thereby benefiting from the exemption in Article 2(7)(d) provided the relevant safety information is available.

Impurities

The guidance on substance identification defines an impurity as "an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance it was not intentionally added."[29]

Recovered substances (as such, in a mixture or an article) may contain impurities which may be different from those in a substance not deriving from recovery processes. This is in particular the case when recovered materials contain unintended constituents which have no function for the recovered material and the only reason for their presence in the recovered material is that they were part of the input waste for the recovery process.

While such constituents may have originally been intentionally added as substances to form a mixture or an article, their presence in the recovered material may be unintended (depending on whether these constituents have a specific function or not) and therefore, they can be considered as impurities, which do not require separate registration on their own.

Constituents present in quantities above 20% (w/w) should, however, in general not be considered as impurities but as separate substances in a mixture. In the case that recovered material is intentionally selected for the presence of certain constituent(s), those constituents should also be considered to be separate substances, even if they are present in smaller quantities than 20% (w/w) (e.g. if PVC is selected for the presence of softeners, it may be necessary to register these softeners, unless they have been registered before).

In mechanical separation of mixed waste, it may often be impossible to derive recovered material of 100% purity (free of alien elements). These alien elements are often either extraneous to the waste stream *per se* (for example, and depending on the waste stream, stones, plastics, pieces of rubber, sand, etc.) or extraneous to the material object of the recovery but part of the final product that became waste (for example, paints, coatings, etc.), of which the composition and total amount are difficult to determine. After appropriate sorting and separation, these fractions should be present in the recovered material only in very small quantities. In this case, such elements can be considered as impurities that do not need to be registered separately on their own.

[29] Guidance for identification and naming of substances under REACH, p. 11.

Even if impurities do not have to be registered separately, they need to be:

- identified to the extent needed in order to facilitate the comparison with another already registered substance,
- covered in the registration of the recovered substances, and
- identified and evaluated to the extent needed for establishing the hazard profile as well as the classification and labelling of the substance or mixture in which they occur (see section 2.3.2).

Whenever the recovered material is considered to be a mixture, the content of this mixture has to be assigned to single substance identities. Each substance identity may include impurities.

2.3 Exemption requirements according to Article 2(7)(d) of REACH

Once the type (mixture or substance) and impurities of the recovered material have been established, identified and documented as described in chapter 2.2, the recovery operator is in a position to examine whether the exemption criteria under 2(7)(d) of the REACH Regulation are fulfilled. It should be noted that companies willing to benefit from this exemption must provide the authorities (on request) with appropriate documentation proving that their recovered substances qualify for the exemption.

Article 2(7)(d) of REACH provides the following exemption for recovered substances:

"*2.7. The following shall be exempted from Titles II, V and VI:*

[…]
(d) Substances, on their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery." [30]
The subsequent two chapters describe how to fulfil these requirements step by step.

[30] Article 2(7)(d) only exempts recovered substances under certain conditions. A general exemption for recovered substances through inclusion in Annex V was, therefore, not intended by the legislator.

2.3.1 Condition 1: "Sameness of name" with substances already registered

Article 2(7)(d)(i) of REACH provides that the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II. This part of the legal text comprises two requirements: The exemption relies on an existing registration and the recovered substance is the same as the substance that has been registered.

The recovered substance must be the same as the substance already registered

This means that if, for some reason, the same substance has not been registered at manufacturing or import stage, the recovered substance has to be registered before the recovery operation can start.

It is worth noting that the obligations related to the life cycle and supply chain ends with the waste stage. This also has the consequence that the uses of a substance as a recovered substance do not have to be covered in the exposure scenario of the "original" substance (i.e. the substance that became waste and which is recovered from that waste), because the life cycle of the original substance ends when it ceases to be waste.

In order to benefit from the exemption in Article 2(7)(d) of the REACH Regulation, it is sufficient that a registration was filed for the substance by any registrant. This registrant does not have to be part of the supply chain leading to the waste generation[31].

In assessing whether the recovered substance is the same as a substance that has already been registered or whether the substances are different, recovery installations need to apply the rules of the guidance on substance identification. In particular, it should be noted that this is an assessment that recovery installations need to make themselves. There is no confirmation given on "sameness" by the European Chemicals Agency. Recovery installations who have pre-registered their substance can however discuss "sameness" questions with other pre-registrants of the same substance in the (pre-)-SIEF[32]. As described in the data sharing guidance, companies can also refine and if necessary correct substance identity, as long as it is clear that the pre-registration was indeed for the concerned substance.

