

# Questions and Answers on REACH

February 2007

The **European Parliament and the Council of the European Union adopted** on 18 December 2006

- **[REGULATION \(EC\) No 1907/2006](#) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
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/
- and **[DIRECTIVE 2006/121/EC](#) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency

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## 1. PRECAUTIONARY PRINCIPLE

<i>Question</i>	<i>Answer</i>
1.1. Is the precautionary principle explicitly mentioned in the Regulation?	Yes, it is explicitly mentioned in art 1(3): The Reach Regulation is underpinned by the precautionary principle.
1.2. How are the provisions ‘underpinned by the precautionary principle’?	<p>The REACH Regulation is based on the precautionary principle, its requirements implement the principle as set out in the Communication from the Commission on the Precautionary principle (COM(2000)1).</p> <p>Some examples of how the precautionary principle is implemented are shown below:</p> <ul style="list-style-type: none"><li>• Safety assessment: If there is uncertainty over scientific evidence (e.g. conflicting data exist), the safety assessment should normally be based on the evidence that gives rise to highest concern. The principles laid down in the PP communication should also be reflected in the guidelines being developed to support industry and authorities with implementation of REACH.</li><li>• Risk management measures: While a company is awaiting further test data on a particular hazard it should make sure that the risk management measures appropriate for the potential risk are in place and describe these measures in the safety assessment; in the case of PBTs and vPvBs, industry is requested to minimise exposure at all times (cf. Annex I, Section 6.5)</li><li>• Authorisation: Industry is required to seek authorisation for uses of substances of very high concern, regardless of the measures taken to control the risks.</li><li>• Restrictions: Member States and the Commission can suggest immediate restrictions in case there are indications of severe risks associated with the use of a given chemical. In this way the PP could be implemented in cases where it would take too long to establish the data necessary for a scientific evaluation or where data does not allow the risk to be determined with sufficient certainty.</li></ul>

## 2. REGISTRATION

### 2.1. What to register

<i>Question</i>	<i>Answer</i>
2.1.1. How many substances have to be registered?	The Commission has estimated about 30,000 substances (excluding intermediates) will be registered; this estimate has been supported by industry organisations. Many of these substances are manufactured and/or imported by more than one company, so there is the potential for many more registrations to be received. The Commission in its planning has estimated about 80,000 registration dossiers (excluding intermediates) will be received over first 11 years of REACH. Joint submission of data as required by article 11 is unlikely to change this significantly as each registrant still has to submit a dossier separately, but the Commission is reviewing the figure.
2.1.2. As stated in the proposed regulation, about 30.000 chemicals out of more than 100.000 existing chemicals should be registered, could you offer us the list of these chemicals?	The number of existing substances marketed in volumes at or above 1 tonne is estimated at 30.000. The European Inventory of Existing Commercial Chemical Substances (EINECS) lists more than 100.000 existing substances that were on the market when the inventory was compiled. The EINECS is published in the Official Journal of the European Community (OJ EC, C 146 A of 15 June 1990: see also

<http://ecb.jrc.it/new-chemicals/>). Out of these, only those substances manufactured or imported in volumes starting at 1 tonne need to be registered. It is not possible for the Commission to provide a list of all substances that will be registered as we do not have knowledge of the precise tonnage of all the substances on the market today, and it will be left to industry (including importers) to decide if they want to continue the production or marketing of these substances. However, substances listed in the HPV-LPV list included in the European chemical Substances Information System (ESIS) might give a good indication of existing substances marketed in volumes at or above 10 tonne per year that will need to be registered. See: <http://ecb.jrc.it/esis/> for further information on the content of this database.

Manufacturers and importers of substances on EINECS will have to pre-register their substances from 12 to 18 months after entry into force of REACH and the Agency will make publicly available the list of all pre-registered substances within 19 months of entry into force (see Art. 28(4)).

2.1.3. Which substances have been exempted from registration?

**Some substances are exempted from REACH altogether** and so will not be subject to Registration: these are radioactive substances, non-isolated intermediates, wastes, substances under customs supervision and, if Member States so choose, substances necessary for the interests of defence (see Article 2).

**Some substances are exempted from registration:**

- **Substances exempted from the present legislation:** Annex IV reproduces the list of substances exempt from the obligation to register under the present Existing Substances Regulation (Reg. 793/93) with the addition of cellulose pulp.
- **Substances that fulfil certain criteria:** Annex V provides a more general list of criteria for exemptions from the obligation to register. The criteria in Annex V are taken from experience in the operation of the present New Substances Directive (Dir. 67/548). A number of classes of substances are exempted from registration unless they are chemically modified: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal and coke. In addition, a number of basic elemental substances for which the hazards and risks are well known are also exempted: hydrogen, oxygen, several noble gases (argon, helium, neon, xenon), and nitrogen.

Note: The Commission will **review** Annexes IV and V within one year of entry into force and that review will take into account substances derived from mineralogical processes; the review will fully take into account the application of Articles 2(7)(a) and (b) and Annex XI to these substances. **Polymers** in accordance with Articles 2.9 and 6.3 (see also section 2.10 of this Q&A).

- **The uses of some substances regulated by other legislation** are exempted (see Art 2 (5, and 6)). For further exemptions related to transport see article 2.

Note: The Commission will review the Regulation 5 years after entry into force to assess whether or not the scope of the regulation needs to be amended to avoid overlaps with other relevant Community legislation. **Substances manufactured or imported in volumes < 1 tonne** do not need to be registered. (NB there is no such volume based exemption for authorisation, restriction or the classification and labelling inventory.)

In addition to the exemptions, a substance that has been notified in accordance with Directive 67/548/EEC is regarded as being registered.

However, if the quantity of a notified substance reaches the next tonnage threshold, additional information corresponding to that tonnage threshold, as well as to all lower tonnage thresholds, shall be submitted. In general biocides and pesticides are also regarded as being registered and no further registration is required for that particular use.

2.1.4. EU-regulation on existing substances has as Annex II a list of exemptions in the regulation - substances like glucose etc. Annex IV of the proposed REACH regulation is the same list of exemptions. Can you explain what the criteria behind the list were?

Regulation 793/93 states in a recital that "*the requirement to provide such information should not apply to certain substances which, on the basis of their intrinsic properties, involve only risks generally recognised as minimal*" so that was the criterion behind the list there. The Commission considered amending Annex II of Reg. 793/93 in 1995 but, after expert review, such an amendment was felt to be unjustified. In 2002, Annex II (now Annex IV of the Regulation) of the REACH Commission Proposal was open for the internet consultation. Here again, no comments were received with justifications for adding substances to the list. During the negotiations in Council additions were again considered and cellulose pulp was added.

Note: The Commission will **review** Annexes IV and V within one year of entry into force and that review will fully take into account substances derived from mineralogical processes (the review will fully take into account the application of Articles 2(7)(a) and (b) and Annex XI to these substances) and substances can be added or removed from the Annex through comitology if necessary.

2.1.5. As we understand, chemicals shall be registered according to its manufactured or imported volume, but how do you calculate the volume of a chemical in a downstream product, especially for those downstream products not originally made of chemicals?

It should be relatively easy to calculate the proportion of a substance contained in a chemical preparation (i.e. a mixture of substances) such as paint, glue etc. Under current EU legislation, the components of imported preparations are already required to meet the existing obligations under the data submission under existing substances regulation (regulation 793/93), the notification of new substances (directive 67/548), the classification and labelling and safety data sheet legislation (directives 1999/45/EC and 91/155/EEC).

For substances contained in articles the calculation may be more demanding. The guidance being produced under the Interim Strategy will address this issue (more information on the development of guidance documents: <http://ecb.jrc.it/REACH/> ). It should be noted that the obligation to register or notify a substance contained in an article only applies when a series of conditions are met. The 1 tonne volume threshold is only one of these conditions. However, if one of the other conditions is not met (i.e. for registration the substance is not intentionally released during use or for notification it does not meet the criteria in article 57 and is not identified according to article 59(1)), then the knowledge of the exact tonnage is not necessary as the obligation to register or notify does not apply.

2.1.6. How would a manufacturer register a preparation containing many kinds of chemicals?

Registration under REACH is only for substances, not preparations or articles. The substances in preparations and articles are potentially subject to registration. However, if all, or certain parts, of a Chemical Safety Report (CSR) are relevant for (an)other substance(s), it can be used for those other substances; e.g., if an exposure scenario (ES) covers the risks of all dangerous substances (at or above 10 tonnes per year) in a preparation, such a ES can be used for all those substances.

N.B. When the SDS is developed for a preparation, the registrant may choose to prepare a chemical safety assessment for the preparation instead of preparing it for each substance in the preparation. But this would not be submitted as part of the Registration, although relevant parts of it might be.

2.1.7. Are there more detailed rules for the registration for downstream uses such as finished plastics, textiles and

No, but if the registrant manufactures or imports a substance in quantities of 10 tonnes or more per year, he needs to prepare a CSR. This CSR will need to cover uses that the manufacturer or importer intends for the substance and uses identified by downstream users to their manufacturers

toys?

or importers, including the use of a substance in production of articles (e.g., finished plastics, textiles and toys). For the identified uses the CSR has also to cover waste management measures that the manufacturer or importer of a substance recommends to be implemented by downstream users. The CSR should also generically cover consumer use of substances as such, in preparations and in articles (e.g. plastics, textiles and toys) and subsequent waste handling. The Commission, together with the Member States and other stakeholders, plans to develop technical guidance to help with carrying out a CSR (more information on the development of guidance documents: <http://ecb.jrc.it/REACH/> ).

Furthermore, there are specific rules for registration of substances in articles (article 7 of the Regulation and section 2.9 of this document).

2.1.8. Shall the importer of a preparation register only those substances defined by dangerous preparation directive (1999/45/EC) and SDS directive (91/115/EC)?

According to REACH, all substances present in a preparation at or above one tonne need to be registered, irrespective of whether they are classified or not. A technical dossier will need to be prepared once the quantity of a substance alone or in a preparation exceeds the 1 tonne threshold per importer per year and a CSR if the quantity exceeds the 10 tonne threshold. The CSR does not have to be undertaken for substances present in a preparation below the concentration limits in 1999/45/EC and an exposure assessment of the substance is not required if it is not classified or a PBT/vPvB.

Note: REACH takes over the SDS requirements from current directives.

2.1.9. When taking into account that in a manufacturing plant, rubber (=polymer, elastomer) is mixed together with additives (a number of preparations) to obtain a blend. If we produce this blend in a factory A where it is partly further processed into an article and the other part is transported to another factory B. Will it then be required to register this blend and is there any difference whether or not this factory B is of the same company or not? What information has to be used for the chemical safety assessment in the case a registration is required (individual substances, individual preparations, blend)?

We assume that both factory A and factory B are inside the European Community.

The blend produced in factory A is a preparation; preparations should not be registered. However, each substance that goes into the preparation needs to be registered by the manufacturer or importer (if  $m/i \geq 1$  tonne; polymers exempted). If factory A is merely blending, not producing or importing, substances, it is a downstream user and, therefore, is not required to register (see also section 4 on Downstream users). Factory A should, based on information from the manufacturer (SDS), assess the risks of the substances in the preparation (unless they have already been analysed by his supplier for this use and that downstream user implements, or recommends on down the supply chain, as a minimum, the identified risk management measures).

This applies regardless of whether factory A produces an article or sells the preparation to factory B. As a downstream user, when factory B receives the preparation it should, in the same way, either make sure that its uses are covered by an analysis performed by its supplier and that it implements, and recommends on down the supply chain, as a minimum, the identified risk management measures or should assess the risks itself.

Whether or not factory A and B belong to the same company does not matter.

Note: The substances in the additive are subject to registration. If company A imports the additives, company A is responsible for registering substances imported in volumes  $\geq 1$  tonne/year.

2.1.10. How can the importer of a preparation be guaranteed that all substances to be registered are declared and therefore known to him?

We recognise that currently it can be difficult in some cases to be sure what substances are being provided by a non EU producer. However, under existing Community legislation (e.g. for classification and labelling of preparations) importers need to know which substances are present in the preparations being imported to be sure they are complying with the law.

It will be up to industry to improve the communication through its supply

chain to be sure of compliance with REACH provisions.

