REACH: Standard Questionnaire for Communication Along the Supply Chain

February 2007

Introduction to REACH

The REACH legislation will enter into force on 1st June 2007.
Substances in volumes over one ton per year must be neither manufactured nor imported in the EU (even in preparations/mixtures and articles under certain conditions), unless they are registered.

Transitional periods will be granted under the REACH Regulation in order to perform comprehensive registration tasks. Depending on substance volumes and certain health and environmental classifications, these transitional periods range from 3.5 to 11 years (Article 23). To be able to benefit from these transitional periods, manufacturers/importers must pre-register a substance.

It is essential for users of substances to know if suppliers (Manufacturer/Importer) will register the substances they require – to confirm that these substances will be available in the future and their specific uses will be covered by a registration.
It is also essential for manufacturers/importers to be informed about downstream applications as well as use and exposure information for the respective substances in order to be able to generate the required chemical safety report covering the identified uses.

This standard questionnaire is intended to help purchasers and suppliers in an adequate exchange of information for registration purposes, without overly specific details on uses or product composition - i.e. confidential business information is respected.

The following points should be considered when using this questionnaire:

- In the questionnaire the term "product" stands for a substance or preparation as sold to down stream users. The questionnaires offer the possibility to defer answering to a later point in time. It is recommended to make use of this option in certain cases, until circumstances allow a proper assessment of the factors influencing this decision.
- A careful completion of the questionnaire will take some time, because in many cases requests for information will have to be sent to sellers' supplier or to purchasers' downstream users. For this reason, a time span of one month is realistic for answering the questions. For complex products (mixtures etc) even more time may be needed.
- One separate questionnaire is completed for each product.
- In case some information is changed, an update needs to be sent.
- The questionnaire might be updated in the next moths, because more definitive information may become available about the definition of downstream uses. RIP 3.2 (Generating CSR) is dealing with this subject, but will not be finished before June 2007. It is expected that once the guidance is finished these questionnaires will be updated accordingly.
- This questionnaire forms the first element in an exchange of information both up and down the supply chain. Further information on use and exposure categories

may need to be completed for some products. If this is the case further specific questionnaires will be sent to the supplier.

Further background information on the REACH Regulation and the terminology/ definitions in the questionnaire is available in national and industry-specific supporting materials and from helpdesks (e.g. those provided by the national or European associations and Competent Authorities).

Thank you for your cooperation in supplying this information.

Contact Details:
Business/supply chain contacts to be inserted

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Part I Questions from Downstream User (Customer) to Supplier REACH: Pre-registration / Registration

Concerning the Product (trade name): X_____

☐ Substance ☐ Polymer

☐ Preparation ☐ Article

1. At this stage, do you expect that the substances, which are contained in the product above and require registration, will be **pre-registered** by your company or by your upstream supplier?

   ☐ yes
   ☐ no
   ☐ too early to decide. Reply probably by …… (expected date of reply)*

2. At this stage, do you expect that the substances, which are contained in the product above and require registration, will be **registered**?

   ☐ yes
   ☐ no
   ☐ too early to decide. Reply probably by …… (expected date of reply)*

3. If questions 1 or 2 are answered with "yes": Regarding the substances that are contained in the product and require registration – please mark the crucial REACH registration deadlines for those substances which are decisive for the product properties.

   ☐ immediate registration
   ☐ 3.5 years
   ☐ 6 years
   ☐ 11 years
   ☐ too early to decide. Reply probably by …… (expected date of reply)*

* Stating a date is desirable, but this is left to the discretion of the seller.

[1] *The information contained in this questionnaire expresses only the intention of the questionnee and does not constitute a bending obligation. Whilst the information is provided in utmost good faith, no representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information*

4. Contact details

   Please provide full contact details for the person in your company responsible for REACH issues

   Name, position, telephone number , mailing address and email

Please return this questionnaire to:

Business/supply chain contacts to be inserted

Explanations regarding Part I

Regarding question 1

If the supplier is not the Manufacturer/Importer but the distributor of substances requiring registration that are contained in the listed products above, it must be clarified whether the supplier can assume that his upstream Manufacturer/Importer will carry out a pre-registration.

If the product is a polymer, the purpose of the question is to find out whether the monomers bound in the polymer or other substances bound in the polymer will be registered by the Manufacturer/Importer. This does not refer to residual monomers in the polymer.

Regarding question 1 and 2

Somewhat more time might be needed to answer this question for preparations, because initially the supplier needs to obtain relevant information from his suppliers up till and including the manufacturer/importer. Answering this question with "yes" is no promise of a registration, as – besides REACH – further factors might exert an influence (e.g. unforeseeable future market situations).

Regarding question 3

Example – Determining the crucial registration deadline for substances decisive for product properties:

A product consists of substances 1, 2 and 3. Substances 1 and 2 are decisive for the product properties; they have registration deadlines of 6, 6 and 11 years due to their production or import volumes. Substance 3 – which is not decisive for the specific use of the product and could be replaced, e.g. a solvent – has a registration deadline of 3.5 years because of higher production or import volumes. In this example, substance 3 is not crucial for the product as it can be replaced without affecting the required product properties. Here, substances 2 and 3 are decisive so that the box “6 years” should be ticked. Box “6 years” should be ticked.

The option "immediate registration" means that there is no pre-registration and the substance will be registered without delay, within 12 months after the entry into force of REACH.

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Part II Questions from Downstream User to Supplier - Use and Exposure -

Concerning the Product (trade name): _____

1. Do you plan to include the following uses and exposures[3] as marked in the Annex (Down stream User fills in the generic use description according to the Annex) in your dossier?

