

Toll Manufacturing and REACH

Executive summary

The Toll Manufacturer (TM) and his principal and could agree (by civil law agreement) that the principal registers a given substance 'on behalf of' the TM. The principal acts in that case as a representative.

REACH provides a qualified representative: the Third Party Representative, who may act without naming the real manufacturer (art. 4).

In the agreement concerned they may - from a civil law perspective – agree that the TM will not see the data that are (to be) submitted by the principal.

From REACH perspective the TM remains as the manufacturer of the substance Reach Registration Responsible. The principal can not take over this responsibility.

The civil law agreement cannot prevent the TM to fulfill his REACH obligations or to executes his rights, which means that if the TM is required to give information (e.g. to the ECHA during a audit) he will have to do so in spite of the civil agreement. He also has his right on information, which is exchanged in a SIEF, taken that both the TM and the principal are members of a SIEF.

TM is Reach Registration Responsible

Reach provides among other things that the manufacturer has the registration obligation.¹ A manufacturer under REACH is any natural or legal person established within the Community who manufactures a substance within the Community. According to Article 3(8) manufacturing means production and extraction of substances in the natural state. Therefore, in general, the operator of the site is likely deemed to be the manufacturer and has the obligation to register the substance- the toll manufacturer has registration obligation, not the company ordering the toll manufacturer to make the product. It has to be noted that roles are also dependent on whether the substance is chemically modified during the process, the raw materials have been register by the supplier, and other details which much depend on the case by case basis.

In the relation between the Toll Manufacturer (TM) and the principal, it is the TM who produces, which is even the purpose of a tolling agreement. Hence the TM is the manufacturer under REACH; hence he has the registration obligation under REACH and to submit its relevant data in the framework of (pre)registration.

Neither IP ownership is decisive for 'manufacturing/production', nor is the fact that the principal remains the owner of the substances. Reach is an Administrative Law regulation, which differs from Civil Law Agreements.

(Non) transfer of information and registration obligation

¹ Article 6(1) *Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of one tonne or more per year shall submit a registration to the Agency.*

Legal aspect of REACH Issue Team September 2007

For registration and submission purposes the TM needs to have various (IP) information, which he may not have because this is (still) in the hands of the principal. But the principal may have (IP) reasons not to disclose this information (to the TM). If so, is there any in-between solution (for the principal) by doing the registration in stead of the TM?

Third Party Representative

In legal cases it is always possible to ask (by agreement) a third party to do specified work for you by representation (“proxy”). One could ask a third party like a consultancy firm or law firm to do legal work “on behalf of”.

REACH qualifies this representation in three cases.

All REACH-proceedings in the framework of (1) pre-registration (Chapter III), (2) joint submission (art. 11/19) and cost sharing (art 53) could be dealt with by a so called ‘Third Party Representative’ (TPR) (art. 4), with the consequence that the name of the represented entity will remain hidden, which is different from ‘normal’ representation.²

Applied to the TM cases, it follows that the TM could appoint e.g. the principal or ReachCentrum as a TPR to do the registration and submission work. The name of the TM remains then hidden.

In the civil law agreement concerned between the TM and the principal, they could agree whether the TM will not see the data that will be submitted by the principal. Nevertheless from an administrative law perspective, the TM remains fully Reach Responsible, so the TM must agree to not seeing the data, knowing that he is and remains REACH Registration Responsible.

Further one cannot exclude that the TM self will be forced by the ECHA to provide information for instance during an inspection or audit.

In addition one should bear in mind that if the TM and principal are members of the same SIEF, they have to exchange data in that SIEF.

Some entities belonging to the same mother company may operate as TM, other as principal. So solutions have to be found on a case by case basis (modal agreements have to be developed).

Liability

The agreement between the TM and the principal on the registration by the principal on behalf of the TM should include the point liability in case of failure of the registration (submission) by the principal.

Non-EU TM

If the TM manufacturers outside the EU, not he but only the EU importer has to register and submit information to the Agency, unless the TM – by mutual agreement with the principal, I would say - has appointed an ‘Only Representative’ who then has to register. In both cases there is no need to disclose data to the non-EU TM.

² Art. 4 last sentence reads: *“In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.”*