



REACH Industry Preparation Letter No 4

September 2006 REACH Industry Preparation Letter No 4

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0. Change of distribution policy

Future editions of this newsletter will be circulated to Cefic member companies and organisations only. Member organisations are then free to distribute the contents further to their own members. Companies and organisations who subscribe to ReachCentrum will be able to access the same information via the ReachCentrum website.

1. Summary of the compromise

In June 2006 the Council adopted its common position on REACH based on its political agreement of December 2005. The European Parliament has not yet officially started the 2nd reading but the Environment Committee has already started informal discussions. The Finnish Presidency of the Council is already seeking solutions to get closer to the Parliament on certain issues.

The official second reading of the EP will start in September and will last 3 + 1 months. The deadline for submission of amendments to the Council common position is 11 September. All three institutions concerned (Commission, EP and Council) aim to avoid conciliation. If this can be done, the political debate will be concluded after the EP second reading in December 2006.

The REACH text will then be translated to all the official languages of the EU and a legal check of the text will be carried out. It is expected that the entire process will be completed by April 2007, **and REACH will enter into force.**

2. REACH Awareness Workshop II

On 3 July the Cefic REACH Implementation Group organised its second REACH Awareness Workshop in the Sheraton Brussels Airport Hotel. Approximately 120 participants attended.

During the morning session the participants were given an update on the latest status of REACH and on the different REACH Implementation Projects (RIPs). In the afternoon several presentations were given regarding the different aspects of how to prepare for REACH implementation. For instance, BYK Chemie and EuPC informed the audience about the practical preparations in their respective organisations.

The last part of the workshop was used to respond to various questions which had either been raised by the participants during the workshop or had been sent in prior to the event.

The positive feedback received in the evaluation forms showed that the workshop turned out again to be a great success.

The REACH Awareness Workshop III is scheduled for 20 and 21 September 2006. This event will be organised jointly with the REACH IT Working Group.

Registration forms for this workshop can be requested at VCC@cefic.be.

3. Pre-registration

➤ Pre-Registration

The chapter on pre-registration is based on the Council common position of 12 June, 2006, and covers the areas:

- [Why is pre-registration important?](#)
- [Which substances can be pre-registered?](#)
- [Who should pre-register?](#)
- [When does pre-registration take place?](#)
- [Which information is needed for pre-registration?](#)
- [What needs to be done now?](#)

➤ Why is pre-registration important?

REACH provides an extended time period for the registration of [phase-in substances](#) which have been pre-registered. Any *manufacturer/importer* (M/I) who manufactures or imports a phase-in substance in quantities of ≥ 1 t/a and intends to register this substance under REACH should therefore pre-register.

substance characteristics / volumes	deadline for registration	
CMR 1, 2 ¹ (≥ 1 t/a) N, R50-53 ² (≥ 100 t/a) $\geq 1\ 000$ t/a	entry into force	+ 3 years
≥ 100 t/a	entry into force	+ 6 years
≥ 1 t/a	entry into force	+ 11 years

These transitional periods for the registration of phase-in substances do only apply if

- the definition of phase-in substance is fulfilled and
- the *manufacturer/importer* (M/I) or their [representative](#) has pre-registered.

If the M/I does not pre-register, he has to register the phase-in substances without delay when Title II "Registration of Substances" applies to phase-in substances.

Thus, the M/I who does not pre-register cannot expect to rely on the support from [SIEFs](#)³ (which are formed by pre-registrants after the pre-registration phase ends) and potential consortia: these will most likely time their activities to meet the deadlines given by the transitional periods and will not necessarily be prepared to provide input at earlier stages of the process.

An M/I who manufactures or imports a phase-in substance for the first-time after the end of the pre-registration phase is entitled to rely on the transitional periods given above provided that he submits the same [information required for pre-registration](#) to the Agency

¹ classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC

² classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC

³ SIEF: Substance Information Exchange Forum

- within six months of first manufacturing or importing the substance and
- no later than 12 months before the relevant deadline (i.e., 2, 5, or 10 years after entry into force, respectively).

➤ Which substances should be pre-registered?