The same EINECS and CAS numbers for substances are an indicator for the sameness of substance. It should be noted that variations in the composition and the impurity profile, including a variation in the percentage of impurities, do not necessarily mean that substances are different. According to the guidance on identification and naming of substances, "*No differentiation is made between technical, pure or analytical grades of*

[31] Guidance on registration, http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm, p. 37.

[32] According to REACH, the exchange of information for the purpose of data sharing takes place for all those potential registrants and others who have submitted information to ECHA for the (same) substance in a Substance Information Exchange Forum (SIEF). Therefore, the data sharing guidance recommends first having discussions on the sameness in a pre-SIEF, before the SIEF is formed.

the substances. The "same" substance may have all grades of any production process with different amounts of different impurities. […].
Where the impurity profile of a well-defined substance from different manufacturing sources differs markedly, expert judgement will need to be applied to decide if these differences affect whether test data generated on one substance can be shared with other SIEF members."[33]
For UVCB substances also – in general - the name is leading to determine the 'sameness'. If the name is the same, the substance is regarded the same, unless available data shows the contrary." [34]

…

2.3.2 Condition 2: Information required

Article 2 (7)(d)(ii) of REACH provides that "*the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery*".

The legal entity that did the recovery must ensure that information on the registered substance is available to it, and that information must comply with the rules on information provision in the supply chain.

This means that the legal entity who undertook the recovery must have obtained one of the following, depending on the case:

- a Safety Data Sheet (SDS) as required by Article 31 (1) or (3), on the registered substance, with the annexed exposure scenarios for the registered substance;
- other information sufficient to enable users to take protection measures, as required by Article 31 (4), for the registered substance in case no SDS is required; or
- the registration number, if available, the status of the substance under the authorisation part of REACH, details of any applicable restrictions under REACH and information necessary to allow appropriate risk management measures to be identified and applied, as required in accordance with Article 32 (1).

In which form this information has to be available to the company carrying out the recovery is not further specified in this provision but this provision aims at allowing recovery operators to comply with their duties under Title IV of REACH. Such information only needs to be available for substances including their impurities. Information does not have to be available for the impurity on its own[35].

[33] Guidance for identification and naming of substances under REACH, p. 46.
[34] Guidance on data sharing, http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.htm , p. 35.
[35] For more information please refer to impurities in section 2.2.3.

Availability of the information

Recovery installations will normally not receive an SDS or other safety information in the framework of Title IV of REACH. In order to benefit from the registration exemption under Article 2(7)(d) of REACH, the required information must however be available to them. Furthermore, whenever required, they need to either prepare SDSs themselves or agree with owners of existing SDSs on using those SDSs. As there are no further legal provisions on this, this is a matter for the manufacturer of the recovered substance. The recovery operator can use any available information, starting with the information on the ECHA website and published in accordance with Article 119 of REACH, but must make sure that he does not violate any property rights. When using an existing SDS, he should, therefore, make sure that he has legitimate access to the information, and that the hazard profile of his recovered substance or mixture is adequately covered by this existing SDS (see below). The same applies to other safety information, if required. Discussions on the use of such information can, for example, take place within the SIEF, if the recovery installation has pre-registered the substance. Provisions can be made in the SIEF agreement on how the necessary information can be provided to the recovery operator without violating property rights. The activities within SIEFs are outside the remit of ECHA, and we suggest contacting the relevant industry associations which could play an important role in preparing standard information for their members.

Companies undertaking recovery operations and wishing to avail themselves of this exemption are advised to ensure as insofar as possible that the information on the registered substance, which was put together to comply with the REACH Regulation, is available to them as well. In case a recovery operator is unable to access the relevant information on the same substance already registered, he cannot rely on the exemption under Article 2(7)(d) and has to register the recovered substance.

