

Annex D: Recommendations and positions of the Automotive Industry on REACH

REACH General

Q1. What is the recommendation for supplier contracts regarding REACH obligations?

A: It is very important that in your relation with your supplier and particularly with new suppliers, you refer to the REACH Regulation.

To formalise these requirements, it is recommended that the REACH obligations are specified in the contracts or other documents defining your requirements. This action is all the more important if your supplier is located outside the EEA because in this case REACH obligations don't apply to him.

One example is provided below: "The different requirements (Registration of the substances, Notification...) of REACH regulation (Regulation (EC) No. 2006/1907 and its amendments) must be duly taken in account to guarantee the conformity of the products delivered to us and to avoid any supply chain disruption."

Q2. We understand that chemical manufacturers/importers are basically responsible for the registration of new and existing substances and automobile manufacturers need only be concerned with substances "intended to be released." What does the TF-REACH think about this point?

A: It is correct that article manufacturers or importers only have to register substances that are intentionally released from their articles. However you may have other obligations. Please identify your roles and responsibilities under REACH. Use the AIG and / or consult the REACH Navigator under: http://reach.jrc.it/navigator_en.htm

Q3. Considering that supply chains spread beyond national boundaries, the implementation of REACH requires the cooperation of different countries. Does the EU have a plan to promote activities to raise awareness of REACH?

A: Each Member State has to establish National help desks, these help desks will network together. Raising awareness is a task for industry and its associations. The responsibility for complying with REACH lies with the industry.

Q4. How about parts purchased from outside the EEA? How will you direct the suppliers to respond to REACH?

A: Non-EEA suppliers have no legal obligation under REACH. However, as you need their information for your own REACH compliance, it is advisable to add a clause into your supplier contract or other equivalent documents. Please refer to Q4.

Q5. What are the obligations of a distributor?

A: A distributor has the obligation "not to interrupt" the information flow within the supply chain. He has to pass the information needed for REACH compliance up and down the supply chain. (Article 34 REACH)

Q6. How to prepare for national REACH audits?

A: Please refer to chapter 5.15 and Annex J (REACH Enforce projects)

Registration

Q7. Which substances are exempt from registration?

A: Some substances are exempted from REACH altogether and so will not be subject to Registration, for example: radioactive substances, non-isolated intermediates, wastes, substances under customs supervision, and, if Member States so choose, substances necessary for the interests of defence. In the REACH regulation you will find a more comprehensive list of general exemptions within Article 2 and Annex V REACH and more specific substance exemptions within Annex IV. Substances manufactured or imported in quantities less than 1 tonne per year do not need to be registered. Refer to chapter 5.2.

- Q8.** Is there an obligation to register steel or other alloys?
A: Alloys (including steel) are mixtures under REACH, albeit special ones where the properties of the mixtures do not always simply match the properties of the components. As mixtures, alloys do not have to be registered but their component metals must be registered if manufactured/imported in quantities greater than 1 tpa. Refer to chapter 2.1.
- Q9.** One of the registration requirements is "(a) the substance is present in those articles, in quantities totalling over 1 tpa producer or importer." We understand that this 1 tonne is for each individual producer or importer. Is our understanding correct?
A: Yes, it is per producer or importer (legal entity).
- Q10.** Will each company that registers a substance receive a different registration number for it?
A: Yes, each company receives an individual registration number.
- Q11.** When is windscreen washer fluid considered a "mixture in a container" and when is it a "mixture within an article"?
A: When you import a car with windscreen washer fluid in it, then the fluid is a "mixture within an article, which is intended to be released". When you import a barrel/bottle etc. with windscreen washer fluid, it is a "mixture in a container." In both cases, the substances within the windscreen washer fluid have to be registered for that use. Refer to chapter 5.8.
- Q12.** Is it right to think that the mechanism for registration and restriction of new chemicals is almost the same as the existing one?
A: Yes, substances put on the market after 1981 and compliant with the existing regime are seen as "REACH compliant".
- Q13.** What substances should OEMs register?
A: Each OEM must identify its role under REACH. If the company imports substances or substances in mixtures then they have to register unless no OR is appointed.
- Q14.** What is the Automotive Industry position on the registration obligation of pyrotechnic devices?
A: Please refer to Annex L2 (Automotive Industry Pyrotechnic Position Paper)
- Q15.** The "use" is the key to REACH. Some metals may serve as a catalyst when reduced to a fine powder but do not have oxidizing properties when used for decoration or plating. In this case, is it right to think that the metal must be registered as a "catalyst"?
A: The substance must be registered for the appropriate "Use and Exposure Category" depending if it is used as a catalyst or alternatively for decoration or plating.
- Q16.** How will notification work for DUs of substances under the product & process oriented research and development (PPORD) exemption?
A: The PPORD exemption from registration (Article 9 REACH) is for manufacturers and importers doing research, either by themselves or with listed customers. The substances for these uses do not require registration (and DU requirements do not apply because the supplier is not required to prepare a CSR) and would not be supplied to others in the supply chain for commercial purposes or to the general public at any time. However if the substance is used in quantities greater than 1 tpa per use, the DU must notify the ECHA.