Subject to pre-registration are substances, even if in preparations or in articles. The necessity to pre-register substances in imported [preparations](#)⁴ and substances to be intentionally released from articles needs to be carefully evaluated. Special attention should be given to the fact that a preparation can consist of several substances which will all require separate pre-registrations. (Further information on preparations is given elsewhere in this newsletter.)

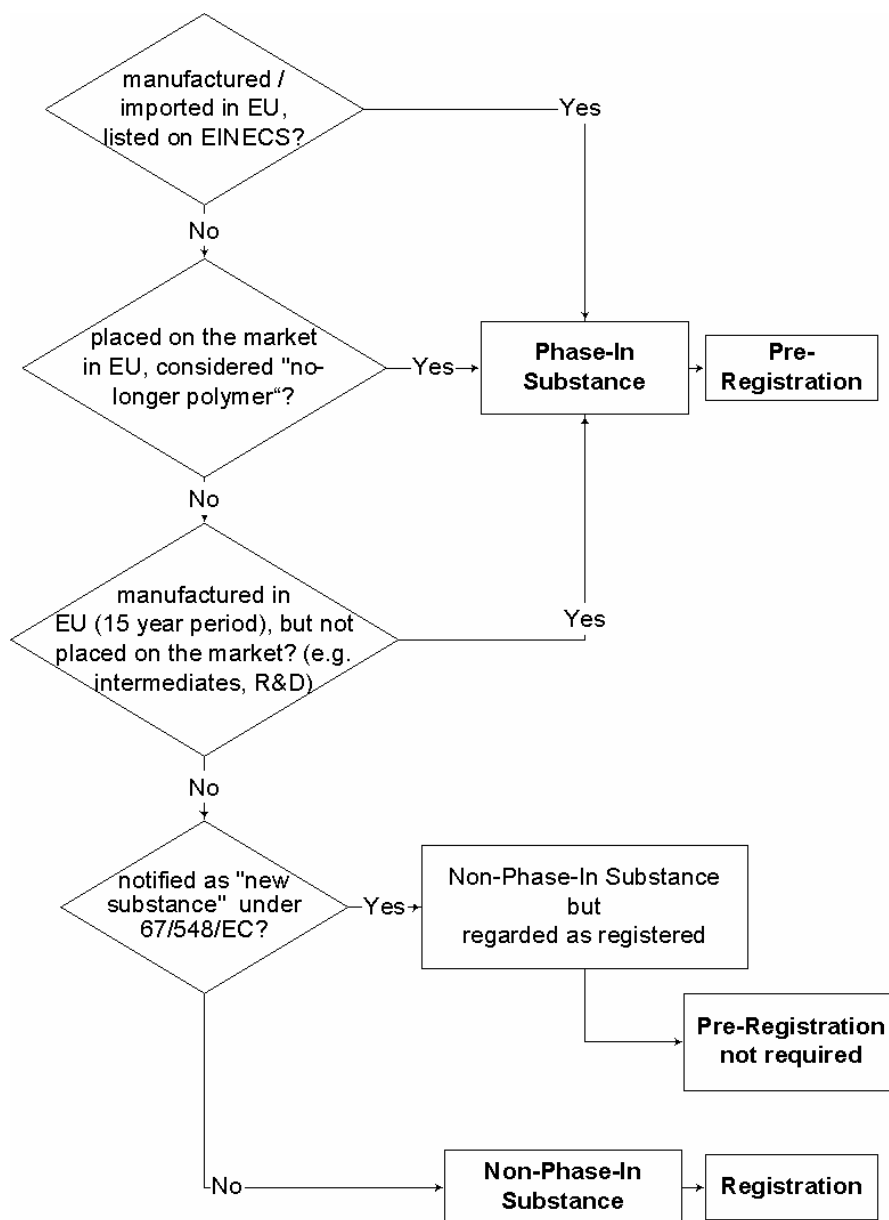
Only phase-in substances can be pre-registered. Phase-in substances are defined as those meeting at least one of the following criteria:

- listed in EINECS (European Inventory of Existing Commercial Chemical Substances)
- having been manufactured in one of the current EU Member States at least once within the period of 15 years before the entry into force of REACH, but not placed on the market (e.g. intermediates, R&D substances)
- "[No-Longer Polymers](#)"⁵ placed on the market in one of the current EU Member States before REACH has entered into force

The manufacturer or importer needs documentary evidence for the two latter criteria. The following flowchart may help to identify phase-in substances.