Relevance and adequacy of the information

Assuming that the recovery operator has established the identity of the recovered substance(s) as such or in a mixture (see section 2.2.3), he should then have available the corresponding safety information for the same already registered substance(s). In order to assess whether this information is relevant and adequate to the recovered substance(s) and their foreseen use, he is advised to check the following:

- What fraction of a recovered mixture can be referred to the same substances already registered? In order to meet his own duties regarding communication of safety information to customers, the recovery operator should take into account all components at > 0.1% in the recovered mixture[36].
- To what extent may the impurity profile of the recovered substance(s) differ from that of the same registered substance, and may these differences (if any) lead to

[36] Please note that "impurities" on their own are not addressed in the exemption under article 2 (7). They are considered part of the substance as such or the substances in the mixture. For more information please refer to impurities in section 2.2.3.

differences in the hazard profiles of the substances? In case the hazard profiles are different although they can still benefit from the earlier registration of the same substance, the information related to the already registered substance is potentially not adequate for the recovered substance. Consequently, these other hazards need to be described, classified and communicated to the customers of the recovery operator.

- Could the foreseen uses of the recovered substance(s) lead to exposure not covered in the exposure scenarios of the same substances already registered? If this is the case, the recovery operator needs to assess whether the substance information available to him covers the anticipated additional uses. This could mean for example that if the information available for the same already registered substance does not include a DNEL for consumer exposure and also no exposure scenarios for consumer uses, the recovery operator may conclude that it would be inappropriate to use the recovered substance in applications leading to consumer exposure.

Wherever neither the registered substance nor the recovered substance(s) meet the criteria for classification as being dangerous or PBT/vPvB and a substance is not on the candidate list and not subject to restrictions, it is unlikely that safety information will be required according to Articles 31 and 32[37].

How to establish the composition of the recovered material, is the responsibility of the recovery operator. It may be based for example on the following non-exhaustive information sources:

- Representative chemical analysis of the waste and recovery stream through sector organisation initiative made available to the single companies involved in a particular type of recovery operations. The same information can possibly also be derived from literature.
- Good communication with the suppliers of the already registered substance or with producers of mixtures or articles to identify product compositions before entering into the waste life stage.
- Quality classes of secondary raw material which often contain limits for impurities and information on the rough composition of the material.

A case by case analytical assessment of recovered material need only be carried out if all other information sources fail to provide sufficient information.

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[37] Article 32 is still applicable in this case and companies should comply with it.

2.4 Considerations concerning particular streams of recovered materials

…

2.4.2 Recovered glass

According to the scientific literature glass is the state of a substance rather than a substance as such. For legislative purposes, it can best be defined through its starting materials and production process, similar to many other UVCB substances. EINECS has several entries for glasses as follows: *Glass, nonoxide, chemicals (EC: 295-731-7), Glass, oxide, calcium magnesium potassium sodium phosphosilicate (EC: 305-415-3), Glass, oxide, calcium magnesium sodium phosphosilicate (EC: 305-416-9) and Glass, oxide, chemicals (EC: 266-046-0)30*[38].

Certain types of glass are exempted through inclusion into Annex V, entry 11. Recycled glass may contain other constituents such as pigments, fillers resulting from production or from consumer waste. Regarding the recovery and recycling process, constituents that have no specific function in the material, could be considered as impurities. Recovered glass consisting exclusively of types of glass complying with the exemption requirements of Annex V with impurities, will therefore be exempted from registration, downstream user and evaluation obligations. However, in case glass is specifically selected for the presence of certain pigments, those pigments should also be considered as separate substances for which the exemption according to Article 2(7)(d) has to be checked, even if they are present in smaller quantities than 20%(w/w).

…

2.4.3 Recovered metals

Recovered metals may go directly into article production when scrap is added to the furnace and directly cast into an article. No further registration requirements then apply unless the substance is intended to be released.

Under REACH pure metal as obtained from ore or recovered, even if containing a certain amount of impurities is considered as a substance Registration requirements for the substance will depend on whether the substance has been registered before and whether the relevant safety information is available.

Alloys are considered as (special) mixtures and the substances in those mixtures are subject to registration. Recovered metal made from mixed alloy metal scrap will normally be a mixture but it could in certain cases also be a substance with impurities (e.g. when the purpose of recovery is only to reclaim one main metal and all other constituents can be regarded as impurities). All components which have been intentionally selected for recovery and which have a main function in the recovered

[38] Please note that the description following the heading in the EINECS listing of these substances is part of the substance entry and in most cases it is most decisive for substance identification.

material should be regarded as separate substances (e.g. steel will besides iron usually contain manganese and consequently, the recycled steel is a mixture). Constituents which only occasionally occur in parts of the waste from which the recovered metal originates or which do not have a particular function in the recovered material can be regarded as impurities (e.g. molybdenum may occur in certain types of steel but not in others).

