REACH

Factsheet

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Information for parties involved in contractual arrangements for toll manufacturing.

Toll manufacturer under the REACH Regulation

For business reasons (e. g. economic advantage, staying competitive, logistics) a company may decide to outsource (some of) its manufacturing operations to a third party. The nature of such contractual arrangements between companies is described using a broad range of terminology. "*Toll manufacturer*" is one of the most frequently used terms for describing a second company carrying out an activity on behalf of a first in cases where the activity is manufacturing. The activity is correspondingly described as *toll manufacturing* and is a common practice in the chemicals industry. The REACH Regulation does not have specific provisions on toll manufacturing. Nevertheless, toll manufacturers may have obligations under the Regulation.

The aim of this fact sheet is to explain the concept of a *toll manufacturer* and the responsibilities that he may have under the REACH Regulation. This document also briefly describes relevant REACH requirements. It additionally gives some initial advice on how compliance may be facilitated for toll manufacturers and for companies who are contracting others to toll manufacture on their behalf.

Toll manufacturing agreements may be very different in scope and arrangements. It is strongly recommended that such agreements explicitly address the REACH obligations related to manufacturing activities in the EU - as a minimum the registration obligation. Provisions for ownership of data, future updates, responsibility for compiling and providing Safety Data Sheets (SDSs), as well as other relevant REACH obligations should be clearly addressed in the contractual agreements. Similarly obligations for correct classification, packaging and labelling of the substances or mixtures subject to the agreement under the CLP Regulation should also be addressed in the agreements.

WHO IS A TOLL MANUFACTURER?

A *toll manufacturer* is normally understood to be a company providing manufacturing services (for a fee) to another company, on the basis of a contract for provision of those services. The following terms are also used to describe such activity:

- **Outsourced manufacturer;**
- **Third party service provider;**
- **Custom chemical manufacturer;**
- **Supplier of outside services;**
- **Contract manufacturer;**
- **Toller.**

WHAT IS TOLL MANUFACTURING?

Toll manufacturing (or *tolling*) implies that processing of materials takes place. The toll manufacturer's services can include for example:

- manufacturing of a substance;
- formulation;
- blending;
- separation;
- distillation;
- centrifugation;
- a combination of the above.

Storage or distribution may accompany the tolling operations, but do not themselves constitute toll manufacturing.

Toll manufacturing arrangements may differ subtantially from case to case.

ACTORS CONCERNED

A toll manufacturing agreement involves two parties:

- **Company procuring the tolling service** ("the customer", also called "the principal") that may provide raw materials, chemical process information and necessary instructions.
- **Toll manufacturer** (provider of service) who (depending on the situation) provides infrastructure, required equipment, operating staff and technical support.

In general, the customer usually owns the process technology and know-how as well as the end product(s). This fact differentiates a toll manufacturing agreement from a standard supply contract.

WHAT ARE THE TOLL MANUFACTURER'S OBLIGATIONS UNDER REACH?

Registration of substance

There is no definition of a toll manufacturer in the REACH Regulation. The Regulation offers no specific rules or provisions for this actor. Therefore, for REACH purposes, a toll manufacturer is to be considered in the same way as any other EU-based **manufacturer** that conforms to the definition in Article 3 (9) of REACH, i.e. as a:

- natural or legal person established within the Community who manufactures a substance within the Community

and the activity of **manufacturing** is defined in Article 3 (8) as:

- production or extraction of substances in the natural state

According to Article 6 (1) of REACH, any EU-manufacturer of a substance in a quantity of one tonne or more per year must register the substance, unless specific exemptions apply[1]. This includes substances on their own, in mixtures or substances in articles when they are intended to be released under normal or reasonably foreseeable conditions of use.

If the above-mentioned criteria for registration are met, it is **the toll manufacturer who has the registration obligation** under REACH, despite the fact that the customer owns the raw materials, intellectual property and end product(s).