⁴ Preparation means "a mixture or solution composed of two or more substances". Formulations, grades, master batches etc. are preparations in the meaning of REACH.

⁵ "No Longer Polymers", NLP: Polymers were not reportable for EINECS. Some substances which were considered to be polymers under the reporting rules when the EINECS was being established are no longer considered to be polymers due to a revised definition of "polymer" within directive 92/32/EEC. More detailed information and the No-Longer Polymers List can be found on the website of the European Chemicals Bureau at <http://ecb.jrc.it/new-chemicals/>



"New Chemicals" notified in accordance with Directive 67/548/EEC shall be regarded as registered, therefore they do not need to be pre-registered under REACH.

Non-phase-in substances and substances not regarded as registered have to be registered without delay when Title II "Registration of Substances" applies, i.e. 12 months after REACH enters into force.

➤ Who should pre-register?

Any M/I who intends to register a phase-in substance manufactured or imported in quantities of ≥ 1 t/a should pre-register.

Any M/I can appoint a third party representative to fulfil the obligations related to pre-registration in order to protect confidential business information. The identity of an M/I who has appointed a representative shall not normally be disclosed by the Agency.

Consequently, any third party representative who intends to register a phase-in substance manufactured or imported in quantities of ≥ 1 t/a should pre-register.

The importer or his representative of a *preparation* in volumes ≥ 1 t/a has the legal obligation to register all substances present in this imported preparation. He should therefore pre-register the phase-in substances in order to benefit from the transitional regime.

The M/I or his representative of *articles* containing substances in volumes ≥ 1 t/a, which are intentionally released under normal or reasonably foreseeable conditions of use, has the legal obligation to register these substances. He should therefore pre-register the phase-in substances in order to benefit from the transitional regime.

M/I or their representatives of *polymers, monomers*, and/or other substances chemically bound in polymer backbones are referred to the "REACH Industry Preparation Letter No. 3". The information given there provides assistance in identifying substances that need to be registered. The respective phase-in substances should then be pre-registered in order to benefit from the transitional regime.

Each legal entity within a corporation should pre-register relevant substances separately.

One month after the pre-registration phase has ended, the Agency will publish the list of pre-registered substances on its website. M/I handling quantities of phase-in substances below 1 t/a, downstream users, and third parties holding information on those substances can then submit information equivalent to the pre-registration requirements to the Agency in order to become part of the Substance Information Exchange Fora (SIEF).

➤ **When does pre-registration take place?**

The information required for pre-registration shall be submitted within a time period

- starting 12 months after REACH enters into force and
- ending 18 months after REACH enters into force,

thus allowing only a 6-month period for the actual pre-registration process.

The time period for pre-registration could be as early as April 2008 – October 2008.

➤ **Which information is needed for pre-registration?**

We base our evaluation of the required data on the Council common position (12 June, 2006). During the 2nd reading in the European Parliament, additional requirements may be added for data to be submitted when pre-registering. In this case, the requirements will be addressed in one of the following newsletters.

The Council common position requires the following information for pre-registration:

- the name of the substance
 - Name(s) in the IUPAC nomenclature or other international chemical name(s)
 - Other names (usual name, trade name, abbreviation)
 - EINECS or ELINCS number (if available and appropriate)
 - CAS name and CAS number (if available)

Other identity code (if available)

- name and address of the potential registrant
- name of the contact person
- the name and address of the representative where appropriate
- the envisaged deadline for the registration/tonnage band
- indicate the substance(s) which you intend to use for [read-across approach](#)⁶ or [\(Q\)SAR](#)⁷ (cf. *REACH Industry Preparation Letter #3* Grouping of Substances)

The Agency will publish the names of the pre-registered substances, including CAS and EINECS numbers, as well as the substances intended to be used for read-across approach, on its website.

For pre-registered substances, companies should have the information on substance identification available internally.