- 2.1.11. A clear product group registration option is needed - currently hundred of our products are "chemically similar", but commercially different ones. Few defined product groups by the industry and based e.g. on applications would solve the problem and save resources.
- REACH allows a wide definition of substance e.g. with a wide range of constituents which could help in this situation. It requires registration for each substance, applying the definition of substance in the Regulation. If one substance is manufactured or imported by more than one manufacturer or importer, the registration shall be submitted jointly (see Article 11). However, companies are allowed to opt out of this with genuine reasons (e.g. confidentiality) and register separately. In addition, Annex XI allows categories of substances that share similar properties to be built and to share the same data. In this case big parts of the CSR could also cover all the substances in the category.
- Note: The Agency is tasked with providing guidance on grouping of substances before the first registration deadline of 3½ year.
- Note: Products understood as preparations (=mix of substances) do not have to be registered – only the individual substances.
- 2.1.12. Is there an obligation to register steel or other alloys?
- Alloys are preparations under REACH, albeit special ones where the properties of the preparation do not always simply match the properties of the components. As preparations alloys do not have to be registered but their components metals must be registered if manufactured/imported  $\geq 1$  tonne.
- However, a CSR need not to be performed for a substance which is present in a preparation under the concentration limits referred to in art 14(2). If the CSR does need to be undertaken for the components the way these components are bonded in the chemical matrix should be taken into account.
- Note: the Commission, in close cooperation with industry, Member States and other relevant stakeholders, will develop guidance to fulfil the requirements under REACH related to preparations (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment of substances incorporated into special preparations – such as metals incorporated in alloys. In doing so, the Commission will take full account of the work carried out within the framework of the REACH implementation projects (RIPs) and will include the necessary guidance on this matter in the overall REACH guidance package. This guidance should be available before the entry into operation of the Regulation.
- 2.1.13. Are fluid glass mass and solid glass products substances, preparations or articles under the REACH?
- Fluid glass mass (produced during the manufacture of glass) is a preparation, albeit a special one, that would render glass comparable to metallic alloys. Those substances in fluid glass mass which are minerals and are not chemically modified during the process do not need to be registered by the manufacturer or importer of these substances. Other substances used e.g., as glass modifying agents, colouring/decolouring agents, coating agents, product lubricants etc. need to be registered. The glass becomes an article when it has been given its final shape (e.g. bottle), but remains a preparation if it cools to a glass mass destined for further processing.
- 2.1.14. Is there an obligation to register metals?
- Yes. Metals are substances according to REACH. Metals have been considered as chemical substances under EU legislation since 1967, and they are recognised as such also internationally (e.g. under the UN Globally Harmonised System for Classification and Labelling). However, minerals and ores are exempted from Registration unless they are chemically modified.
- 2.1.15. How will substance X be treated under REACH?
- We are not in the position to give detailed responses to requests for the status of individual chemicals under REACH. This is because:
- REACH is still subject to change in the co-decision process.

- There are over 30,000 substances and millions of preparations. We could not possibly start to answer questions on all of them.
- Industry has access to the same criteria as the Commission services (they are written in the Regulation). As they know their chemicals best, they are best placed to judge whether or not the chemicals fall within particular REACH requirements.
- Decisions about which substances will fall under authorisation will be taken only after REACH enters into force in a two-step procedure: The first step is that the Agency will produce a candidate list of substances for eventual authorisation, based on information provided in Annex XV dossiers, and will indicate which substances are on its work programme. In a second step, the decision to actually subject certain substances to authorisation will be taken by a committee procedure. For the time being, Companies are advised to assess their data against the criteria in Annex XIII to the Regulation, but should be aware that decisions to include substances with PBT and vPvB properties or which have properties that give rise to equal concern will be taken through a committee procedure. However, once REACH enters into force, the Agency will, based on information provided in Annex XV dossiers, produce a candidate list of substances for eventual authorisation and indicate within this list which substances are on its work programme. Today it is normally very difficult to state whether a particular substance will fall under authorisation.

Already this very brief list of the various procedures exemplifies how unwise it would be to start judging chemicals in advance of REACH being implemented and proper information being available and scientifically assessed.

## 2.2. Who may act as a registrant

	<i>Question</i>	<i>Answer</i>
2.2.1.	Who can register a substance (on its own or in a preparation)?	EU-manufacturers, importers, EU-based representative of a non-EU manufacturer (called an only representative).
2.2.2.	What is the process for a "pan - European" registering instead of a national one - we are producing under same product names in many EC countries? Would it be cheaper to register European wide - any limitations to do it?	Registrations will be sent to the European Chemicals Agency and so any registration is pan-European. We interpreted the question as whether one substance produced in different Member States could be covered by one registration. REACH requires each manufacturer and importer to register but requires a joint submission of the registration of the same substance. The lead registrant submits the hazard information for all registrants, and if companies choose the CSR as well, for each substance. However, companies are allowed opt out of this with genuine reasons (e.g. confidentiality). But of course bear in mind you are registering substances. Preparations and articles (product is not a term used in REACH and it can be used to refer to substances, preparations and articles in different circumstances) are not subject to registration under REACH.
2.2.3.	What benefits could the companies get from forming consortia?	Under the joint registration of data principle there is only one submission of the hazard information for the substance, and if companies choose, the CSR as well, unless a company opts out. The registration fees, set by a Commission Regulation by the latest one year after entry into force of REACH, will take into account whether the submission is joint or separate. There is also intrinsic saving of sharing the load of dossier preparation with other companies. On the other hand, managing collaboration between multiple registrants requires resources.
2.2.4.	Could companies use consortia to exclude new entrants from	No, they could not. A company manufacturing or importing a substance after a joint submission has been made must use the hazard information from that submission, against payment of a fair compensation, unless they

	registration?	wish to 'opt out' of using some or all of the information and justify this opt out.
2.2.5.	Is it possible for a non-EU enterprise to register jointly with an EU enterprise?	No; manufacturers outside the EU are not covered by REACH. However, an importer of a substance manufactured by a non-EU enterprise or an 'only representative' of such an enterprise must, jointly with other EU manufacturers, importers or only representatives, submit the hazard information for the substance unless they choose to opt out. They may also choose to jointly submit a CSR.
2.2.6.	Is it possible for industrial associations not located in the EU to register collectively on behalf of a specific industry?	An industrial association can provide very valuable assistance to companies for the preparation of registration dossiers, and can help co-ordinating the process. They could also be appointed to represent a company in discussions with other companies regarding preparation of the joint submission of hazard data. However, the actual registration should be done by the manufacturer or the importer and cannot be done by an industrial association.  It should be noted that the registrant always needs to be established in the EU, both in case of an importer and an only representative. For the only representative, specific requirements need to be fulfilled to make sure the authorities can communicate with a person with sufficient knowledge in the practical handling of substances.
2.2.7.	Basic chemicals will be registered by European producers. Why should well known international chemicals be registered still by an importer - of course some kind of announcement on volume etc. is needed?	One reason is to stop 'free riders'. Why should EU manufacturers pay the cost of registering a substance and importers take advantage for free? Another reason is to ensure that importers take full responsibility for the safe use of the substances they import as these uses may be specific to them or their clients. Furthermore, if the non-EU manufacturer decides to nominate an only representative to register the substance(s) he exports to the EU, the importer shall be regarded as downstream user.
2.2.8.	When importing the same product from different manufacturers in different third countries, is it necessary for the EU importer to conduct repetitive registrations for the different manufacturers? And who does the related property right belong to?	No, they register per substance they import, provided that it is the same substance (*). Companies have to share test data with other registrants (non-animal data only on request of a potential registrant who needs a study to meet an information requirement) but are entitled to a fair financial compensation. REACH does not impinge on other legislation. 12 years after registration the data submitted (i.e. the robust study summaries or study summaries) is made freely available to other registrants of the same substance.  (*).Guidance on substance identification will be developed (more information on the development of guidance documents: <a href="http://ecb.jrc.it/REACH/">http://ecb.jrc.it/REACH/</a> ).
2.2.9.	For a group company and its branches, and for a holding company, is it possible to share the registration property right and pay one registration fee?	REACH requires each legal entity that is a manufacturer and importer to register some information (regardless of it being part of a group or a head office and its subsidiaries), and pay a fee, but requires one submission of the hazard information by all manufacturers and importers of the same substance, and if companies choose the CSR as well, but allows companies with genuine reasons (e.g. confidentiality) to opt out of this.  The Agency will produce guidance on opting out to assist companies, especially, SMEs.
2.2.10.	May non EU manufacturers of preparations or articles appoint an 'only representative'?	Yes, an 'only representative' may only be appointed by a non-EU manufacturer of a substance (on its own, in preparations, or articles), a formulator of a preparation, or producer of an article. In case an "only representative" is appointed, any importers of the substance produced by that non-EU manufacturer shall be regarded as downstream users.
2.2.11.	What is the difference between the role of conventional 'sole representative' and 'only	The "only representative" needs to have 'sufficient background in the practical handling of substances and information related to them' whereas the sole representative in current legislation just had to be designated by

representative' in art 8?

the non-EU manufacturer.

- 2.2.12. Why should non EU manufactures use an 'only representative'?
- The non EU manufacturer is free to choose whether to appoint an 'only representative' or to let the importer register his substances. By appointing an 'only representative' the manufacturer gets more control over the registration process and avoids having to disclose potentially sensitive information to the importer. Also for EU importers, the 'only representative' has advantages; the importer will be relieved from his obligation to act as a registrant under REACH and will be regarded as downstream user.
- 2.2.13. Does Art 8 empower the 'only representative' to carry out the non-EU manufacturer's obligations?
- No, as the non-EU manufacturer has no obligations. But rather than each importer acting as registrant and having to make a separate registration, and presumably being in contact with the non-EU manufacturer to gather the necessary information, the non-EU manufacturer can appoint somebody to meet the registration obligations covering their total volume being imported into the EU. The importers from that non-EU manufacturer would no longer have duties as importers but will be regarded as downstream users.
- 2.2.14. Will non-EU manufacturers of chemicals through their representative be subject to all the obligations imposed on importers under the REACH?
- The representative would have the legal responsibility to comply with all relevant obligations under REACH. In addition, the legal representative must be based in the EU.
- 2.2.15. Does it mean that the representative "substitutes" the manufacturer?
- In effect the "only representative" substitutes for the importer of the substance as the 3<sup>rd</sup> country manufacturer cannot register.
- 2.2.16. Article 8(3) stipulates that the exporter should inform "importers in the same supply chain" of the appointment of an only representative. What is the meaning of those words?

When the non-community exporter has appointed an "only representative", the importers of the substance are relieved of their duties as registrants under REACH but will be regarded as downstream users. Hence, they need to know who will act as registrant. It should be noted that the "only representative" would not be covering the registration duties for the same substance manufactured by another non-EU manufacturer; if the importer obtains the substance from a number of non-EU sources he may still have to act as registrant.

The concept of "same supply chain" relates to when a substance is transferred from a manufacturer or an importer to a downstream user(s) or a distributor(s), and then on to other downstream users, possibly being incorporated into a preparation or an article, until it reaches a retailer who supplies to the public or it is incorporated into an article.

### 2.3. Information requirements

#### *Question*

#### *Answer*

- 2.3.1. Is a new registration required each time the degree of purity is changed (that is substance quality is improved)? Wouldn't that hamper innovation?
- It is up to the Registrant to decide, in relation to his substance and any variable composition, what to register. Recital 45 in the Regulation makes clear that substances of unknown or variable composition, complex reaction products or biological materials can be registered as a single substance, despite their variable composition, provided that they warrant the same classification.
- If the registrant has defined his substance with narrow ranges of impurities or even single figures, then the registration might need to be updated. However, the change in composition would be the only update that is needed (Article 22(b)) provided that the existing CSR still shows that risks are adequately controlled.
- 2.3.2. If there were 20 producers and importers manufacturing or importing the same chemical substance at the
- This is not needed for registration, but the Agency may require it under substance evaluation. The Agency might identify a substance for the Community rolling action plan, because they suspect it poses a risk and

level of 50 tons per year, should those registrants submit information required under Annex X?

this suspicion could be based on the aggregated tonnage. The evaluating Member State Competent Authority (CA) could then identify that more information is needed to clarify the suspicion (this is unlikely to be every test in Annex X in the example given). The information request would then need to go through an agreement procedure that allows the Agency and all other Member States, and the registrants, to comment.