The issue of **who should bear the administrative burden** of registration and associated costs needs to be agreed between the two actors. The toll manufacturer may not be capable of taking on such costs. Also, the company procuring the tolling services may want to control the registration, as it often

[1] For more information on exemptions from REACH provisions, please consult sections: 2.2.2, 2.2.3 and 2.2.4 of the Guidance on registration.

holds the registration data and confidential business information concerning the substance and its uses.

As long as this is not in conflict with the obligations of the manufacturer under REACH, the practical arrangements can be made between both parties in any way satisfactory to both parties. For example, the customer may decide to compile the registration dossier and pay for the registration costs. Also there may be a contractual agreement between the customer and the toller covering data ownership and containing provisions whereby one or both parties commit to compensate the other for any loss, damage, or legal liability that may arise out of the agreement. Since toll manufacturing circumstances vary from business to business, each scenario should be judged on a case by case basis, allowing for practical solutions. It should be noted that there may be a need to review and update the content of the registration dossier following a request from authorities or as a result of new information becoming available. Both parties should pre-define clearly how to act in case of such update needs.

In addition to the registration obligation, the REACH Regulation defines other responsibilities for manufacturers which tollers will have to comply with. The following paragraphs explain some of these obligations.

Toll manufacturing and substances subject to restriction

If the toll manufacturer is contracted to manufacture a substance, he also needs to ensure that manufacture, placing on the market or use of this substance is not restricted by Annex XVII (*Restriction on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles*) of the REACH Regulation.

For more information about restrictions, please consult the Guidance for the preparations of an Annex XV dossier for restrictions. It is also recommended to visit the Restriction section on the ECHA website.

Toll manufacturing and authorisation provisions

The authorisation requirements may apply to the substances that are used by the toll manufacturer (i.e. raw materials used in the process). This information should be indicated by the supplier of the substance, usually in the safety data sheet (SDS). If the substance is listed in Annex XIV to the REACH Regulation (*List of substances subject to authorisation*), the toll manufacturer must check whether or not he needs to apply for an authorisation for his use. However, if an authorisation for this specific use has been granted to an actor up his supply chain (e.g. the customer) the toll manufacturer may benefit from it (provided that he uses the substance according to the conditions of an authorisation granted to an actor up his supply chain).

For more information on the authorisation process, please consult the Guidance on the preparation of an application for authorisation and Questions and Answers on application for authorisation. It is also advised to view the Authorisation section on the ECHA website.

Requirements for safety data sheets (SDSs)

Article 31 (1) of the REACH Regulation, requires the **supplier** of a substance or a mixture to provide an SDS formatted according to Annex II of REACH, whenever:

a substance:

- meets the criteria for classification as hazardous in accordance with the Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation); **or**

- is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII of the REACH Regulation; **or**

- is included in the candidate list of substances which may be subjected to authorisation.

or a mixture:

- meets the criteria for classification as dangerous in accordance with the Dangerous Preparation Directive (DPD)[2];

[2] Note that from 1 June 2015 also the criterion for mixtures will be based on the CLP Regulation.

A supplier is defined in Article 3 (32) of REACH as "*any manufacturer, importer, downstream user or distributor* ***placing on the market*** *a substance, on its own or in a mixture, or a mixture*". With regard to the REACH definition of placing on the market (*"supplying or making available, whether in return for payment or free of charge, to a third party"*) substances (or mixtures) made available to the customer (i.e. the third party) by the toller can be considered to have been placed on the market. Therefore, the toll manufacturer is the supplier of a substance (or mixture) and the customer or a DU of the customer is the recipient. The toll manufacturer is thus formally responsible for providing the SDS for the substance(s)/mixture(s) that he manufactures to the customer. However, if agreed between the parties, the compilation of the SDS can be carried out by the customer.

Note that even if the substance is not classified as hazardous, or the conditions of Article 31 for when an SDS must be provided are not fulfilled, the supplier may under certain conditions have to provide the recipient with other information according to Article 32 of the REACH Regulation.