Some metals are recovered from simple and rather pure materials (Al, Cu, Pb, Zn from e.g. construction products, pre-consumer scrap) and complex materials (electronic scrap containing e.g. Cu, precious metals) into pure metals. Other metals (Mo, Mn, Ni e.g. present in steel products) are not recovered into the pure metals and used for the production of new metal alloys because of their target metal content, resulting in mixtures. Certain metal compounds (e.g. antimony trioxide, Pb- and Cd-based stabilizers in plastics) are directly recovered from plastics master batches.

The impurities may vary as the metals that are recovered and refined from scrap materials into pure metals depend on several factors, such as the available (refining) technology, the amounts present in the scrap, value of the materials versus cost to recover. While recovered metals may be directly incorporated into other mixtures, the presence of a certain metal may in one case be considered as an impurity and in another case be a constituent depending also on the potential end-application.

The manufacturers of recovered metals should also have information to the extent needed on the identity and quantities in which hazardous minor constituents or impurities are present in the recovered metal or alloy/mixture as described in the section on impurities (chapter 2.2.3).

For metals several tools are available in order to analyse in a relatively easy way the composition of the material. Representative sampling may be an issue for analysis.

Recovered metals can be used for exactly the same purposes as primary metals because the recovering process usually takes place without deterioration of the material properties. Therefore the uses are assumed to be the same. However, as it is still conceivable that not all uses are covered, the non-ferrous metal industry is encouraging recyclers producing secondary metals, alloys/ mixtures to approach the non-ferrous consortia or SIEFs to cooperate and exchange information.

2.4.4 Recovered aggregates

Recovered aggregates[39] should be understood in this paper as covering aggregates resulting from the processing of inorganic material previously used in construction (e.g.

[39] As explained in the introductory section of chapter 3, for the purpose of REACH, recovered substances (on their own, in mixtures or in articles) should be only understood as substances that, after having been part of waste materials, have ceased to be waste according to the Waste Framework Directive. Aggregates which have undergone certain recovery stages and which are still waste, are not considered as substances,

concrete, stones), as well as certain aggregates of mineral origin resulting from an industrial process involving thermal or other modification (e.g. certain slags, fly ash).

The question was raised whether such recovered aggregates can be seen as articles or whether they are substances or mixtures.

Recovered aggregates from construction consist of concrete, natural stones, masonry and/or asphalt, either alone or in certain cases mixed. They can have diverse applications, such as in civil engineering works, in roads and as railway ballast. The main function of this application is to provide stability and resistance to degradation/fragmentation. If for this function the shape, surface or design is more important than the chemical composition, the recovered aggregates would in line with one of the decisive elements to be considered as articles. By definition, this would however only be the case if the shape, surface or design of the material has been deliberately determined and given during its production (e.g. in order to meet certain recognised aggregate standards based on size and shape). If for this function the shape, surface or design does not determine the function of the material to a greater degree than its chemical composition, then the aggregate would not be in line with the basic elements to be considered as an article, and should be seen as a substance or mixture.

Aggregates from construction
Aggregates from construction that fulfil the requirements described above are treated under the same legal principles applicable to articles in the context of this guidance although not fulfilling all the criteria established in section 2.2.3 and elaborated in the Guidance on requirements for substances in articles. This exceptional application of the article definition is justified by the fact that a large fraction of the recovered aggregates originating from construction contain mainly stones and reacted concrete that do not require a registration.

Slag
Most of the slag produced by the iron and steel industry throughout the world is used in applications as asphaltic concrete aggregate and road bases. Other applications are in e.g. concrete products, cement extenders, railroad ballast and roofing granules. The slag used in e.g. road bases is comparable to cement and is mixed with water upon application. Although the size of the slag particles is important, the chemical composition of the slag is clearly more important. Thus slags are to be considered as substances.