2.3.3. Do article 11 and Title III apply to producers and importers of articles?

Yes. Article 11 and Title III apply to importers and producers of articles from which substances are intended to be released. For substances of very high concern in Articles, Article 11 and Title III can be applied if the Agency requires a registration.

2.3.4. Importers may not have information on the substances in the preparations or articles they are about to import into the EU.

Under today's chemicals legislation, importers of preparations are obliged to provide information on substances in their imported preparations as well, so there is no change from today in this respect (Directive 67/548 for substances marketed after 1981, Regulation 793/93 for existing substances). REACH intends to fill in the current data gap about substances, in the interest of proper management of the risks for human health and the environment.

Importers have also to comply with the existing marketing and use restrictions laid down under Directive 76/769/EC and the Dangerous Preparations Directive 1999/45/EC.

2.3.5. Can a chemical manufacturer refuse to register a particular use communicated by the user ("identified use")?

Manufacturers and importers are obliged to cover in their registration uses made known to them by their customers, which could be in the form of a brief general description of use, provided that the DU has delivered appropriate information to allow the manufacturer or importer to prepare an exposure scenario. Note that uses can be made known sequentially up the supply chain of the substance in question. Thus a DU may make the use known to his supplier, who may be a DU himself and may decide to prepare an exposure scenario for that substance or pass it on in turn to his supplier. Clearly, the manufacturer or importer is the final link in any such chain.

However, in the following situations the M/Is are not obliged to cover the use(s) in the ES:

- If they choose not to sell to the downstream user.
- If they find that it is not possible to develop an exposure scenario for a given use for reasons of protection of health or the environment.

In the latter case, this must be reported (in Annex VI, Section 3.7) as part of the general update obligations (See Article 37.3). However, in this case, a downstream user can still make his own chemical safety report to demonstrate protection of health and environment, implement the resulting exposure scenario and notify, where required, the chemical safety report to the Agency. In other cases they may not supply the substance for that use.

This issue and the complexity of product chains will be taken carefully into account when developing guidance.

## 2.4. Chemical Safety Assessment / Chemical Safety Report

### *Question*

### *Answer*

2.4.1. A non phase in substance ( $\geq 10t/yr$ ) would require a manufacturer or importer to have a CSR in place 60 days after entry into force. Please

No, the timing for the registration requirements for non-phase-in substances apply 12 months after REACH enters into force (article 141 (2)) on 1 June 2007. A manufacturer or importer can manufacture or import a non-phase-in substance if there is no indication to the contrary from the Agency within 3 weeks after the submission date of the technical

confirm this is correct.

dossier, including a CSR if required.

2.4.2. For a phase in substance a CSR is required when the substance registration is required for a 10-100-1000 tonnes/annum substance. Please confirm this is correct.

Yes. This applies also to non-phase in substances.

2.4.3. For all substances/preparations (phase in and non phase in) the enhanced SDS is required, if relevant, 20 days after entry into force. Please confirm this is correct.

We understand that by 'enhanced SDS' you mean SDSs which have to include an exposure scenario (ES) as an annex.

The generation of an ES is only required in the following cases:

- a substance is manufactured or imported in quantities of 10 or more tonnes per year - in this case a Chemical Safety Report (CSR) needs to be completed - and the substance meets the classification criteria or is assessed to be a PBT or a vPvB, or
- additionally, to justify omitting testing by substance-tailored exposure-driven testing (waiving).

The supplier shall place the relevant exposure scenarios in an Annex to the SDS that is provided to that DU.

Title IV of REACH applies immediately at the entry into force but until a substance has been registered it will not be mandatory to attach the relevant exposure scenarios to the SDS. For phase-in substances therefore, the ESs, where necessary, will only have to be annexed to the SDS, 3,5, 6, or 11 years after entry into force, depending on the tonnage.

2.4.4. Substance versus preparation. According to the CSA/CSR/exposure scenario requirements, there is no obligation to assess preparations. Only substance assessments are required.

The REACH requirements relating to Chemical Safety Reports (CSRs) and thereby to Exposure Scenarios (ESs) only require assessment(s) to be conducted at the substance level. It is possible, however, that an ES that is relevant for the use of one substance in a preparation can also be applied for another substance in the same or a different preparation.

A formulator of a preparation (e.g. as a downstream user) has to develop exposure scenarios (for substances manufactured/imported at or above 10 tonnes/year) for uses not covered by the SDSs. He will have been supplied by his M/I with SDS for the (different) substances. How does he prepare an SDS for the preparation that he will supply to his DU? NB: When REACH enters into force, the Safety Data Sheet for a preparation should describe safe use of the preparation – just as today? In other words, the CSR/exposure scenario requirements seem to clash with the SDS requirements for preparations.

The REACH requirements relating to SDSs require that for preparations they give guidance on their safe use (in the same way that is required today). However, if a SDS for a preparation is required the supplier may undertake a CSA for the preparation for that purpose.

The DU, in preparing an SDS for his preparation, will first need to consider if his supplier of the substance has assessed the uses of the substance both:

- in the formulation of his preparation, and
- the use(s) of (the substance in) the formulated preparation. Note: The supplier is only obliged to assess the safety of 'his' substance(s) in the preparation.

The formulator then has to check if the intended use(s) of his preparation are appropriately covered by the ESs that he received:

- If yes, the formulator can either:
  - Attach all the exposure scenarios for the component substances to the safety data sheet for his preparation (where one is required) or
  - (more likely) Attach an exposure scenario developed for the preparation, based on the SDS and exposure scenarios of the single substances
- If not, the formulator can either make known the use(s) of the substance in his preparation, and the use of the preparation itself, to his supplier(s) of the substances **or** if the relevant substance was

Similarly, the substance-by-substance assessment does not comply with Dir. 98/24, requiring that chemicals (substances and preparations) can be used safely. What should the formulator do? The formulator that forwards the preparation needs to assess the

preparation?

manufactured/imported in quantities of 10 tonnes or more, he has to prepare a CSR for that substance.

Such a CSR, including ES(s), should cover the use(s), for the individual dangerous substance contributing to the classification of the preparation, unless the DU uses less than 1 tonne of the substance per year. If he makes use of the 1 tonne exemption, he must also notify the Agency. If the formulator relies on the 1 tonne exemption he still needs to consider the use(s) of the substance and identify, apply and recommend appropriate risk management measures further down the supply chain.

The formulator then has to document in the SDS of the preparation the RMMs that he recommends to be implemented further down the supply chain.

Note, however, that for the substances present in the preparation under the concentration limits referred to in Art 14(2), the formulator has no further obligations.

For substances manufactured/imported in quantities at or above 10 tonnes/year, the CSRs prepared by the supplier and the additional work conducted by downstream formulators (putting together information from different ESs or preparing own CSRs) should ensure a quality SDS that will assist the employer comply with the requirements of Dir. 98/24.

2.4.5. According to Article 14, a full CSA shall be conducted for substances manufactured in a volume > 10 tpa, if it meets the criteria for C&L. According to annexes IX & X, some of the ecotoxicity tests may be waived, if direct or indirect exposure is unlikely. This pertains to e.g. bio-concentration, effects on terrestrial organisms (short and long-term), effects on birds.

Assuming that it will not be possible to document that exposure is unlikely without conducting an exposure assessment and an exposure assessment is only required for hazardous substances (meeting the C&L criteria), but not for non-hazardous substances. Does this mean that these tests are then always required for non-hazardous substances, while they may be waived for hazardous substances? One could assume that implicitly such tests are not required, but it is not stated anywhere that the data requirements should be interpreted in this way.

Waiving on the basis of no or no significant exposure or that direct or indirect exposure is unlikely is indeed explicitly permitted for certain tests within Annexes IX and X. For other tests, there is a reference to waiving on the basis of the results of chemical safety assessments. More specifically, according to Annex XI section 3 exposure based waiving is possible for tests of Annex VIII, section 8.6 and 8.7, Annexes IX and X. It is clearly stated that an adequate justification and documentation shall be provided based on an exposure assessment. It has to be demonstrated why the use of the substance does not lead to any relevant exposure (e.g. closed system) or why the risk management measures chosen will make significant relevant exposure unlikely. For hazardous substances this is anyhow covered by the exposure assessment in the CSR. For all other substances, an exposure assessment needs to be performed. The issue of how to apply exposure based waiving is addressed in the RIP 3.2 and RIP 3.3 projects where guidance is prepared on how to carry out a chemical safety assessment and how to fulfil the information requirements of REACH.

Given that the question addresses the gathering of data on hazard, it is not meaningful to talk of “non-hazardous substances” at this stage. If the registrant currently has no data indicating that a substance is hazardous, then he has the option of performing an exposure assessment to justify waiving the further testing or performing the test. If he performs the test and it shows no hazard, then he would not be required to perform any exposure assessment. Essentially he can make a commercial choice over how to approach the testing/waiving issue.

The Commission will come forward with proposals for criteria defining adequate justification for the application of Annex XI.3 within 18 months of entry into force, taking into account the results of RIP 3.3.

2.4.6. What is the difference between CSR and SDS?

Chemical Safety Reports (CSR) are documents that provide industry with a tool for demonstrating that it can use chemicals safely. Manufacturers and importers are required to prepare CSRs for substances in volumes at or above 10t/y. Downstream users may require their suppliers to address their use in the chemical safety report (called an identified use). Alternatively, they may decide to protect information on their use from their manufacturer or importer, and – in case their use is not covered in the exposure scenario

annexed to the SDS and in total they use 1 tonne or more of the substance - prepare their own CSR. If they use less than 1 tonne of the substance they should consider the use(s) of the substance and identify and apply any necessary risk management measures.

Safety Data Sheets (SDS) are summaries of information on the properties of substances and the safe means of using them. They are a long-established means of transmitting safety information down the supply chain. REACH will take over the current safety data sheet requirements. Furthermore, by establishing more data on the properties and uses of chemical substances, as well as triggering information exchange in the chemical product chain, REACH is expected to improve the quality of SDSs. In particular, the exposure scenarios derived from chemical safety reports are to be annexed to safety data sheets and this is expected to facilitate the application of appropriate risk management measures. This quality improvement will also depend on enforcement at the Member State level that can be facilitated by the Forum of the Agency. The person responsible for placing a substance on the market is required to prepare SDSs for substances or preparations that meet the criteria for classification as dangerous or is a PBT or vPvB.

NB: SDSs are required in accordance with the provisions of Article 31 of the Regulation and regardless of volume (just as today).

- 2.4.7. Should not all the information in the CSR go down the supply chain? It would be impractical in all cases to send complete chemical safety reports down the supply chain, because of the large numbers and amount of detailed information involved in some cases. Information on safety is provided by the safety data sheets, with which industry is already familiar and by any annexed exposure scenarios. However, it should be noted that already today many suppliers provide their customers with more information on the safe use of their chemicals than strictly required by legislation and this will also be welcome once REACH enters into force.
- 2.4.8. What about criticism that SDSs are ineffective today? Much of the criticism levelled against safety data sheets (SDS) today is that clear information on hazardous properties of the substance(s) is not available. By basing safety data sheets for substances manufactured or imported at or above 10 tonnes per year on the information in a chemical safety report, REACH will significantly improve the prerequisites to produce high quality safety data sheets. For priority substances manufactured or imported between 1 and 10 tonnes registered with a full Annex VII, the minimum data requirements should still ensure a standard level of data regarding health and environment effects.
- The quality of SDSs will also depend on enforcement at the Member State level that can be facilitated by the Forum of the Agency.
- Some of the information contained in the SDS for a substance will also have to be presented in registration dossiers (as set out in Annex VI Section 5) and this could be examined during any evaluation of a substance.
- 2.4.9. Concerns related to proprietary of information submitted during the registration phase of a substance. Exposure Scenarios have to be annexed to SDSs and, hence, made public. Exposure scenarios have to be annexed to SDS. The property right would reside with the person who wrote and holds the CSR that gave rise to the exposure scenario. This means that a DU who is not (or is no longer) a customer of the M/I could not legally use his exposure scenario.