The final format for the submission of the pre-registration data is yet unknown.

➤ What needs to be done now?

1. Identify substances that you intend to pre-register. Substances for which pre-registration needs to be considered are
 - substances manufactured and/or imported on their own
 - substances in imported preparations
 - substances in articles if the substance is present in those articles in quantities totalling over 1 ton per producer or importer per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use
 - substances in polymers like e.g. additives under certain conditions (cf. *REACH Industry Preparation Letter #3*)
 - monomers (cf. *REACH Industry Preparation Letter #3*)
 - on-site isolated intermediates
 - transported isolated intermediates
 - substances which have been synthesized at least once in the 15 years before the entry into force, but not placed on the market
 - No-Longer Polymers
2. Collect the information required for pre-registration ([see above](#))

For pre-registered substances, companies should have the information on substance identification available internally.

⁶ read-across approach: Information on intrinsic properties of substances may be generated by means other than tests, in particular from information from structurally related substances (grouping or read-across)

⁷ (Q)SAR: Qualitative or Quantitative structure-activity relationship; Results obtained from valid (Q)SARs may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when certain conditions are met.

4. Preparations⁸

The Council's common position on REACH of 12 June 2006 will affect the registration of both **individual substances and substances in preparations** in the following way:

- If you buy a preparation from a manufacturer or importer located in the EU the individual substances in the preparation will have to be registered by your supplier when it exceeds the 1 t/a threshold. Furthermore, the registration should cover your usage (or your use/exposure category).
- If you buy a preparation from a downstream user or a distributor located in the EU the substances in the preparation will have to be registered by the M/I at the origin of the European supply chain (for S > 1 t/a. The registration should cover your usage (or your use/exposure category).
- If you import a preparation yourself you will first have to pre-register phase-in substances (see also the chapter on pre-registration in this newsletter) and register each substance of the preparation if the volume of the substance exceeds 1 t/a (per legal entity) taking into account exemptions/exclusions and deadlines for registration. *If multiple preparations are imported, the volumes of the same substance need to be aggregated to determine the tonnage band for registration.*
- *In those instances where manufacturing of preparations (in the EU) leads to another substance (via reaction(s) occurring in-situ), that substance is in itself a manufactured substance and will need to be pre-registered and registered (taking into account all relevant exemptions and exclusions such as f.i. Annex V)*

We suggest doing the following to prepare yourself:

1. Make an inventory of all preparations you are dealing with.
2. Check current Safety Data Sheets and other sources for all preparations in order to identify dangerous components, especially substances that may be subject to authorisation whereby security of supply might be in doubt. These substances will require careful monitoring as the system develops.
3. Determine whether the preparations are supplied by an EU-based supplier (manufacturer or distributor), an EU importer (directly or via [Only Representative](#)⁹), or imported by yourself.
4. If you are supplied by an EU-based supplier or importer, you should ensure with your supplier that your usage is covered in the registration of the supplier. In case your usage is not covered, you can either ask your supplier to include your usage in his registration or register your usage yourself for all substances in the preparation.

⁸ Preparation means a mixture or solution composed of two or more substances.

⁹ A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under title II.

5. Indicate which preparations you import from manufacturers or traders located outside the EU, i.e. suppliers that have no obligation to register under REACH. Identify which preparations you import via an Only Representative. In this case you, as the importer, will be considered as a downstream user as the Only Representative will do the registration.
6. Indicate which substances as such or in preparations you import were exported from the EU. These substances have to be registered even if exported. If the substance is the same as the exported substances and has been registered by an actor of the same supply chain, you don't have to register again.
7. If you have discovered that the registration of certain substances in your preparation is not done by other parties, you have to register them!
8. Establish the annual volumes of the preparations and substances in preparations that need to be registered by you.
9. Collect information from the supplier of the preparations you import. It may be prudent to establish your supplier's possible intent to import the preparations themselves or to establish "Only Representative" status.
10. For component chemicals that you will need to pre-register and register, gather the same information that we had suggested to collate for individual substances in *REACH Industry Preparation Letter #3*. If you do not have the *Letter* at hand, please contact Valérie Cremades at Cefic (VCC@cefic.be) for a copy.