   ☐ Yes
   ☐ It is too early to provide the relevant information.
   Expected date of reply _____
   ☐ The information provided is not sufficiently detailed to provide an answer.

2. Which of the uses and exposures listed in the **Annex** will you probably not support in future?

   ☐ Relevant information is given in the Annex (marked with a "**-**" symbol)
   ☐ It is too early to provide relevant information.
   Answer probably by _____* (expected date of reply)

[2] *The information contained in this questionnaire expresses only the intention of the questionnee and does not constitute a bending obligation. Whilst the* information *is provided in utmost good faith, no representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information*

[3] Uses and Exposures refer to the structuring as given in the final REACH regulation Annex VI

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Part III Questions from Supplier to Down stream User - Use and Exposure -

Concerning the Product (trade name): X_____

Preliminary Remark:

Please answer the following questions only in respect of your own company and – to the extent that this knowledge is available to you – for your customers.

1. Are all of your current or foreseeable uses over 1 ton per year exempt from REACH ?
   ☐ yes
   ☐ no
   If "yes" then do not fill out the remainder of this questionnaire.

2. Are you currently using, or will you be using in the foreseeable future (at least once after 1 June 2007) over 1 ton per year of product "X"?
   ☐ yes
   ☐ no
   If "no" then do not fill out the remainder of this questionnaire.

3. Product "X" is (check all that apply):
   ☐ used in an open system
   ☐ used in a closed system
   ☐ a transported intermediate

4. In the **Annex**, please mark in the matrix with a "**+**" symbol those uses and exposures[4] for which you require a registration referring to product "X".

5. Do you plan to develop your own Exposure Scenario(s) for your specific use(s)?
   ☐ yes
   ☐ no, please include in your (supplier) dossier.

[4] "Uses and exposures" refers to the structuring as given in the final REACH regulations Annex VI no. 6. This set of information is regarded to be the minimum information requirement on exposure data.

6. Do you know the amount, frequency, duration and route of exposure (data, experiences, etc.) regarding the uses and exposures[1] listed in the **Annex**?

☐ yes

☐ no

☐ too early to decide. Reply expected by _____

7. Do you possess experiences, data or information on appropriate, sector-specific risk management measures (not general measures!) referring to the uses and exposures[1] listed in the **Annex**?

☐ yes

If "yes", please mark the respective fields of the matrix with 1.), 2.) etc. and state the sector-specific measures in the following comment lines.

☐ no

☐ too early to decide. Reply expected by _____

	Sector-Specific Risk Management Measure	Removal Efficiency
1.)		
2.)		
3.)		
4.)		
5.)		
6.)		

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Annex to Part II and III

Concerning the Product (trade name): _____

Exposure			Industrial Use	Professional Use	Consumer Use
Human	Oral	Short Term			
		Long Term/ Repeated			
	Dermal	Short Term			
		Long Term/ Repeated			
	Inhalation	Short Term			
		Long Term/ Repeated			
Environment	Water	Short Term/ Single instance			
		Long Term			
	Air	Short Term/ Single intance			
		Long Term			
	Soil/Solid Waste	Short Term/ Single intance			
		Long Term			

Explanations regarding the matrix:

The above general information on uses and exposures conform to the obligatory requirements pursuant to the final REACH regulations **Annex VI no. 6**. It is differentiated between three main use categories (industrial, professional and consumer), with a view to possible final uses.

Differentiation is made between human routes of exposure (oral, dermal, inhalation), environmental media exposure (water, air, soil/solid waste) and exposure patterns (short term and long term).

When completing the matrix, “uses” in the meaning of REACH (such as filling into containers or transfer from one container to another) should be assessed as to whether they are frequently performed activities leading to a long-term exposure of humans and the environment, or if they are infrequently performed activities (such as occasional transfer from one container to another in repair work, sample taking) leading to a short-term exposure of humans and the environment. For convenience,

[5] *The information contained in this questionnaire expresses only the intention of the questionnee and does not constitute a bending obligation. Whilst the* information *is provided in utmost good faith, no representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information*

"infrequent" and "occasional" exposure are summed up under "short term"; "continuous" and "frequent" exposure are summed up under "long term" in this matrix. To provide guidance, the following time-based criteria are recommended for assigning “short term” and “long term” to exposures.[6]

Human

Definition of „short-term“:

- ***Inhalation exposure***
  - **industrial or professional use (worker)**

    a) less than 7 x 0.5 hours per week (0.5 hours per day, e.g. for sampling), or

    b) less than 1 x 4 hours per week (e.g. for maintenance work) - does not apply for substances with log Pow > 3
  - **consumer use**

    a) less than 1 x 0.5 hours per week, or

    b) less than 1 x 4 hours per month, or

    c) less than 2 days per annum
- ***Dermal exposure***
  - **industrial or professional use (worker)**

    a) less than 7 x 0.5 hours per week, or

    b) less than 1 x 4 hours per week

    (exposure of hands only)
  - **consumer use**

    a) less than 1 x 0.5 hours per week, or

    b) less than 1 x 4 hours per month, or

    c) 2 days per annum
- ***Oral exposure***
  - **industrial, professional, consumer use**

    In industrial and professional use, short-term oral exposure usually occurs only in accidents. In the given context, continuous oral exposure does not need to be examined. However, this does not necessarily apply to consumer use.

Definition of „long term“:

Duration and frequency that exceed the criteria for the definition "short term".

Environment

Definition of „short term": less than once per each 28 days

Definition of „long term": more than once per each 28 days

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[6] Source: VCI Paper "Safe use of substances using use and exposure categories" (status: 7 August 2006)