Fly ash
Fly ash is a heterogeneous mixture of constituents consisting of amorphous and crystalline silicon dioxide (SiO2), aluminium oxide (Al2O3), iron oxide, calcium oxide and carbon. It has various uses such as in cement and grout, cement clinkers, embankments and structural fill, stabilization of soft soils, road subbase and as a mineral filler in asphaltic concrete. For its use the chemical composition is more important than

mixtures or articles under REACH. They are subject to waste legislation but not to obligations for substances, mixtures or articles under REACH.

the shape, surface or design of particles. Therefore fly ash is considered to be a UVCB substance.

For aggregates that are substances or mixtures it will be necessary to determine the exact status of the material under REACH and to verify whether the conditions of Article 2(7)(d) apply. If the substance is not exempted from registration, late pre-registration - provided that all conditions under Article 28(6) are fulfilled - or decreasing the quantity below 1 tonne until the substance has been registered (by any actor) are possible alternatives for potential registrants.

In determining the exact status of the recovered aggregates, the following considerations should also be taken into account:

a) Some of these materials, such as certain slags and residues of various melting or metallurgic processes, will normally be UVCB substances. There may however also be cases where such substances are multi-constituent substances (e.g. when the substance is the result of a chemical reaction during recovery and consists of a limited number of constituents).

b) Some recovered aggregates may consist of materials which are exempted from registration, evaluation and downstream user obligations under other REACH provisions, in particular Annex V. Examples include minerals which are not chemically modified (e.g. natural stones) or substances occurring in nature which are not chemically modified and do not meet the criteria for classification as dangerous (e.g. wood).

c) In the case where recovered aggregates consist of one main constituent (possibly with impurities), they will be a mono-constituent substance. In case they consist of several constituents, those constituents may either be seen as separate substances (i.e. then the recovered aggregate will be a mixture) or as constituents of one complex UVCB substance. As outlined in section 2.2.3, the two interpretations are to a certain degree interchangeable and it is up to the manufacturer of the recovered material to decide which interpretation is more appropriate in the individual case.

In determining the registration status of the recovered aggregates, information on the origin may be important in order to establish which constituents may be present in the material and whether they should be seen as impurity or separate substance. To identify the substances, that in principle, are subject to registration an analysis of the waste material will only be necessary insofar as constituents may in normal cases occur in quantities above 20%[40] (or are intended to be present in the recovered material – however, in this case the recovery installation should know about their presence).

[40] In cases where such constituents are regularly close to this limit, it is recommended to take a safe approach and consider the constituent as a separate substance. Where constituents exceed 20% only in rare, individual batches which cannot be realistically expected under normal conditions, those constituents do not have to be considered as separate substances. It is also not necessary to examine each individual batch of waste material for the presence of such constituents.

The manufacturers of recovered aggregates should also have information on the identity and quantities in which hazardous minor constituents or impurities are present in the recovered aggregate to the extent needed as described in the section on impurities (chapter 2.2.3).

…

H European Union legislation summaries, glossary

Excerpts from
http://europa.eu/legislation_summaries/glossary/index_en.htm:

The European Union website has a section on legislation summaries, and in this sub-section, there is a glossary. It gives brief explanations to a number of basic principles. Some of them are expecially relevant for the present report and are therefore quoted in the following.

Environmental liability

The glossary is being updated given the recent signing of the Treaty of Lisbon.

Environmental liability is an application of the "polluter pays" principle outlined in the Treaty establishing the European Community. Arrangements for applying it are set out in Directive 2004/35/EC.

It applies to environmental damage and the risk of damage resulting from commercial activities, once it is possible to establish a causal link between the damage and the activity in question. Environmental damage is defined as direct or indirect damage caused to the aquatic environment, flora and fauna and natural habitats protected by the Natura 2000 network, as well as direct or indirect contamination of the soil which could lead to a serious risk to human health.

Two systems of liability have been created: a system with no fault to be proved and a system where evidence of a fault or negligence must be presented. The former applies to dangerous or potentially dangerous commercial activities listed in the Community legislation. In this case, the operator may be held liable even if he has committed no fault. The second system applies to all other commercial activities where species and natural habitats protected under Community law have been damaged or are at imminent risk of damage. In this case, the operator will not be liable unless he has committed a fault or has been negligent.

Proportionality principle

The glossary is being updated given the recent signing of the Treaty of Lisbon.

Like the principle of subsidiarity, the principle of proportionality regulates the exercise of powers by the European Union, seeking to set within specified bounds the action taken by the institutions of the Union. Under this rule, the institutions' involvement must be limited to what is necessary to achieve the objectives of the Treaties. In other words, the extent of the action must be in keeping with the aim pursued.