Pre-registration and registration of the subsequent components contained in the preparations is still the only admissible approach in the original Commission REACH proposal and the Council common position, which could cause serious problems regarding the protection of confidential business information of the supplier. We cannot force suppliers to divulge proprietary information, but we do have to engage them and make them aware of the information we need. There may be ways to facilitate transfer of this information via the use of confidentiality agreements or the Only Representative facility (in this latter case, transfer of information on composition of mixture is no more required). The latter allows a non-EU manufacturer of an imported substance to appoint an EU-based representative to fulfil his registration and associated requirements, thereby effectively making the importer a downstream user. However, this may be impractical for an imported preparation that contains many substances.

If you have to do the registration yourself and you want to keep some business information confidential, you can appoint a third party representative as described in art 4.

We will of course inform you of any new developments.

5. Intermediates

1. We suggest you start to prepare for REACH by answering the following questions:
 - 1) Do the substances which your company manufactures in the EU and/or imports itself from outside the EU follow the definition of intermediates?
 - 2) In case you are a manufacturer:
 - a. Are these intermediates non-isolated or isolated intermediates?

- b. In case these intermediates are isolated, are they used on-site or transported off-site?
 - c. If they are transported, is their volume below or above 1000 t/a?
- 3) In case you are an importer, is the volume of the transported intermediates below or above 1000 t/a?

Below you can find some help to answer some of the questions:

Question 1

Article 3.14: *intermediate* means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called synthesis).

This transformation should be intentional (see Annexe V including cases where substances are transformed in other substances).

Question 2.a

Article 3.14 a): non-isolated intermediate means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance passes during a continuous flow or batch process as well as the pipe work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance is stored after the manufacture.

The item of the legal entities and the notion of placing on the market are not part of this definition.

If there is no storage at the end of the manufacturing process, the intermediate is still a non isolated intermediate. It could be the case for instance when there is a transfer from an entity to another one (or from one site to another site) without storage at the end of the manufacture.

Question 2.b

Article 3.15: site means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared.

Article 3.14 b): on-site isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an) other substance(s) from that intermediate take place on the same site, operated by one more legal entities.

Article 3.14 c): transported isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

The mode of transport is not part of the definition.

Storage at the end of the manufacture should occur: an intermediate transported by pipe without storage is not a transported isolated intermediate according to the above definition.

As a next step, refer to the REACH proposal in order to determine the requirements for the different types of intermediates.

➤ Scope of REACH

Article 2.1 c): REACH shall not apply to non-isolated intermediates.

➤ Registration

Any manufacturer of an on-site isolated intermediate in quantities of 1 ton or more per year shall submit a registration to the Agency for the on-site isolated intermediate.

Any manufacturer or importer of a transported isolated intermediate in quantities of 1 ton or more per year shall submit a registration to the Agency for the transported isolated intermediate.

Note: this does not apply to intermediates that are exempted from registration according to Annexes IV or V.

Registration dossier

On-site isolated intermediates

If the intermediate is only manufactured and used **under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle** (see Article 17) and is not a monomer, there are reduced information requirements.

In this case, the registration shall include all the following information (without any additional testing):

- the identity of the manufacturer
- the identity of the intermediate
- the classification of the intermediate
- any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted
- a brief general description of the use
- details of the risk management measures applied

There is no obligation to perform a CSA and/or to produce a CSR.

Transported isolated intermediates

If the manufacturer or importer confirms* himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites **under strictly controlled conditions** (see Article 18) and is not a monomer, there are reduced information requirements.

**Needs formal communication (i.e. in writing) between the registrant and his immediate customer.*

In this case, the registration shall include all the following information:

- the identity of the manufacturer or importer
- the identity of the intermediate
- the classification of the intermediate
- any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted
- a brief general description of the use
- information on risk management measures applied and recommended to the user

If the volume is 1000 t/a or above: the registration shall include the information specified in Annex V in addition to the information required above 1 t/a.

There is no obligation to perform a CSA and/or elaborate a CSR.

If the above special conditions are not met either for on-site or transported intermediates, the registrant has to provide a “full” registration dossier.

