ORGALIME

**Model letter for structuring communication between companies and upstream suppliers**
**Pre-registration and registration of substances on their own, in preparations or in articles**
**Letter to be adapted according to companies' needs**

*Date*

**Object: REACH Regulation N°1907/2006**[1]

Dear Supplier,

The European "REACH" Regulation N°1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemicals entered into force on 1 June 2007. While setting new rules for the management of chemical substances, REACH leads to the need for more communication between customers and suppliers on the substances, preparations and articles they buy and sell. Given the new legal requirements, we are writing to you to request some information about substances on their own, in preparations, and in articles that you supply to us, in order to allow us to fulfil our legal obligations under REACH.

You will therefore find enclosed in this letter our requests concerning:

1. Your policy towards pre-registration and registration of substances on their own, in preparations or intentionally released from articles. **To ensure smooth continuity of business, our common interest is that all substances on their own and/or in preparations and/or intentionally released from articles that you supply to us are pre-registered (between 1 June and 1 December 2008) and then registered.**
2. For our suppliers outside the European Union (EU), whom you have or will nominate as your "only representative" in the EU, fulfilling the obligations of importers under REACH.
3. Details of the contact person responsible for REACH issues.

These requests are detailed in Annex I of this letter. To facilitate communication, we would suggest that you use the model questionnaire outlined in Annex II to respond. You will also find some background information about REACH in Annex III.

If you are not in a position to answer our requests, would you please forward this letter to your upstream suppliers acting as registrants/having the requested information available and inform us as soon as possible, preferably by *(to be completed)*

Please note that this is a first communication letter that will be followed by further requests regarding the inclusion of our uses/brief description of uses in your registration dossier. We will also request information on substances of very high concern present in articles at the latest when the candidate list is available with a view to accomplishing our legal obligations under REACH. In order to prepare for this, we kindly ask you to already forward to us now any information on substances of very high concern you may have. In case of authorisation procedure for a substance of very high concern that we are using, information will follow.

Please return the requested information to: *(name of company sending the letter)*

We thank you for your time and hope to hear from you soon.

Yours sincerely,

[1] For more information on REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at the following address: http://publications.orgalime.org.



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## ANNEX I: Our requests

**Please complete the following information. You may use the model questionnaire attached.**

### 1. Information on pre-registration and registration

You can understand that we need to ensure supply continuity of the input we use, to anticipate possible changes of the substance or preparation we use, as well as process re-approval. For these reasons, **we kindly ask you to answer the following questions:**

- Your roles as ***e.g.*** manufacturer (M), importer (I), distributor (D), downstream user (DU) (including formulators), article supplier (AS) according to the definitions in REACH with regard to the substance/preparation/article you supply to us.

- **If you are the registrant**, we need to know whether you intend to pre-register and register the substance on their own, in preparations or intentionally released from articles that you supply to us.

- **If you are not the registrant**, we need to know whether **all** substances on their own, and/or **all** substances in preparations and/or **all** substances intentionally released from articles that you supply to us are intended to be **pre-registered and registered by an actor up the supply chain**. In case you do not have the information available yet, please inform us by when it will be available (day/month/year). Please also inform us about the registrant's identity.

- **If there is no intention to pre-register or register a specific substance, we wish to know if the production and/or commercialisation of the substance or preparation/article containing that substance is to be abandoned, or the composition changed. Please fill in the column "remarks" in the table in Annex II**.

### 2. Suppliers outside the EU

REACH only applies to European Union (EU) based legal entities. If you are a manufacturer, formulator of preparations, producer of articles **who exports into the European Union, we recommend that you appoint an** "**only representative of a non Community manufacturer**" **(that is an exclusive representative) established in the EU**, according to Article 8 of the REACH Regulation. Your only representative will carry out the importers' required REACH obligations. **Please let us know whom you have appointed as your "only representative" and forward this letter to him. Thank you.**

### 3. Contact details of the contact person for REACH issues in your company

*For more information on REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at the following address: http://publications.orgalime.org.*