## 2.5. Prioritisation of registration

*Question*

*Answer*

- 2.5.1. The risk of a chemical substance toward human health and the environment does not necessarily have a proportionate relationship with the volume of production. Why are registration requirements based on volume?
- Volume is used as a proxy for exposure. It allows a clear, enforceable priority setting for registration which also gives legal certainty. Note though that the further steps in the REACH process are not determined by volume e.g. evaluation for suspected hazard, authorisation for substances of very high concern.
- 2.5.2. Why is there not more prioritization?
- Prioritisation is built into the system throughout. For example:
- Registration is prioritised by tonnage (as a proxy for exposure) and hazard.
- Note : for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years.
- All CMRs category 1 and 2 at or above 1 tonne per year, and those substances classified with N R50-53 (potential PBTs and vPvBs) at or above 100 tonnes per year, are required to be registered at the beginning of the process (3½ years after entry into force of REACH) and those substances manufactured or imported at or above 1000 tonnes per year. Thus the timetable of registration is prioritised, using criteria which are risk based, enforceable and give legal certainty to the registrants.
  - For the registration of phase-in substances in quantities between 1 and 10 tonnes per year the information requirements are based on a prioritisation regime according to the criteria set out in Annex III. In principle, only information on physicochemical properties and all relevant and available test data is required. The full Annex VII information is only required if a substance is prioritised by the manufacturer and importer according to the given criteria, i.e:
    - substance is likely to be CMR category 1 and 2 or PBT or vPvB or
    - has dispersive or diffuse use(s), particularly where the substance is used in consumer preparations or incorporated into consumer articles, and is likely to be hazardous to health or the environment.
  - Priority will generally be given to compliance checks of dossiers if the registrant has opted out of joint submission of data under art 11(3), it is a 1-10 tonne substance that does not comply with the requirements of Annex VII as applied under Article 12, or it is a substance in the Community rolling action plan. The Agency will also take into account where a 3<sup>rd</sup> party or a competent authority has submitted information on the substance to the Agency.
  - Substance evaluation will be prioritised according to criteria developed by the Agency. These criteria shall take into account hazard and exposure data as well as tonnage. Priority for substance evaluations is given to substances that are suspected of presenting a risk to human health or the environment and that are therefore included on the Community rolling action plan (further criteria also apply). Thus the work of the authorities is prioritised based on complete and comparable information on all substances in a certain tonnage band.
  - Authorisation is prioritised as it only applies to substances of very high concern. Furthermore, the Agency shall recommend substances to be subject to authorisation (as the system will only be able to cope with a certain number of substances of very high concern at the same

time) taking account of certain criteria (i.e. PBT/vPvB, wide dispersive use, high volumes). Uses or categories of uses may also be exempted so allowing yet further prioritisation.

## 2.6. Mutual recognition on testing results

	<i>Question</i>	<i>Answer</i>
2.6.1.	Which laboratories or institutions in which countries could be recognized or designated to supply their testing data or information? Is the European Commission going to develop a detailed list of recognized or designated laboratories of institutions?	<p>REACH places the onus on industry to provide adequate information. No laboratories will be recognised or designated under the provisions of REACH. New toxicological or ecotoxicological tests and analyses need to be carried out in accordance with Good Laboratory Practice (GLP) or another international standard recognised by the Commission or the Agency.</p> <p>REACH is not intended as a testing programme. New testing should only be a last resort and available information should be used wherever possible. The registrant will have to make decisions as to what is reasonable information for use in a registration. Annex XI sets out the general rules for what information is acceptable. Guidance on information requirements will be developed. (more information on the development of guidance documents: <a href="http://ecb.jrc.it/REACH/">http://ecb.jrc.it/REACH/</a>).</p>
2.6.2.	Under the REACH regimes, it is stipulated that existing toxicity and bio-toxicity information and epidemiological evaluation results should be fully taken into account. What information is acceptable?	<p>Annex XI sets out the sort of information that can be used. The registrant has to assess the information available and decide if it is adequate.</p> <p>Further guidance on information requirements will be developed (more information on the development of guidance documents: <a href="http://ecb.jrc.it/REACH/">http://ecb.jrc.it/REACH/</a> )</p>

## 2.7. Completeness check

	<i>Question</i>	<i>Answer</i>
2.7.1.	How does the Commission see the completeness check carried out?	<p>This will be a completely automated check of the registration dossier, to ensure that all the required information elements have been submitted but which does not constitute a quality check. This could for example be as simple as a check if any information, a testing proposal, derogation statement or waiving statement is present or go as far as checking that a number of fields have been filled in for all the information requirements in Annexes VI through X. The result of the completeness check would be sent to the potential registrant by the Agency. Decisions to reject a registration by the Agency will not be an automated but a manual check. These decisions would be subject to an appeals procedure. Once the decision of rejection is taken, this would be enforced by the MSs.</p> <p>The Commission intends to provide a tool within the IT system that will allow the registrant to perform a check for the completeness of his dossier before he submits it.</p>

## 2.8. Fees

	<i>Question</i>	<i>Answer</i>
2.8.1.	How will the fees be shared when products are imported to EU through a trading partner in a third country?	<p>It is the importer or the only representative of a non-EU manufacturer who is responsible for registering imported substances (whether the substances are on their own, or contained in preparations or in articles (see criteria for substances in articles, Article 7) and, if necessary, paying a fee. The proposed legislation does not state how registration fees should be</p>

recuperated in the supply chain; this should be settled by the market.

2.8.2. For a registered chemical, any following registrant should pay for sharing the initial registration fee, we wonder what's the proportion for them and as for separate downstream users how do they pay for the share of initial registration fee? As for one use of one chemical, there may be hundreds, thousands downstream users or even more, if each of them should pay half of the initial registration fee, it is obviously unreasonable and the Chemical Agency and the first registrant will make a lot of profit from it.

A registrant of a substance that has already been registered by another registrant or multiple registrants does not have to pay the first company a share of the registration fee, even if it uses the jointly submitted hazard information (note that payment of data is regulated in Title III). Each registrant must pay its relevant registration fee to the Agency when it registers a substance. The level of the fee will depend on the tonnage that is registered, if the hazard data is submitted jointly or separately, or if the company is an SME (who will pay a reduced registration fee).

Downstream users are not directly involved in this system, as they do not register substances.

Note: DU might be required to report certain information to the Agency on its substances. Such a report will, however, not be associated with a fee.

## 2.9. Articles

### *Question*

2.9.1. How are the requirements for substances in articles related to the existing requirements under Dir 67/548/EEC on the notification of new substances in articles?

### *Answer*

The approach taken under Directive 67/548/EEC for the notification of new substances in articles, which is documented in the Manual of Decisions (<http://europa.eu.int/comm/environment/dansub/mdeurolook.pdf>), requires two questions to be addressed:

- (i) is there a release of the substance during use of the object? If the answer is yes, then:
- (ii) is there a barrier preventing exposure of the user or the environment? If no, then notification is needed.

Some practical examples of the need to notify a new substance in an article (from the Manual of decisions) are:

- a fluid in a sealed container on the back of an instant photographic film as the container could break during normal use or disposal and members of the public could come in contact with the substance.
- in printer ink cartridges. Although the cartridges themselves could be considered articles, it was agreed that there was the possibility of exposure to the chemicals contained therein. It was agreed therefore that the new substance in the ink cartridge has to be notified.

The requirement in REACH obliges registration of a substance that is intentionally released from articles (e.g. ink from printer cartridge) and is present in those articles in quantities of one tonne or more (registration according to Article 7(1)).

If a substance of very high concern meeting the criteria for, and being identified as a candidate for authorisation is contained in the article in a concentration above 0.1% then a notification is required unless the producer or importer can exclude exposure from that substance under reasonably foreseeable conditions of use including disposal, or if its use of such substance in the articles is below 1 tonne per year. The Agency can decide whether or not to require a registration for notified substances. In addition, as a safety net, the Agency can also ask for a registration of any substance contained in an article if specific conditions are met.

## 2.10. Polymers

	<i>Question</i>	<i>Answer</i>
2.10.1.	How are polymers covered by REACH?	<p>Polymers are exempted from registration and evaluation but they may still be subject to authorisation and restriction.</p> <p>However, substances used as monomers, that are manufactured or imported at or above one tonne, should be registered and through any Chemical Safety Assessment that is required, the risks of identified uses, such as polymer manufacture and use, can be assessed.</p> <p>In addition article 6(3) of the Regulation requires the registration of monomers, and other substances, contained in a manufactured or imported polymer. The concept of using monomer information to determine the risks of the polymer is based on a number of principles:</p> <ul style="list-style-type: none"><li>- any reaction of monomers will lead to the production of a number of polymers of different chain lengths. Even if the average chain length is large there will be a fraction of either free monomer or of smaller chain lengths, and it is usually this fraction that leads to any polymer (eco)toxicity. These smaller chains, or oligomers, are conventionally defined as components with a molecular weight (MW) of less than 1000 Daltons;</li><li>- any oligomers are likely to be bioavailable due to this low molecular weight;</li></ul>
2.10.2.	What is the difference between:  67/548/EEC (Art. 13(2)): polymers, with exception of those which contain in combined form 2 % or more of any substance which is not on EINECS;  REACH: The polymers consists of 2% weight by weight or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);	<p>The wordings are based on the same principles but have the same effect in relation to assessment of any risks of the polymer. Directive 67/548 exempted polymers containing less than 2% of a non EINECS monomer from notification. The REACH wording requires registration of monomers if they are contained in a polymer <math>\geq 2\%</math> in the form of monomeric units.</p>
2.10.3.	What should be registered in practice - monomer or/and polymer?	<p>The monomer needs to be registered, not the polymer. What is required to be registered is the monomer that is the building block of the polymer providing the other conditions in Article 6(1) or 6(3) have been met. Other substances that are incorporated into the polymer also need to be registered if the conditions in Article 6(3) are met. Clearly the big advantage of this is that once the monomer is registered in a supply chain there may be other polymers (covering a wide variety of molecular weights) that will in effect be covered by that registration.</p>
2.10.4.	Who would be responsible for registration of monomers - polymer producer vs. chemical supplier?	<p>If the monomer is manufactured in the EU, the monomer manufacturer is responsible for registration. If the monomer is imported alone or as part of a polymer, the importer is responsible for registration. However, a polymer manufacturer or importer will have to register monomers under certain circumstances (i.e. the polymer consists of <math>\geq 2\%</math> of a monomer that has not already been registered by an actor up the supply chain and that monomer makes up <math>\geq 1</math> tonne/year). See also 2.10.7.</p> <p>Note: An EU-based polymer manufacturer using already registered monomers must check if his use of the substance is covered by the ESs</p>

attached to the monomer SDS if an ES is required (see also 2.3.5). Otherwise, he will have to inform his supplier of this use or conduct his own CSR for that use unless the conditions of Article 37(4) are met (e.g. if the use is below the 1 tonne threshold or if his supplier was not required to do a CSR.)