“Strictly controlled conditions” are for on-site isolated intermediates the same as for transported isolated intermediates, that is listed in article 18.4. Article 18.4a) gives an indicative list of stages in the life-cycle for “rigorously contained by technical means during its whole life cycle”.

In case where for instance 600 t/a of the substance fit the definition of intermediate together with conditions allowing reduced information requirements and 500 t/a do not fit the definition of intermediate, two registration dossiers have to be submitted: one for 600 t/a and the other one for 500 t/a.

Phase-in intermediates

To benefit from the transitional regime (registration deadlines: 3, 6 or 11 years), each potential registrant of a phase-in intermediate manufactured or imported in quantities of 1 ton or more per year, shall pre-register within a time period starting 12 months and ending 18 months after entry into force of REACH.

That means that these registrants shall be participants in a substance information exchange forum (SIEF) and will have to share data. Rules for joint submission of data rules will also apply (art 17).

If the manufacturer or importer decides or forgets to pre-register, he will have to register 12 months (and in practice 18 months) after the entry into force of the regulation.

➤ Evaluation

On-site isolated intermediates that are used under strictly controlled conditions, are exempted from both dossier and substance evaluation. However, competent

authorities may require further information and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question (Article 48).

Transported isolated intermediates follow the normal evaluation procedure.

➤ Authorisation

On-site isolated intermediates and transported isolated intermediates are exempted from authorisation.

➤ Notes

Research & Development: exemption from the general obligation to register for product and process orientated research and development (PPORD) applies to on-site isolated intermediates or transported isolated intermediates.

Monomers: for monomers that are used as on-site isolated intermediates or transported isolated intermediates, reduced registration does not apply.

6. REACH and your supply chain

The chemical industry itself is the biggest downstream user of chemicals and supply chains are normally rather long and would be jeopardized by any withdrawal of a chemical substance on whatever step. To assure a smooth transfer to the REACH process and a proper availability of chemical products to the whole EU economy, it is of utmost importance that every party along the supply chain brings its substances to pre-registration thus enabling to make maximum use of the transitional period for subsequent registration of these "phase-in" substances.

Cefic "REACH Implementation Group" has prepared two standard letters that can be used to inform your supply chain about REACH and to advise suppliers to pre-register under REACH to make maximum use of the transitional period.

The letters can be found in the [Annex I](#) and [Annex II](#).

7. Status of RIP's and Cefic organisation

There are 7 individual Rips (REACH Implementation Projects) set up by the Commission. Some of them have been divided into sub-projects:

Rip 1: REACH Process Description: Development of a detailed description of the REACH processes

Rip 2: REACH-IT: Development of the IT system set up to support REACH implementation

RIP 3: Guidance Documents: Development of guidance documents for industry

3.1: Guidance Document on Preparing the Technical Dossier for Registration.

3.2: TGD on preparing the Chemical Safety Report.

3.3: TGD on Information Requirements on Intrinsic Properties of substances.

- 3.4: Guidance Document on Data sharing (Pre-registration).
 - 3.5: Guidance Document on Downstream-User Requirements
 - 3.6: Guidance on Classification and Labeling under Global Harmonized System
 - 3.7: Guidance on preparing an Application Dossier for Authorization
 - 3.8: Guidance on fulfilling the Requirements for articles
 - 3.9: TGD on carrying out a Socio-Economic Analysis or input for one.
 - 3.10: TGD for characterization and checking of Substance Identity
- RIP 4: Guidance Documents: Development of guidance documents for authorities
- 4.1: Guidance Document on Dossier Evaluation
 - 4.2: Guidance Document on Substance Evaluation
 - 4.3: Guidance Document on Inclusion of Substances into Annex XIII
 - 4.4: Guidance Document on preparation of Annex XIV Dossiers
 - 4.5: Guidance Document on Priority Setting for Evaluation.
- RIP 5: Setting up the Pre-Agency
- RIP 6: Setting up the Agency
- RIP 7: Commission preparation for REACH

Details on each of the projects can be found at the ECB website:
<http://ecb.jrc.it/REACH/>

It is important for you to know that of the RIPs that are being run at the moment, Cefic is directly involved in RIP 2, RIP 3.2 task 4 and RIP 3.3. For the other RIPs Cefic has nominated a representative for the Stakeholder Expert Group (SEG) meeting. To support the SEG representative Cefic has organised Industry Support Teams. In case you want to have information about these support teams or want to contact a SEG representative for a RIP specific issue, please contact the Product Stewardship Secretariat via VCC@cefic.be

8. ANNEX I

➤ Letter to Supplier

Dear Supplier

The EU Commission has put forward a draft of a European regulation on chemicals, titled REACH (Registration, Evaluation and Authorisation of Chemicals).