## ANNEX II: Questionnaire to be completed by supplier and returned to: (*coordinates of company sending the letter*)

### 1. Information on pre-registration and registration

**Table to be completed by EU suppliers/only representatives of non EU supplier <u>of substances on their own</u>**

| Name of substance | EINECS or CAS number | Supplier's code | Role In the supply chain | **If you are the registrant** will you **pre-register** the substance? (yes/no) | **If you are the registrant** will you **register** the substance? (yes/no) | **If you are not the registrant**: will the substance be **pre-registered** up the supply chain? /Information available by (day/month/year) Registrant's identity? | **If you are not the registrant**: will the substance be **registered** up the supply chain? /Information available by (day/month/year) Registrant's identity? | Remarks |
|---|---|---|---|---|---|---|---|---|
| xxx | | | | | | | | |
| xxx | | | | | | | | |

**Table to be completed by EU suppliers/only representatives of non EU supplier <u>of preparations</u>**

| Name of prepa-ration | Supplier 's code | Role In the supply chain | **If you are the registrant** will you **pre-register ALL** substances in preparations? (yes/no) | **If you are the registrant** will you **register ALL** substances in preparations? (yes/no) | **If you are not the registrant** will **ALL** substances in preparations be **pre- registered** up the supply chain? / Information available by (day/month/year) Registrant's identity? | **If you are not the registrant** will **ALL** substances in preparations be **registered** up the supply chain? / Information available by (day/month/year) Registrant's identity? | Remarks |
|---|---|---|---|---|---|---|---|
| xxx | | | | | | | |
| xxx | | | | | | | |

**Table to be completed by EU suppliers /only representatives of non EU supplier <u>of articles intentionally releasing substances</u>**

| Name of article | Supplier's code | Role In the supply chain | **If you are the registrant** will you **pre-register ALL** substances intentionally released from articles? (yes/no) | **If you are the registrant** will you **register** ALL substances intentionally released from articles? (yes/no) | **If you are not the registrant** will ALL substances be **pre-registered** up the supply chain? /Information available by (day/month/year) Registrant's identity? | **If you are not the registrant** will ALL substances be **registered** up the supply chain? /Information available by (day/month/year) Registrant's identity? | Remarks |
|---|---|---|---|---|---|---|---|
| xxx | | | | | | | |
| xxx | | | | | | | |

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## 2. Suppliers outside the European Union

Please let us know the coordinates of your appointed “only representative”.

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## 3. Details of contact person for REACH issues

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**Thank you for your time.**

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## ANNEX III: Basic facts about REACH

Please find below for information some basic facts about REACH, which you may find useful for your further proceedings.

### Pre-registration and Registration of substances

You may know that according to REACH, European manufacturers and importers (*i.e.* each European legal entity) are obliged to register substances on their own or in preparations they manufacture or import in volumes **of one tonne and more** per year, per manufacturer/importer, unless exemptions apply. Registration also concerns substances in articles in case of intentional release of the substance under certain conditions.
Failure to register means that the substance may no longer be manufactured in the EU nor be placed on the EU market, according to the principle of "no data-no market".

In order to be granted transitional periods varying from 3.5 to 11 years for registration (depending on substance volumes and properties *i.e.* 30 November 2010 – 31 May 2013 – 31 May 2018), substances on their own/in preparations/intentionally released from articles already present on the market (so-called "phase-in substances") **must be PRE-REGISTERED with the European Chemicals Agency between 1 JUNE 2008 AND 1 DECEMBER 2008**.

Missing pre-registration means that manufacture or import of the substance must be suspended until the complete registration dossier has been submitted to the European Chemicals Agency. There is an additional three week delay after submission, before manufacture or import may start again. This situation may lead to supply disruption with availability for customers being a problem since the substance may no longer be available on the market for a certain period of time.

### Substances of very high concern

REACH further foresees specific provisions for **substances of very high concern**, on their own, in preparations and present in articles.
Substances of very high concern include those

- Classified as Carcinogens, Mutagens and toxic to Reproduction (so called "CMRs") category 1 and 2,
- Persistent, Bioaccumulative and Toxic (PBTs),
- Very Persistent and very Bioaccumulative (vPvB)
- Substances of equivalent concern.

New legal requirements for substances of very high concern under REACH include *inter alia*:

- (Pre-)registration procedure (Title II REACH)
- Notification (Article 7.2 REACH and ff.)
- Communication duties (Article 33 REACH)
- Authorisation procedure (Title VII REACH)

The inclusion of substances of very high concern in the so-called "candidate list" (Article 59 REACH) will trigger the notification and communication requirements for substances in articles under certain conditions. The procedures for including substances of very high concern in the candidate list will start as of 1 June 2008. The authorisation procedures apply to substances of very high concern which have been included in Annex XIV REACH.

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