This means that when various forms of intervention are available to the Union, it must, where the effect is the same, opt for the approach which leaves the greatest freedom to the Member States and individuals.

The principle of proportionality is clearly laid down in primary law under Article 5, third paragraph, of the Treaty establishing the European Community (TEC). A Protocol on the application of the principles of subsidiarity and proportionality, annexed to the TEC by the Treaty of Amsterdam, sets out the criteria for applying both these principles.

Simplification of legislation

The glossary is being updated given the recent signing of the Treaty of Lisbon.

Simplifying legislation means weeding out the superfluous by rigorously applying the principles of necessity and proportionality. The exercise mainly involves the recasting and formal or informal consolidation of legislation.

This concept has grown in importance in relation to the internal market since the White Paper on the Completion of the Single Market. It was highlighted by the Edinburgh European Council in 1992. Over the past decade a concentrated effort has been made to establish a market giving priority to the four freedoms, but this has meant a wealth of European legislation, simplification of which has now become a priority in order to ensure that Community action is transparent and effective. The pilot programme (Simplification of Legislation for the Internal Market — SLIM) covering four specific areas was launched in May 1996 and has been reinforced by a multiannual programme on the simplification and updating of Community legislation adopted by the European Commission in February 2003.

In response to the declaration on the quality of the drafting of Community legislation appended to the Final Act of the Intergovernmental Conference (1997), an interinstitutional agreement defining the guidelines for improving the quality of the drafting of legislation was adopted in December 1998.

A new interinstitutional agreement which goes beyond drafting quality alone and is entitled ‘Better Lawmaking’ was adopted in December 2003.

Subsidiarity

The glossary is being updated given the recent signing of the Treaty of Lisbon.

The principle of subsidiarity is defined in Article 5 of the Treaty establishing the European Community. It is intended to ensure that decisions are taken as closely as possible to the citizen and that constant checks are made as to whether action at Community level is justified in the light of the possibilities available at national, regional or local level. Specifically, it is the principle whereby the Union does not take action (except in the areas which fall within its exclusive competence) unless it is more effective than action taken at national, regional or local level. It is closely bound up with the principles of proportionality and necessity, which require that any action by the Union should not go beyond what is necessary to achieve the objectives of the Treaty.

The Edinburgh European Council of December 1992 issued a declaration on the principle of subsidiarity, which lays down the rules for its application. The Treaty of Amsterdam took up the approach that follows from this declaration in a Protocol on the application of the principles of subsidiarity and proportionality annexed to the EC Treaty. Two of the things this Protocol introduces are the systematic analysis of the impact of legislative proposals on the principle of subsidiarity and the use, where possible, of less binding Community measures."

Sustainable development

The glossary is being updated given the recent signing of the Treaty of Lisbon.

The concept of sustainable development refers to a form of development that meets present-day needs without compromising the ability of future generations to satisfy their own requirements. It aims to improve individuals' living conditions whilst preserving their environment in the short, medium and -- above all -- long term. The objective of sustainable development is threefold: development that is economically efficient, socially fair and environmentally sustainable.

In May 2001, an EU strategy in favour of sustainable development was adopted and in 2005 it was revised to give it new impetus. The global partnership for sustainable development, adopted by the Commission in 2002, gave it an external dimension.

The inclusion of environmental issues in the definition and implementation of other policies is essential for achieving the objective of sustainable development. This principle was confirmed in the Treaty of Maastricht and in the Cardiff Summit in 1998

and formed the cornerstone for coordinated action at Community level for the integration of environmental issues.

To promote sustainable development, the public authorities must take appropriate measures to limit the damaging effects of transport and the risks to health, improve the management of natural resources, in particular their consumption, and combat social exclusion and poverty in Europe and the rest of the world. They must also take measures to counter climate change and limit its consequences.

The European Union and its Member States are taking action to promote sustainable development not only within the Union but also beyond its borders, mainly through international bodies and at meetings such as the World Summit on Sustainable Development, which took place in Johannesburg in August-September 2002.

Värmeforsk är ett organ för industrisamverkan inom värmeteknisk forskning och utveckling. Forskningsprogrammet är tillämpningsinriktat och fokuseras på energi- och processindustriernas behov och problem.

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