- 2.10.5. For non-registered monomers the registrant is not specified by an actor up the supply chain. Does this mean that any monomer already registered by someone is exempted from the registration obligation?
- 2.10.6. Does the term “consists of” mean a monomer “used” for more than 2% in the production of the polymer or a monomer “contained” in the polymer over 2% as a monomer unit?
- 2.10.7. The plastic industry to a large extent imports plastic granulates. The only processing is that they melt it and form the final product. The granulates consist of polymer(s) and various additives, colorants, etc. Should these granulates be considered as polymers, preparations, or something else?
- 2.10.8. Requiring the importer of polymers to register non-registered monomers that were reacted offshores
- puts the importer at a knowledge disadvantage: details on monomer identities and their percentages are often confidential and not available for importers
  - jeopardizes non-European exporters’ intellectual property
  - creates a disincentive to import polymers
- Any manufacturer or importer of a polymer shall submit a registration for monomer substance(s) that has not been registered up the supply chain.
- The 2 % limit refers to the monomers that are contained in the final polymer in form of monomeric units, any monomers present in the reaction mixture that do not appear in the final polymer are not considered. This requirement reflects that Directive 67/548 exempts polymers containing less than 2% of a non EINECS monomer from notification.
- NB! Monomers used during EU based production need to be registered if used in quantities at or above 1 tonne/year.
- The imported granulates containing a polymer mixed with other substances (e.g. colorants, stabilisers) are considered to be preparations. But only the ‘other substances’ will need to be registered as the polymer will be exempt (although article 6(3) on the registration of monomers in polymers may apply).
- The polymers are exempted from registration. When drafting Article 6(3) of the Regulation, the Commission took as a reference the philosophy expressed by Article 13(2) of Council Directive 92/32/EEC. This article requires that the monomers or other substances will have to be notified as new substances if they are contained in combined form in a polymer at 2 % or more and are not on EINECS.
- To make it easier for importers to obtain the necessary information on the composition of a polymer, Article 8 of the REACH Regulation introduces the option of the “only representative of a non-Community manufacturer” by analogy to the same concept of current new substances Community legislation, i.e. Article 2(1)(d) of Council Directive 92/32/EEC. This provision aims at addressing the legitimate interests of a manufacturer to protect commercially sensitive business information. It also ensures in Article 6(2) that a domestic manufacturer of a monomer will not benefit from reduced registration costs for a monomer claiming the “intermediate status” for this monomer, whereas a non-domestic producer would not. Therefore, the costs resulting from registering monomers in a polymer will be triggered by the same legal requirements for domestic and non-domestic manufacturers.
- We consider therefore that the way the provisions of the REACH Regulation on polymers and monomers are designed, will provide importers of such substances with a level playing field and that Article 6(3) does not create a difficulty in that respect.

## 2.11. Intermediates

**Question****Answer**

- 2.11.1. How are the non-isolated intermediates covered? Non-isolated intermediates (substances which, except for sampling, are not removed from the equipment where they are manufactured and used up) are excluded from REACH altogether.
- 2.11.2. How are the on-site isolated intermediates covered? Isolated intermediates that are used on the site of their production will have to be registered but information requirements will be limited to that which the manufacturer holds or can obtain through the data-sharing provisions of Title III. These limited requirements apply as long as the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. They are not subject to dossier or substance evaluation (article 49), or authorisation. If there is evidence that any of these substances pose a risk equivalent to substances under authorisation, the Competent Authority of the Member State, where the site is located, can ask for additional data.
- 2.11.3. How are the transported isolated intermediates covered? Isolated intermediates that are transported to and used on other sites will have lower information requirements than “normal” substances at the registration stage but of course the requirements are greater than for on-site intermediates. They can be subject to evaluation.
- 2.11.4. Does the authorisation system cover different intermediates? No, use as an intermediate is not subject to authorisation but restrictions can apply.

**3.DATA SHARING****Question****Answer**

- 3.1. Why is it obligatory to share data from animal tests? Because if each registrant is allowed to carry out his own tests, a great number of laboratory animals will have to suffer needlessly. Test results are company property and owners of test results are entitled to fair compensation for their data.
- 3.2. Why can all test results not be shared? All test results can of course be shared on a voluntary basis.  
  
We can oblige registrants to share the results of animal tests because it is in society's interest to limit the number of tests on animals.  
  
For other data there are not so strong reasons for requiring its sharing (protection of health and the environment, and cost reduction have been mentioned) and in some cases it may not be appropriate or cost effective to share data (e.g. from physicochemical tests). In these cases REACH leaves it to the registrants who need the test to decide if they want to request it. The registrants who own a test must share it if it is requested.
- 3.3. Is the cost sharing for the tests proportionate? If test results are to be shared, then everyone who benefits should pay for them. The text requires cost sharing to be carried out in a fair, transparent and non discriminatory way, and may be facilitated by cost sharing guidance adopted by the Agency. If no agreement between the participants is reached voluntarily then the costs are shared equally. It is up to the registrants to decide and agree on how the costs for the test should be documented. However, registrants should only pay for the data they are required to have (e.g. a low volume producer would not share the cost of

tests required for registration at higher tonnage levels).

3.4. If a Consortium would like to register a substance or polymer or intermediate, how to avoid "free riders" to get registering without costs? How to value "fairly" the knowledge needed for registration?

REACH requires compulsory sharing of information involving tests with vertebrate animals and of other information on request of a potential registrant. In both cases, payment of fair compensation is foreseen. It should be kept in mind that the information required by registrants in a consortium may vary widely (e.g. to reflect different tonnages, uses, information available etc). Data only becomes 'freely available' 12 years after it has been submitted to the Agency in a registration dossier. 'Free-riders' should not be a problem as REACH is constructed.

#### 4. DOWNSTREAM USERS

##### *Question*

##### *Answer*

4.1. Is there a tonnage trigger for the DU obligation to conduct a CSR?

Yes, the DU does not need to prepare a CSR if he uses the substance or preparation in a total quantity of less than 1 tonne per year.

A DU is only required to prepare a CSR for those uses outside the conditions described in an exposure scenario. In practice, this will be in those cases where a DU does not want to make his use known to his supplier, where the supplier does not support the identified use for health or environment protection reasons, or where the DU does not regard his supplier's exposure scenario as appropriate and wishes to make his own.

The DU need not to prepare a CSR if:

- A SDS is not required
- A CSR is not required by his supplier (i.e. M/I is less than 10 tonne per year)
- The DU uses the substance or preparation in quantities of less than 1 tonne per year
- The DU implements or recommends a relevant exposure scenario as communicated to him in the SDS.

However, a DU relying on the 1 tonne exemption still needs to consider the use(s) of the substance and identify, apply and recommend appropriate risk management measures.

4.2. Exemption from general obligation of registration for product and process oriented research (PPORD), how will notification work for Downstream users? How can they get a substance from a supplier if it is for an unidentified use and will they have to reveal the necessary information for notifying the agency to their supplier? Or is there no protection of research by DUs?

The PPORD exemption from registration requirements in Article 9 is for manufacturers and importers doing research, either by themselves or with listed customers. Therefore the substances for these uses do not require registration (and Downstream User requirements don't apply because the supplier is not required to make a CSR) and would not be supplied to others in the supply chain for commercial purposes.

The PPORD exemption in Article 37(4)(f) applies to DU using a substance for PPORD and where risks to human health and the environment are adequately controlled. However, if the substance is used  $\geq 1$  tonne per use per year then the DU must report this to the Agency.

4.3. At present, a significant part of substances and preparations on the market are lacking of MSDS or of SDS accuracy. Which modifications shall be expected in the frame of Directive 2001/58/EC, especially in the view of the downstream users,

REACH will replace Directive 91/155/EEC (and its latest amendment 2001/58/EC) and all the provisions of this Directive have been transferred into REACH, with some changes to the Annexes to reflect the greater information that will be available under REACH.

One of the modifications to the current SDS regime is that they will now be required for substances that are PBTs or vPvBs or for preparations that

which will have to verify the already covered intended use of the purchased substances and preparations?

contain them in concentrations greater than or equal to 0.1%. In addition, SDSs will be required for substances identified on the candidate list of substances for authorisation (Article 59) where they don't otherwise require them.

DUs have the right to make known in writing an identified use to the manufacturer, importer or DU who supplies him with a substance. In case the substance is manufactured or imported in quantities at or above 10 tonnes per year and a SDS is required, the supplier, if he supports the use, has to prepare an exposure scenario for the identified use in the chemical safety assessment that he compiles. This exposure scenario should be annexed to the SDS for the benefit of the DU - the latter point is one of the modifications that have been made to the SDS provisions.

If the SDS supplied to the DU does not contain the exposure scenario covering his use (e.g. if the DU chose not to make it an identified use) then a specially tailored CSR needs to be prepared by the DU in accordance with Annex XII.

For substances that do not require an SDS (e.g. are not dangerous), but which have risk management measures required, article 32 lists the information requirements to communicate along the supply chain. In such cases there is no duty on the DU to prepare a CSR.

4.4. How will DUs get information about the substances covered by REACH?

They will get information mainly from their suppliers; through use of the enhanced Safety Data Sheet. Of course they can also access the publicly available information which the Agency will make available and other existing data in databases and literature. Users of articles containing substances of very high concern identified in the candidate list in a concentration above 0,1 % will also get information on their safe use.

4.5. A DU is required to pass on up stream (new) information he receives. The DU is therefore required to inform supplier 1 (let us assume he is in the 10-100 tonnes per year range) about the data/information he has received from supplier 2 (let us assume he is in the >1000 tonnes per year band), both producing the same substance. Does supplier 1 need to use ALL available data when registering, including studies that might have been produced by supplier 2 to produce the SDS information provided by supplier 2 to the DU?

When registering a substance, the registrant is required to use all available information, including information which is only mandatory required at higher tonnage bands. A 10-100 tonnes per year registrant of a substance, which is already registered at >1000 tonnes per year by another registrant is thus obliged to use the information on hazardous properties, which is freely available via the internet. However, he is not obliged to share the costs of a test, if the test is not required in his tonnage band.

A DU will not have the task to supply information from supplier 2 to supplier 1 which is publicly available. Information from the safety data sheets will be available on the internet (note article 119(1) and 119 (2)(d)) and this way of updating registration dossiers shall be used.

4.6. According to Art. 32(1)(a), all actors in the supply chain of a substance or a preparation who do not have to supply a SDS, have to supply the registration number(s) of the substance(s), if available. A strict interpretation of this means that even for very low concentrations of not dangerous substances in preparations, the supplier will have to identify the substances towards his customers and therefore also provide detailed information on his product.

Article 32 requires for substances where there is available and relevant information on risk management (but do not need an SDS) for this information to be indicated to the next actor in the supply chain. In such cases, the registration number should also be provided if it is available. This enables the next actor to implement any necessary controls. In addition, some hazardous substances in preparations will not be included in its SDS as they are below the concentration limits and this ensures that necessary information on those substances is forwarded down the supply chain to enable appropriate risk management measures to be identified and applied. However, the supplier does not need to provide data on the actual concentrations of non dangerous substances in the preparations.

## 5. EVALUATION OF SUBSTANCES

<i>Question</i>	<i>Answer</i>
5.1. Where lies the exact boundary between registration (completeness check) and dossier evaluation?	<p>Registration includes a completeness check, which in itself is only an automated check of the availability of all the required information elements in the dossier - it does not constitute any check on quality.</p> <p>Dossier evaluation enables a quality check of selected elements of the registration dossier(s) of at least 5% of the dossiers registered in each tonnage band and the evaluation of all testing proposals for tests listed in Annex IX and X.</p>
5.2. Fast decisions are needed regarding testing proposals during dossier evaluation.	<p>The proposal foresees deadlines for the evaluation of testing proposals (180 days in the case of new substances and between 2 and 4 years in the case of existing substances, depending on the tonnage band)..</p> <p>It should be noted that registrants are not obliged to have carried out all tests before the registration deadline, they only need to submit a testing proposal for carrying out the tests in Annex IX and X they are required to do. After they have received go-ahead from the Agency, they will be given a new deadline for submitting the test data.</p>
5.3. Which substances will be evaluated under substance evaluation?	<p>The Agency shall develop criteria for prioritising substances for substance evaluation and will select substances for the Community rolling action plan based on those criteria and if it is suspected that the substance constitutes a risk to health or the environment. The rolling plan is initially for 3 years and is updated annually; the first plan should be drawn up within 4 years of entry into force of REACH. MS then choose substances from the list. The plan will allow the Agency and MS to plan their resources, give reassurance to citizens that substance evaluations are being carried out and give some measure of certainty to business when their substance might be evaluated. A mechanism for resolving where more than one MS wants to carry out a substance evaluation has been included.</p>
5.4. On which criteria is the prioritisation of evaluation by the Agency based?	<p>Prioritisation criteria for substance evaluation will be developed and they will be risk-based.</p>
5.5. Decisions on evaluation: what will happen when there is no decision reached within the deadline between the different parties?	<p>Deadlines are set within the evaluation title for the various actors (authorities, registrants and downstream users). For evaluating testing proposals the Agency must complete its action in either 180 days (for non-phase-in substances) or 5 ½, 9 or 15 years (for phase-in substances depending on when the registration containing the testing proposal is submitted). The Agency must complete dossier evaluations within 12 months. Member States must complete any substance evaluation within 12 months. If the relevant authority does not produce a draft decision asking the relevant registrant(s) or downstream user(s) for additional information within that period the evaluation will be deemed closed. However, there is also an agreement procedure in the MS Committee for these Agency decisions with deadlines, including for registrants and downstream users to comment. If comments are not provided within these deadlines then the authorities may proceed with taking a decision.</p>
5.6. Is the procedure of Evaluation a barrier to trade?	<p>Evaluation does not have any effect on a company until its conclusion, i.e. that further testing is or is not needed. Where further testing is needed, all other MS and the Agency are consulted on the draft proposal and if there are any comments that cannot be solved, a committee procedure is invoked to agree the final decision. The Agency has the role of ensuring consistency by developing criteria. The Agency is responsible for taking the decision prepared by a MS if no comments are received. If the</p>

evaluation indicates that further action under some other part of REACH, such as a restriction, is required, then other processes, including consulting the affected company and other interested parties, come into play. There is no impact on the marketing of a substance during this process.