During the legislative process the chemical industry continually expressed a general concern about the potential for some chemical substances to be withdrawn from the European market as a consequence of REACH, either due to regulatory action or commercial considerations, and the impact this may have for downstream users. As a downstream user, we strongly share this concern.

The future regulatory statutes of REACH have not yet been finalized, but are likely to come into force in Q2, 2007. Hence, we are fully aware that you cannot yet make any definitive statements with regard to continued supply under REACH.

All substances manufactured and/or imported in quantities ≥ 1 ton/year, even though only supplied in mixtures or preparations, will need to be registered under REACH. All substances meeting the criteria for "phase-in" substances should therefore be pre-registered in order to benefit from the transitional periods provided by pre-registration under REACH. Assumed the REACH legislation become effective on April 1st, 2007, pre-registration will have to be completed as early as April 1st – October 31st, 2008.

We intend to include all our manufactured and imported substances in the pre-registration (optional).

We therefore insist that you, as our supplier of important products, subject all substances included in these products that you manufacture or import in the EU to the pre-registration and registration under REACH. If you as well have to rely on raw material shipments by your suppliers, please assure that they will be informed accordingly, so they can behave in the same manor. If any party up the supply chain is not intending to pre-register we need to know, as early warning is critical for our own planning. Any gap will affect our own business as well as the business of our customers.

The chemical industry itself is the biggest downstream user of chemicals and supply chains are normally rather long and would be jeopardized by any withdrawn of a chemical substance on whatever step. To assure a smooth transfer to the REACH process and a proper availability of chemical products to the whole EU economy it is of utmost importance that every party along the supply chain brings its substances to pre-registration thus enabling to make maximum use of the transitional period for subsequent registration of these "phase-in" substances

Your earliest response in this regard is therefore essential.

We are confident that the transitional periods will give you, our supplier, and us sufficient time to find satisfactory solutions for the preparation of our respective registrations and future legal compliance with REACH.

If you need additional clarification on pre-registration and registration or any other issue on REACH, please contact us.

Specific notes: (to be used where relevant)

- We would like to emphasize that all starting materials for polymers will have to be properly registered, even though polymers themselves are exempt from the registration requirements.

9. ANNEX II

➤ **Standard letter that can be used to reply to customers' enquiries or questionnaires**

We are well aware of REACH and the fact that it will become a European regulation in the course of 2007, and the projected timetable for pre-registration and registration.

The draft regulation in its present form remains complex and when adopted will have significant impacts on all manufacturers, importers and downstream users in the European Union, and require their joint collaboration across all supply chains.

There is a general concern about the potential for some chemical substances to be withdrawn from the European market as a consequence of REACH, either due to regulatory action or commercial considerations, and the impact this may have for downstream users.

We are committed to meeting our legal obligations under REACH, as a manufacturer / importer / downstream user and have started preparing for it. However, as the final text and related important technical details – e.g. guiding documents (RIPs) are still under development – as well as financial elements e.g. registration costs are not available yet, we cannot yet fully assess the impact of REACH on our product portfolio.

In the circumstances therefore we cannot provide any guarantee that all our products will continue to be available under REACH, although this will be generally the case (optional). Furthermore, at this time we are not in a position to provide detailed answers to your questions or fill up any detailed questionnaire.

However, if you consider that any product(s) we supply to you is very critical component in your operations, we would be happy to discuss this with you in more detail.

Otherwise, as the REACH legislation becomes clearer, we will be communicating further with our own suppliers and customers to gather the information that we will need to ensure compliance in a timely manner.

Meanwhile, if you have any question...