For more information on for which substances and mixtures SDSs need to be provided and by whom, please consult the Guidance on the compilation of safety data sheets.

Obligation to keep information

As is the case for any other EU-based manufacturer, a toll manufacturer is required according to Article 36 of REACH to collect and keep available all the information he requires to carry out his duties under REACH.

The toll manufacturer should be able to demonstrate REACH compliance upon request of (inspecting/enforcing) authorities or ECHA. Depending on the service provided by the toll manufacturer, the set of such information may vary. For toll manufacturers carrying out manufacturing as defined in REACH this information may include for example:

- SDSs of substances/mixtures that are manufactured for the customer and made available to the customer or third parties;
- SDSs of substances/mixtures that are made available by the customer to the toll manufacturer;
- registration numbers of all substances manufactured (provided that they require registration);
- any other information on substances made available to the customer or third parties as required by Article 32 of REACH;
- invoices and proof of payment concerning fees for registration of manufactured substance(s);
- copy of tolling contract;
- the toll manufacturer should also be able to document the volume of each substance that he manufactures.

CONFIDENTIALITY

Toll manufacturing agreements may be confidential. In particular the customer may not want to reveal to his final clients the identity of the toll manufacturer or to disclose that there are other tollers acting on his behalf.

If both actors are situated within the EU, the customer may use the possibility given by Article 4 of REACH (*General provision*) and act as a **Third Party Representative** (TPR) for discussions with other registrants within the Substance Information Exchange Forum (SIEF) for a phase in substance. The toll manufacturer might appoint the customer as a TPR. In this case the identity of the registrant (i.e. the toll manufacturer) will not be disclosed to other manufacturers or importers by ECHA in the inquiry process. As a TPR, the customer will be a visible participant in discussions in any SIEF for the individual substances concerned. However, when concluding SIEF agreements and agreements for access to data the specific status of the TPR needs to be taken into account. It needs to be ensured that the actual registrant (i.e. the toll manufacturer), who is represented by the TPR, also himself obtains permission to refer to the data in the joint registration.

Moreover, both sides of the toll manufacturing agreement should bear in mind that when the customer acts as a TPR, he (like all TPRs) cannot register a substance for the company he represents (i.e. the toll manufacturer). In such cases, the registration itself has to be made by the toll manufacturer (in his own

name). The role of the TPR is limited to maintain anonymity in the SIEF discussions (so that other SIEF members do not know who the actual manufacturer is). The (toll) manufacturer legally remains the registrant.

When preparing a registration dossier, the registrant (toll manufacturer) can claim certain information contained in the SDS (such as the company name) as confidential for the purposes of dissemination of information from the registration dossier by ECHA. This possibility is given by Article 119 (2) (d) of the REACH Regulation. The registrant needs to submit a justification as to why publishing this information would be potentially harmful to his commercial interests or to the commercial interests of any other party concerned. The fact that the registrant is not acting as a direct supplier and has appointed a TPR is a supporting factor in this situation. Such a confidentiality claim must be accompanied by the corresponding fee according to Annex IV of the Fee Regulation. The justification will be assessed by ECHA in accordance with Article 119 (2) of the REACH Regulation. Where it is accepted as valid, the information concerned will not be revealed by ECHA during dissemination of information from registration dossiers or for data sharing purposes.

For further instructions please consult section 4.3.4 of the Data Submission Manual Part 16 - Confidentiality Claims.

For more information about appointing a TPR, data sharing obligations and SIEF formation, please consult the Guidance on data sharing.

It may also be the case that the toll manufacturer is located outside the EU, and the customer inside the EU. In such a situation, the customer is an **importer** and may register the substance in this role[3]. This way the customer both owns the registration dossier and controls the registration.