## 6. AUTHORISATION

### 6.1. Authorisation procedure

<i>Question</i>	<i>Answer</i>
6.1.1. Is it predictable for industry which substances may be subject to an authorisation? Are the criteria clear enough?  How will PBTs and vPvBs be identified and agreed?  How will “substances of equivalent concern” be identified and agreed?	<p>The identification of the different groups of substances that may be subjected to authorisation is clearly defined. For CMR category 1 and 2 substances the criteria are long established in the present legislation (Directive 67/548), for PBT and vPvB substances the criteria are included in Annex XIII. For any other substance there must be scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern as CMRs category 1 and 2, PBTs or vPvBs.</p> <p>However, to provide more certainty for industry all substances will be identified through an open process, and the decision to include the substance in Annex XIV will finally be taken by the Commission in accordance with the Comitology procedure.</p> <p>The preparation of this decision is as follows:</p> <p>Dossiers to identify a substance for the authorisation procedure will be prepared either by a Member State or by the Agency if asked for by the Commission. All dossiers will be published and will be open for comments by interested parties. Substances identified as having any of the listed properties of very high concern will be included on a candidate list published by the Agency within which the Agency indicates the substances that are on its work programme. The Agency then recommends substances to the Commission for inclusion in Annex XIV. Priority will normally be given to substances with PBT or vPvB properties, with wide dispersive use or in high volumes.</p> <p>These substances may then finally be included in Annex XIV.</p>
6.1.2. Will the authorisation system be unworkable due to the number of substances, uses and enterprises concerned?	<p>Many substances fall under the scope of authorisation but not all of them can be dealt with at once.</p> <p>The Agency will make recommendations for priority substances for authorisation based largely on risk (use, volumes, PBT/vPvB properties). When prioritising substances, the Agency will have workability considerations in mind. The authorisation system allows for exemptions with conditions; it will therefore be possible to have generic exemptions covering uses or categories of use.</p> <p>The system also allows for group applications for authorisation to be made, covering one or more uses, substances or applicants.</p>
6.1.3. What is ‘adequately controlled’ for the purpose of the granting of authorisations under Article 60(2)?	<p>The expression “adequately controlled” for the purpose of the granting of authorisations under Article 60(2) is defined in Annex I point 6.4 where it is stated that “the exposure of humans and the environment can be considered to be adequately controlled if the Derived No-effect levels (DNELs) for human and the Predicted No-Effect Concentrations (PNECs) are not exceeded”. It has been explicitly stated that for CMRs, and substances with effects of equivalent concern, without a threshold of effect (i.e. a level at which no observed effect for humans is likely) and PBTs/vPvBs (identified either through the criteria in Annex XIII or through Article 57(f)) an authorisation cannot be granted on the basis of</p>

adequate control of risk. The Commission will review within 6 years of entry into force whether or not to include substances identified under Article 57(f) as having endocrine disrupting properties.

The Commission will review Annex I within 12 months of the entry into force. For that purpose, methodologies to establish thresholds for carcinogenic and mutagenic substances may be developed taking into account the outcomes of REACH Implementation Projects. In accordance with article 13(3), Annex I section 6.4 may be amended on the basis of these methodologies to allow thresholds where appropriate to be used in the context of authorising the use of carcinogenic and mutagenic substances.

- 6.1.4. Can applications for authorisation be submitted together?
- Grouping of applications for authorisation is made possible in the Regulation. Groups can be of: manufacturers, importers and down stream users; substances; and uses; or any combination of these groups.
- This is to enable costs to be minimised and the system to process applications rapidly.
- 6.1.5. How are substances of high concern produced in small volumes treated under REACH?
- Authorisation may cover any substance identified as being of very high concern regardless of volume. This means that also use of small volumes will need to be authorised. However, if a particular substance has never been registered in the EU due to its very low production volume (less than 1 tonne/year), and never has been tested otherwise, its hazardous properties may not be known and it is not likely to be a priority for subjection to authorisation.
- The tonnage-triggered system for registration is based on trade-off between workability and the need to cover all substances. The safety net is the Competent Authorities of the Member States. If they identify substances with potentially very high concern properties, they can draw attention to them and suggest that they be subject to authorisation.
- Authorisation will also include a prioritisation process which, amongst other criteria, will be based on volume. This will mean in many instances that low volume substances will not be selected for authorisation at an early stage.
- 6.1.6. Decisions on authorisation: what will happen when there is no decision taken by the Commission within the deadline?
- Time periods are defined by when applications have to be made and by when the use of a substance is not allowed any longer without an authorisation. The key point though is that banning will not occur by default and a decision on such applications will always be taken by the Commission. Where the time limit for a decision has been exceeded, article 56(1)(d) provisions apply – i.e. can be placed on the market until a decision is taken.
- 6.1.7. Should the applicant always submit a substitution analysis if he decides to submit an SEA (SEA only applicable if there are no suitable alternatives)?
- The applicant always has to include an analysis of alternatives in his application for an authorisation, including information about any relevant research and development activities, if appropriate. If the applicant has identified a suitable substitute then he also has to submit a substitution plan but it is up to the applicant to decide whether he wants to include a SEA or not. However, if he wants to get an authorisation on the basis of Art 60(4), it is in his interest to include in the application information needed to support such an authorisation.
- 6.1.8. When is it necessary to present a substitution plan?
- If the applicant has identified a suitable substitute in his analysis of alternatives then he also has to submit a substitution plan (this information will influence the length of the time-limited review for an authorisation).
- 6.1.9. Role of SEA committee. What does the SEA committee do if it does not receive any input or only input for a SEA. Create its own SEA? What
- Authorisation:  
Here, the SEA Committee will prepare an opinion only if a SEA is included in the authorisation application. Socio-economic factors are not

does it do if it receives an SEA which it does not agree with? Can the SEA committee reject a restriction proposal or allow an authorisation in case proper data/analysis is lacking? The very limited time to make a decision should be taken into account when answering these questions.

taken into account if the applicant does not provide a SEA. The SEA Committee has to assess the socio-economic factors related with the use(s) described in the application.

Restrictions:

Here the SEA committee will always have to provide an opinion on the suggested restrictions and on the related socio-economic impact on the basis of the relevant parts of the Annex XV dossier. When preparing its opinion the Committee has to take into account any information provided by interested parties. It is up to industry and other interested parties to decide whether they want to provide information for this decision process or not.

Guidance on socio economic analysis will be developed (more information on the development of guidance documents: <http://ecb.jrc.it/REACH/>).

## 6.2. Substitution

### *Question*

### *Answer*

6.2.1. How will substitution be promoted?

The REACH system has been constructed to act as an incentive for substitution, in at least 4 ways.

- REACH places a clear responsibility on industry to ensure that chemicals are managed safely. In this respect, the increased availability of hazard information and safety assessments for downstream users and the general public should act as an incentive to manufactures and importers to replace the substances or uses of higher concern with less risky alternatives.
- The requirement for the substances of highest concern to be authorised will also promote substitution. Applications for authorisation are costly (if the risks of the use of the substances cannot be adequately controlled, a company has to demonstrate that the socio economic reasons outweigh the risks. In addition, if a suitable substitute is identified for a substance also for substances authorised under the adequate control route), then the Commission may amend or withdraw the authorisation at review, in which case it will require the applicant to submit a substitution plan. The strict conditions for authorisation and the related costs will encourage companies to invest in research to find safer substitutes to avoid having to go through the process. In addition all authorisations should have an analysis of suitable alternatives provided with the application for authorisation, which will require applicants to have thought about substitution, and a time-limited review.
- Also registration will act as a drive for substitution. The demands for information may require testing which may lead to increased costs. In order to avoid this, industry will look for safe and well-tested alternatives to replace potentially problematic substances.
- The requirements to send information down the supply chain will empower downstream users, the retail sector and consumers to demand safer alternatives.

6.2.2. Substitution will cause additional costs for companies.

Substances subject to authorisation are substances of very high concern: substances causing cancer, gene mutations, birth defects etc., and substances that accumulate and persist in the environment. This causes costs to society as a whole; the Commission impact assessment points to the substantial potential health benefits from REACH illustrated by an

estimation of €50 billion over 30 years due to reducing cancers.

If companies cannot adequately control the risks, they need to examine ways of substituting these substances or changing processes so that the risk can be controlled.

If suitable substitutes are not currently available, the applicant may provide information about any relevant R&D. The assessment whether a suitable alternative is available must take into account both technical and economic feasibility of substitution for the applicant.

Substitution is not necessarily linked with long-term costs. Substitution can trigger innovation and prepare new market opportunities.

- 6.2.3. How can one be sure that the principle of substitution is not misused under pressure of NGOs? It is important to recognise that a decision to substitute one substance for another substance or change processes is not taken easily. At the same time substitution is part of the development that industry does as an inherent part of its work. NGOs or others may point out that there are substitutes available but the availability of a substitute has to take into account the specific technical and economic circumstances of the applicant. Thus, before the Commission takes a decision in the authorisation or restrictions procedure, the Agency committees will assess all information, including information on the alternatives, and in defined cases also give their opinion on the suitability to substitute. The final decision on whether to grant an authorisation will be taken by the Commission via the Comitology procedure.
- 6.2.4. Worker protection - Can substitution be strengthened? REACH will improve worker protection by making more information available about hazards of substances used in the workplace and providing better safety advice. If a carcinogen or mutagen is to be used in a workplace, the employer has to apply the carcinogens directive (2004/37/EC) hierarchy (i.e. elimination, substitution, control) before he uses it. In these cases the process he goes through in considering substitution will assist in his analysis of substitutes, if required. Employers using that carcinogen in the workplace, if it has been included on Annex XV for that use, will need to seek an authorisation, or use the provisions of Art. 66 if an authorisation for that use has been granted.
- 6.2.5. What will be the content of the substitution plan? A plan for substituting the substance including a timetable for proposed actions by the applicant. In addition, the analysis of alternatives should show, if appropriate, any action the applicant is taking to work towards a substitute for their product, the Research and Development work towards this goal and the likely timescale for it. This timing can be taken into account, for example, when setting the length of a review period. RIP 3.7 will develop guidance in this area.

## 7. CLASSIFICATION AND LABELLING

### *Question*

- 7.1. The scope of the harmonised classification and labelling is too limited. It should be extended to cover more end-points.

### *Answer*

The text of the Regulation extends the Commission's proposal in this regard to also include classification and labelling of effects other than CMR or respiratory sensitisers, when justified on a case-by-case basis. Complete harmonisation is still not required based on the following considerations:

- responsibility for classification of substances should normally be with industry, not on authorities, except for hazards of the highest concern;
- non-adherence by industry to the criteria is a compliance issue, which is not resolved by placing it into an equivalent of Annex I

of Directive 67/548.

Furthermore, there are currently around 8,000 substances in Annex I but there are 100,000 existing substances on the market. It is unrealistic to expect that authorities will be able to agree on harmonised C&L for these substances and any effort to do so would divert authorities' attention from activities that would have a greater effect on risk reduction.

7.2. Why does evaluation not foresee a mandatory conformity check of all industry C & L proposals?

The consequence of placing the responsibility on industry is that the authorities' role will need to be changed. Authorities should no longer check and agree to industry's dossiers systematically, as this would place the responsibility on authorities. They should only need to evaluate and explicitly state their opinion in those cases where they significantly disagree with a specific item in the dossier, which could be a suggested classification and labelling. The C&L of a substance is also set out in Annex VI point 4. This information is possibly subject to dossier evaluation and hence the conformity of the C&L to Annex VI of Dir. 67/548 can be carried out here, albeit it is not mandatory.

7.3. Why was the Globally Harmonised System for classification and labelling (GHS) not included in the REACH Regulation?

- GHS was not formally adopted by the UN (at the time of the drafting and agreement of the REACH Regulation in the Commission).
- The GHS in itself was technically not mature enough for use instead of the current EU classification system, on which REACH draws. Thus, implementing GHS required extensive efforts to develop a useable and practicable system.
- Inclusion of GHS at this stage would have further delayed the REACH Regulation.

The Commission is preparing a proposal for a regulation to implement GHS. If agreement with the European Parliament and Council can be reached at first reading, the phasing-in of the GHS provisions could be made consistent with the relevant provisions of REACH, in particular the classification and labelling inventory.

## 8. AGENCY AND COMPETENT AUTHORITIES

### *Question*

### *Answer*

8.1. What is the task of the future European Chemicals Agency?

The new Chemicals Agency will manage the technical, scientific and administrative aspects of REACH, ensuring that it functions well and has credibility with all stakeholders.

The Agency will be at the centre of the REACH system. It will manage the registration process and will undertake dossier evaluation (compliance check and evaluation of testing proposals). It will also play a key role in supporting the Commission, Member States and other actors with technical expertise, coordinating action in substance evaluation, and by establishing and running the IT infrastructure. It has significant decision-making powers, and judicial review is provided by a Board of Appeal.

Through its expert Committees, it will advise the Commission:

- on priorities to set up the authorisation procedure,
- on applications for authorisations for the uses of substances of very high concern,
- on other risk reduction measures for dangerous substances (restrictions).

Furthermore, the Agency will help ensure a level playing field in MS, in particular in:

- the substance evaluation stage; and
- enforcement issues. To accomplish this, it has a forum of MS

representatives that will co-ordinate a network of enforcement authorities to promote a common approach to the enforcement of REACH.

- 8.2. How will the Agency be organised? The Agency will be established with an Executive Director appointed by the Management Board on the proposal of the Commission and responsible to the Board consisting of representatives of all Member States, 6 representatives nominated by the Commission and 2 representatives nominated by the European Parliament.
- All Member States will be invited to make nominations for appointment to the Agency's risk assessment and socio-economic analysis committees; the Management Board will appoint members on the basis of established competence. The aim will be to have nationals from all Member States, which make suitable nominations, present on these committees.
- Each Member State shall also appoint one member to the Member State Committee and one member to the Forum.
- 8.3. How can companies legally challenge Agency decisions under Authorisation and Restrictions? The Agency does not take decisions under the authorisations and restriction procedures. REACH allows companies to see the draft opinions prepared by the Agency in the restrictions or authorisation procedures. If a company has comments on the drafts, then the Agency must indicate how these have been addressed in the final opinion.
- The Commission will review the comments and how they were addressed, and then take the final decision by the Comitology procedure stating reasons for this decision. Such a statement of reasons would cover how comments were addressed, if appropriate.
- A company still retains its right to go to the European Court of Justice to overturn a Commission decision.
- 8.4. How can companies legally challenge Agency decisions under registration and evaluation? A special Board of Appeal and procedures are foreseen.
- 8.5. Accessibility to Agency databases and available information. How will the permissions management work? Relationship amongst registrants, Agency and local authorities. A procedure is established in article 118 whereby requests for non-confidential information are to be made directly to the Chemicals Agency according to Regulation 1049/2001 on the Public Access to Information. The Agency will make this available on request unless the information is commercially sensitive. The details of the operation of this aspect of the Agency will be the subject of implementing rules to be adopted by the Management Board before REACH operations start. Responsibilities for Competent Authorities are laid down in Title XII.

## 9. ENFORCEMENT

- | <i>Question</i>  | <i>Answer</i>  |
|--|--|
| 9.1. What types of enforcement mechanisms has the Commission considered when developing REACH? | REACH has been designed keeping both the expected competences of actors and enforcement needs in mind. It is expected that actors down the supply chain, in particular in smaller enterprises, have a competence in risk management (this is required by current legislation), but not necessarily in risk assessment. This is also the case for inspectors. The know-how regarding the hazards and potential risks of chemicals generally lays with the manufacturers and importers and with the national agencies/authorities. The exposure scenarios are the conditions of use, including risk management measures, which, when implemented, can ensure safe handling and use of the substance. It therefore is built up of elements which the local risk managers down the supply chain understand and can |

apply. They are also enforceable by inspectors as they are formulated in risk management terms, not requiring any deep knowledge of toxicology from the inspector. Inspectors, therefore, will be able to check if the exposure scenario listed in the CSR/SDS or the CSR developed by the DU in fact is implemented. The national agencies have full access to this information and they can check if the emissions generated by applying the ES are sufficiently low. This concept is more easily enforceable and provides better protection than does the current legislation.

9.2. Which mechanisms has the Commission envisioned for enforcement of the REACH provisions on Classification & Labelling?

The database containing the classification and labelling information will include the names and addresses of all companies manufacturing or importing dangerous substances along side their classification and labelling. All downstream users who classify or label differently than the supplier will also be included. Member State enforcement authorities would therefore be responsible for checking if the information on the industry list indeed is a true reflection of the companies' practices, in terms of classification and labelling on the products and in the SDS. It would be the responsibility of the national CA to screen the classification and labelling inventory to identify non-compliance with C&L criteria, encourage harmonisation of entries or to identify candidates for harmonised classification.

## 10. REVIEW OF THE PROVISIONS

### *Question*

10.1. According to the Regulation, the obligation whether or not to extend the obligation to perform a chemical safety assessment to substances within the 1-10 tonnes threshold will be reviewed after 12 years. Why cannot this revision be carried out earlier?

### *Answer*

It is true that the revision deadline for whether or not to extend the obligation to perform a chemical safety assessment also to substances within the 1-10 tonnes threshold will be reviewed after 12 years. However for substances that are classified as carcinogenic, mutagenic or toxic to reproduction (CMR substances in category 1 and 2) this review will already be carried out 7 years after entry into force of the Regulation.

## 11. RIGHT TO BE HEARD AND APPEALS

### *Question*

11.1. Where in the REACH Regulation are companies given the right to be heard?

### *Answer*

The right to be heard has been explicitly recognised throughout the REACH Regulation.

For example:

- Art 50(1) / Evaluation: Comment to competent authority on draft decision requiring further information.
- Art 64(5) / Authorisation: Comment on draft opinions of Agency committees.

In addition, interested parties are invited to comment on the following:

- Art 58(4) / Authorisation: draft recommendation to add substance to Annex XIV
- Art 64(2) / Authorisation: information on alternative substances or technologies
- Art 69(6) / Restrictions: proposal for a restriction.

11.2. When can industry appeal?

Companies can appeal against Agency decisions to the Agency's board of appeal, in particular against the following decisions:

- Art 9(10) / PPORD: decisions to impose conditions or to refuse

the extension of the deadline for the PPORD exemption to apply.

- Art 20(5) / Registration: decision to reject a registration because it is incomplete.
- Art 27(7) / Data sharing: decision to make data available to potential registrant.
- Art 30(5) / Data sharing: decision to make data available to SIEF members.
- Art 51(8) and 52(2)/ Evaluation: decisions under dossier and substance evaluation.

In addition, industry can appeal any decision by the Agency to the Ombudsman if there is a question of mal-administration. Furthermore, any decision by the Agency's board of appeal or by the Commission can be appealed to the European Court of Justice.

## 12. INTERFACE BETWEEN REACH AND OTHER PIECES OF COMMUNITY LEGISLATION / INTERNATIONAL AGREEMENTS

### 12.1. Waste legislation

	<i>Question</i>	<i>Answer</i>
12.1.1.	How are wastes addressed under the REACH?	<p>Waste is not a substance, preparation or article under REACH. However, REACH follows the life-cycle of a substance and the waste stages have to be taken into account when the registrant performs the chemical safety assessment and the CSR has to address waste management measures. These measures have to be communicated through the supply chain via SDSs (heading 13). However, waste treatment is not a downstream use under REACH and waste treatment operators will not receive SDSs on how to handle the substance during the waste phase.</p> <p>If the recovery of waste results in the manufacture of a different substance, preparation or article, the provisions of REACH apply to this different substance, preparation or article.</p>
12.1.2.	Is there an obligation to register process wastes?	<p>No, waste is not a substance, preparation or article under REACH. If the process waste is managed and disposed of as waste, it does not have to be registered. The risks resulting from process waste have to be addressed in the CSR of the manufactured substance, if the CSR is required for the registration of the substance.</p> <p>However, if the process waste is used to create other substances, or it is marketed as a substance or in a preparation, it will fall under REACH.</p>
12.1.3.	Is there an obligation to register residues from waste treatment operations?	<p>As long as residues are waste, i.e. that they are discarded and disposed of (e.g. land filled or stored in salt mines), they do not fall under REACH. Residues which are used as any other substances or preparations fall under REACH.</p>
12.1.4.	Is there an obligation to register waste solvents distilled to a higher degree of purity?	<p>Yes, a manufacturer of a substance has to submit a registration regardless of the method of manufacture or the origin of raw materials. However, if the solvent manufacturer also distils the waste solvent and the distillation of the waste solvent is covered by his registration, he does not need to prepare a new registration.</p>
12.1.5.	Is there an obligation to register substances included in imported	<p>Waste paper and scrap metal are neither preparations nor articles under REACH and, therefore, substances in them need not to be registered.</p>

waste paper or scrap metal?	However, if the waste is used to make new substances in quantities of 1 tonne or more, these substances need to be registered by the manufacturer of the substance, unless they are otherwise exempted.
12.1.6. Does article 7 apply to the producers or importers of articles from recycled material? E.g., production or import of newspaper from waste paper.	Yes.  NB: Substances are not intended to be released from newspaper, therefore, there might at most only be an obligation to notify substances under art 7, if the conditions of para 2 are met.
12.1.7. Is a waste treatment operator a downstream user under REACH?	The treatment of waste material itself is not a use of a substance or preparation and, therefore, the operator is not a DU under REACH.
12.1.8. Are wastes exempted from authorisation?	Yes, waste is not a substance, preparation or article under REACH.  However, for recycled products in the form of different substances, preparations or articles that are generated by a process of transformation and which will be placed on the market or used, an authorisation may have to be applied for depending on the substances contained in them.
12.1.9. Do restrictions apply to wastes?	No, waste is not a substance, preparation or article under REACH.  However, for recycled products in the form of different recycled substances, preparations or articles the restrictions apply as for any other substance, preparation or article.

## 12.2. International agreements and programmes

<i>Question</i>	<i>Answer</i>
12.2.1. Has the European Commission taken account of the present international chemical control regimes and whether they could prevent the negative affects of deleterious chemical substances effectively and be the basis or a part of REACH regime?	We have taken the existing international programmes into account and have taken inspiration from them. On their own they are not sufficient to provide the level of protection required. Existing regimes had not provided the necessary protection for human health and the environment. We believe that REACH will contribute massively to these activities and will not be in conflict with them. We plan to implement GHS and for this to come into force at the same time as REACH.
12.2.2. Are there other related international activities?	Other related areas of international participation include the World Summit on Sustainable Development, in particular the WSSD implementation plan; United Nations Environment Programme (UNEP): where a strategic approach to international chemical management was adopted on 6 February 2006 ( <a href="http://www.chem.unep.ch/saicm">http://www.chem.unep.ch/saicm</a> ); and the OECD which has initiated a co-operative action programme for testing and assessing High Production Volume (HPV) chemicals in a systematic way. Furthermore, a new version of IUCLID (IUCLID 5) is under development in cooperation with OECD. IUCLID 5 will contain internationally accepted data formats compatible with REACH and templates to be used during REACH registration as well as reporting to various other regulatory schemes in OECD countries.