Another option could be to appoint the customer as an **Only Representative** (OR) of the non-EU toll manufacturer. Note that Article 8 (3) of the REACH Regulation requires the non-EU manufacturer (i.e. the toller) to inform all the EU importer(s) within the same supply chain of the OR appointment (so they would know who the non-EU toll manufacturer is). However, this problem does not arise if the customer acts as a sole importer.
A non-EU manufacturer can only appoint one OR per substance. An OR can represent several non-EU manufacturers of the same given substance, but would then need to register the substance separately for each legal entity he represents for that substance (i.e. by creating separate UUIDs for each legal entity he represents and by submission of a separate registration for each of those legal entities). This makes appointing an OR by the non-EU toll manufacturer more complicated in case the non-EU toller manufactures several different substances for several customers.

For more information about appointing an only representative and his role and duties under REACH, please consult section 2.1.2.5 of the Guidance on registration.

CHANGE OF TOLL MANUFACTURER

A company procuring tolling services should also be aware of legal consequences when changing the toll manufacturer to a different company (different entity).

According to Article 22 (1) (a) of REACH any change in the identity of a registrant has to be notified to ECHA. If the change also involves a change in legal personality of the registrant, it triggers the need to update the registration dossier and for payment of an update fee according to Regulation (EC) No 340/2008[4] (the Fee Regulation).

If the company procuring the tolling services decides to transfer toll manufacturing to a different company, it cannot be treated simply as a change of legal personality, unless there is a legal link between the old and the new legal person. Therefore, in such a case **a new registration accompanied by the relevant fee** would be required.

A new registration accompanied by the relevant fee may also be required if there is a change of a non-EU toll manufacturer which has appointed an OR. In such a case it is either the EU importers or a new OR

[3] It is not an option for the non-EU toll manufacturer to register a substance, as only an EU legal entity can register a substance under REACH.

[4] As amended by the Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013.

appointed by the new non-EU toll manufacturer that needs to register.

If the new toll manufacturer (or the respective new OR or importer) is the first time manufacturer (or importer) of a phase in substance in a quantity between 1-100 tonnes per year (and the substance is not classified as CMR category 1 or 2, or as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC[5]) he can still benefit from "late" pre-registration up to 31 May 2017, within 6 months of first manufacturing in a quantity of 1 tonne or more per year. This possibility is foreseen under Article 28 (6) of the REACH Regulation. Note that late pre-registration does not apply for non-phase in substances.

For more information on legal entity change, it is recommended to consult REACH-IT Industry User Manual Part 17 – Legal Entity Change. This manual provides an overall context for legal entity change, defines some key terms and summarises the duties of companies with respect to changes of name and changes of legal personality. It also describes the use of those functionalities required by industry to comply with the REACH Regulation when a company changes its legal personality. For more specific instructions on how to report a change in legal entity, please consult Practical Guide 8: How to report changes in identity of legal entities.

WHERE CAN I FIND FURTHER INFORMATION AND SUPPORT?

National REACH helpdesks offer practical advice in local languages: http://www.echa.europa.eu/nationalhelp/

Industry associations often also provide information and support to their members.

[5] Directive 67/548/EEC has been replaced by Regulation (EC) No 1272/2008 (the CLP Regulation). 67/548/EEC will be fully repealed with effect from 1 June 2015. Until then there are transitional provisions in place in accordance with Article 61 of CLP. The reference to classification contained in this text applies to the concept of harmonised classification of substances listed in Part 3 of Annex VI to the CLP Regulation and self-classification in accordance with Article 4 of the CLP Regulation.

LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006

CLP Regulation (EC) No 1272/2008

Fee Regulation (EC) No 340/2008 as amended by Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013.

REACH Guidance: this section of the ECHA website is a single point of access to general and detailed technical guidance on REACH.

Guidance in a Nutshell: this section of the ECHA website contains a series of shortened versions of the REACH guidance documents to make the corresponding full guidance documents published by ECHA more accessible for industry.

Guidance Fact Sheets and Frequently Asked Questions (FAQs) can be found in the "support" section of the ECHA website.

For the current FAQ on toll manufacture (as at July 2013) see: FAQ link.

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