## 13. COMPETITIVENESS

### 13.1. Confidentiality

<i>Question</i>	<i>Answer</i>
How will the new legislation ensure confidentiality of information with a public list of chemical substances?	The first list of substances that the Agency publishes will be the list of pre-registered substances. This list will only comprise the names of the substances and not the names of any company manufacturing or importing

How does REACH ensure transparency?

it. The purpose of this list is to give an overview about the substances that will be phased into REACH.

REACH will give the public access to specified information about chemicals, especially as regards safety and environmental aspects. However, it will also respect industry's legitimate right to protect confidential business information.

The Regulation includes:

- a list of safety-related data that is never to be confidential (e.g. the properties of a substance – such as that it is acutely toxic or a sensitiser); some other pieces of information (e.g. the study summaries or robust study summaries or the degree of purity if it is essential to classification and labelling) will not be published if a party submitting such information submits a justification and the Agency accepts this justification.
- For other items the standard rules on access to information apply. If there is a request for information that was submitted by a registrant or another company (in legal terms a third party – compared to the authority holding the information), the companies will be informed and may claim confidentiality for these items. The Agency decides whether such confidentiality claims are justified. There is also a list of items that shall normally be deemed to undermine the protection of commercial interests of the concerned person (e.g. precise tonnage produced by a company, precise list of ingredients of a preparation). These items will normally not be released on request of a third party and will also not be made public on the internet;
- Detailed rules are set out in Regulation (EC) No 1049/2001 of the European Parliament and the Council of 30 May 2001. A registrant may request that one or more pieces of information be kept confidential. Where the Agency agrees that this information is confidential then such pieces of information may only be disclosed in emergency situations. The registrant must provide justification for any such requests, for example commercial sensitivity of the information.
- The Agency will decide whether to agree to such requests.
- The design of the REACH-IT system will be such that information can readily be protected or made public according to the provisions.

How is commercially sensitive information safeguarded?

Will REACH require exact formulas of preparations to be revealed?

Disclosure of exact formulas is generally considered to undermine the protection of commercial interests of the concerned person (Article 118.2). In making information available, the Agency will take full account of the ECJ's jurisprudence on the protection of commercial interests.

## 13.2. SMEs

### *Question*

### *Answer*

13.2.1. Could different requirements be introduced for SMEs?

Small and medium-sized enterprises (SME) are a vital part of the EU chemicals industry; for that reason we have endeavoured to make the Regulation workable also for them (e.g. a lower registration fee for them). Since safety is a key concern, regardless of company size, the REACH information requirements relate to production volumes, uses and properties of the chemicals, and not to turnover or the number of employees of the companies.

13.2.2. Due to the big differences between the large-scale enterprises and SMEs on financing, technology, and human resource, SMEs will

For the most part SMEs are more likely than other companies to be registering at the 1- 10 t/y level. They will therefore not have to register for 11 years after entry into force and a lower registration fee will be required. The information requirements for these volumes are also light compared to

face more difficulties in compliance with REACH administration than large-scale enterprises. How did the European Commission balance the different interests between the large-scale enterprises and SMEs?

the higher tonnages and no CSR has to be developed. Research and development exemptions have been extended thus encouraging innovation in particular by the speciality chemicals sector. Registration does not start until 1 t/y as opposed to the current regime for new substances starting at 10 kg/y. This again will reduce the load on SMEs.

Most SMEs affected by REACH are DUs. The system has been designed so that the duties placed on them are again light.

13.2.3. How are the interests of SMEs addressed then?

SMEs as manufacturers will benefit from a number of measures:

- Exemption from testing requirements for substances used in product- and process- orientated research and development (PPORD). For research on volumes below 1 tonne per year, there is of course never an obligation to register.
- No registration below 1 tonne.
- Light information requirements for low volume substances (registration threshold at 1 tonne/year per manufacturer/importer, mainly in vitro testing for substances between 1 and 10 tonnes) and if a full Annex VII data set is provided then no fee is required. To further reduce the costs for SMEs an even more targeted system has been introduced. Only for substances that fulfil prioritisation criteria in the Annex, the complete “Annex VII” dataset will need to be generated and submitted and then there will be no fee. For other substances, only the physicochemical information set out in that Annex and any other available information on toxicological and ecotoxicological properties has to be submitted.
- The information requirement can be met in a wide number of ways, so helping SMEs avoid testing costs. Exposure control may be used to justify reduced information in registrations again allowing SMEs to avoid testing (Annex XI.3).
- The provision in current legislation to aggregate tonnages over several years to trigger a requirement for further information has been removed. This will benefit SMEs who steadily produce a small quantity of a substance over many years.
- Administrative burdens and costs can partly be shared between registrants in the pre-registration process.
- The formation of consortia is encouraged (Art 11). This will save SMEs a considerable amount of money by sharing the costs of the preparation of the dossier.
- Reduced fees will be set for SMEs.
- No chemical safety assessments are required between 1 and 10 t.
- Forced data sharing for animal testing, and other data sharing on request, is also in the interest of SME registrants.

DU SMEs:

- The ‘identified’ uses. Each registration must cover all identified uses. DUs have the right to identify uses to be addressed by their supplier in his registration. ‘Non intended’ uses, for which a downstream user must do a safety assessment, will thus be minimised to cases where a DU chooses to keep his use secret.
- No CSR is required where the DU uses a substance in a total quantity of less than 1 tonne per year.
- Avoiding costly and time-consuming process. An authorisation granted to one enterprise can be used by its customers if they

abide by the conditions of that authorisation (art 66).

- Information passed down the supply chain: optimal use of the Safety Data Sheet, already known in the sector but expanded to meet REACH aims.

The Commission is developing guidance documents and software tools to help SMEs perform their tasks (more information on guidance documents: <http://ecb.jrc.it/REACH/>).

### 13.3. Trade issues

#### *Question*

#### *Answer*

- 13.3.1. REACH will affect the chemical trade inevitably and may lead to trade unbalance and disputes after its entry into force. How is the European Commission going to resolve these potential problems?
- We don't see why trade disputes should arise. REACH has been designed to be fully WTO compatible. The internet consultation was notified to WTO as advanced notice under TBT Art 2.9.1. The REACH proposal was notified under the TBT Agreement on 21 January 2004 (notification G/TBT/N/EEC/52). The initial deadline for comments had been set 90 days from the date of notification. Following requests from some WTO members, the Commission subsequently extended the period for comments to 21 June 2004 (i.e. 150 days). Comments were received from the USA, Japan, Canada, China, Brazil, Australia, Chile, Singapore, Taiwan, Thailand, Cuba, American Chemistry Council (ACC) and the Asia-Pacific Economic Co-operation Chemical Dialogue (APEC). The Commission responded to those comments on 28 October 2004.
- The Regulation will be made available to WTO.
- 13.3.2. On the implementation of REACH, is it possible to allow a deferment for developing countries and provide certain financial, technical assistance referring to the implementation of the provision concerning protection of ozonosphere in Montreal Protocol?
- No, a deferment is not possible. We cannot differentiate between the origins of the substance. Support may be possible, e.g. a technical assistance programme. Note the role of the Agency at request of the Commission to play a supportive role for developing countries in terms of capacity building. This will be considered further by the Commission.
- 13.3.3. Which measures will the EU take to reduce the negative impacts of the REACH Regulation on trade?
- Extensive guidance, software tools, etc. will be made available. If a company is producing a substance in such volumes that it has to be registered, we believe that they should have the resources available to demonstrate its safe use. If these resources are not available one would question whether they should be producing the substance.
- 13.3.4. Are substances that are exported from the EU within the scope of REACH?
- Yes. Manufacture is within the scope of REACH in general and registration in particular.
- 13.3.5. Any ideas on how to eliminate the negative impact on chemical substances exported from non-EU countries to EU after entry into force of REACH regime?
- Companies should prepare well. Communication up and down the supply chain will become important. The high level of transparency in developing REACH and ongoing dialogues should help in this respect.

### 13.4. Innovation

#### *Question*

#### *Answer*

- 13.4.1. How will REACH promote innovation and the development of safer substitutes?
- To enhance industry's competitiveness, one of the objectives of REACH is to promote R&D and innovation. For example:

- Substances manufactured or imported for the purposes of product- or process-oriented R&D do not need to be registered for up to 5 years, renewable for a further 5 years (for substances used in medicinal products or not placed on the market, the maximum total exemption is 15 years).
- Very wide definition of PPORD.
- The REACH threshold for registration (1 tonne/year) is much higher than the current 10 kg threshold for new substances.
- The costs of registering a new substance will be significantly lower than the current cost of notification.
- Registration will be quicker than the current notification, thus reducing the time to market.
- The requirements for authorisation will encourage companies to increase their search for safer substitutes.
- The discrimination of new substances versus existing substances will be significantly reduced.
- Less information requirements for lower volume substances.

### 13.5. Impact assessment

#### *Question*

Will the current produced and imported volumes of single substances and of the substances within preparations, be available also with the relevant breakdown through out all the production chain of the chemicals, for DUs, in order to estimate the impact of REACH for this sector? How can the impact on chemicals be estimated which are produced (within or outside EU) by means of other chemicals, which are unknown DUs.

#### *Answer*

The Commission is not in the position nor able to do an impact assessment on every sector or individual substances. However, the Commission has carried out an extensive Impact Assessment on its REACH proposal of 2003. The main document as well as the background documents can be found on the Commission's website ([http://europa.eu.int/comm/enterprise/reach/eia\\_en.htm](http://europa.eu.int/comm/enterprise/reach/eia_en.htm)); the large amount of data contained therein is also a useful starting point for those who want to develop an idea of the REACH impacts for particular cases.

Following discussions with stakeholders on the impacts of REACH, the Commission decided to engage in further work on the Commission's REACH Impact Assessment. It has been carried out under a Memorandum of Understanding (MoU) between the European Commission (DG Enterprise and DG Environment) and industry (UNICE/CEFIC) dated 3 March 2004. The involved studies used a business case study approach in order to deal respectively with the potential withdrawal of substances for commercial reasons, innovation and the potential impact on New Member States.

Two studies were undertaken under the MoU. The study by KPMG for the UNICE/CEFIC industry consortium has focused on the first two areas. This study has examined four downstream sectors (i.e. automotive industry, high-tech electronics, flexible packaging industry, inorganic material producers) and included 6 SMEs.

The study of the Joint Research Centre (JRC) has dealt with the potential impacts of REACH on the New Member States (NMS), including both a general survey of the chemical industry in the NMS and a focus on the impacts of REACH on the specialty chemicals industry in three NMS.

The Commission has drawn the following conclusions from this further impact assessment work on its REACH proposal of 2003:

- There is limited evidence that higher volume substances are vulnerable to withdrawal following the REACH registration requirements. However, lower volume substances under 100 tonnes are most vulnerable to being made less or non profitable by the

REACH requirements.

- There is limited evidence that downstream users will be faced with a withdrawal of substances of greatest technical importance to them.
- SMEs can be particularly affected by REACH having regard to their more limited financial capacity and lower market power in terms of passing on costs.
- Companies have recognised some business benefits from REACH.

The results of this further work together with its conclusions have been taken into account in the decision-making process. For instance, compared to the initial Commission Proposal the Regulation contains modifications to the registration system for substances below 10 tonnes and made further modifications on the requirements for substances below 100 tonnes. The average registration costs for this group will be substantially reduced, for a large part through reducing the number of substances requiring testing. The Regulation also includes a fee reduction for SMEs and a help desk arrangement.

## **Annex: Abbreviations**

C&L	classification and labelling
CMR	substances that are carcinogenic, mutagenic, toxic for reproduction
CSA	chemical safety assessment
CSR	chemical safety report
DNEL(s)	derived no effect level(s);
DU	downstream user
ES	exposure scenario
GLP	good laboratory practice
M/I	manufacturer / importer
MSDS	material safety data sheet
OSOR	one substance one registration
PBT	substances that are persistent, bioaccumulative and toxic
PPORD	product- and process- orientated research and development
PNEC(s)	predicted no effect concentration(s)
RMM	risk management measures
SDS	safety data sheet
SIEF	substance information exchange forum
vPvB	substances that are very persistent, very bioaccumulative