SVHC Communication Authorisation and Notification

- Q17.** Approximately how many substances are treated as SVHC?
A: There are today around 2000 Substances fulfilling the criteria of SVHCs. ECHA is publishing twice a year an updated Candidate List. Following latest statements from EU Commission, it is planned to have around 500 SVHCs added to the CL until 2020.
- Q18.** What kind of SVHC do we need to take care of?
A: See Chapter 5.8.
- Q19.** What is the recommendation for Article 33 REACH?
A: Please refer to Annex P (Article 33.1 FAQ) and to chapter 5.10.

Q20. Can the industry predict which substances may be subject to an authorisation? Are the criteria clear enough?

A: The identification of the different groups of substances that may be subjected to authorisation is clearly defined. For CMR categories 1A and 1B substances, the criteria are described in CLP Regulation, for PBT and vPvB substances the criteria are included in Annex XIII REACH. For any other substance there must be scientific evidence of probable serious effects to humans or the environment, which give rise to an equivalent level of concern as CMR categories 1A and 1B, PBTs or vPvBs.

To provide more certainty for industry, substances will be identified through an open process and the decision to include the substance in Annex XIV REACH will finally be taken by the Commission in accordance with the Comitology procedure. The process for such decisions is as follows:

Dossiers to identify a substance for the authorisation procedure will be prepared either by a Member State or by the ECHA if requested by the Commission. All dossiers will be published and will be open for comments by interested parties. Substances identified as having any of the listed properties of very high concern will be included on a CL published by the ECHA, within which the ECHA indicates the substances that are on its work programme. The ECHA then recommends substances to the Commission for inclusion in Annex XIV REACH. Priority will normally be given to substances with PBT or vPvB properties, with wide dispersive use or in high volumes. These priority substances may then finally be included in Annex XIV REACH.

Q21. Can applications for authorisation be submitted together?

A: Grouping of applications for authorisation is possible in REACH. Groups can be of manufacturers, importers and DUs; substances; uses or any combination of these groups. This is to enable costs to be minimised and the system to process applications rapidly.

Q22. Which are the substances within articles that require ECHA notification?

A.: Pursuant to Article 7(2) REACH, substances listed on the CL for Annex XIV that meet the following two conditions must be notified under REACH:

1. the substance is present in the manufactured or imported articles in quantities above 1 tpa per importer and 2. the substance is present in the manufactured or imported articles above a concentration 0.1 % w/w.

Q23. If an article contains more than 0.1% w/w of CL-substance, a manufacturer is liable to submit notification. Should 0.1% be calculated in terms of vehicle weight or component weight?

A: Always use the weight of the article manufactured in or imported into EEA.

Q24. Could you provide more detail about what is meant by “the substance is present in those articles above a concentration of 0.1% w/w”? Because if a vehicle weighs say 1,500 kg., then 0.1% is 1.5 kg. and presumably the notification obligation would only apply if the CL substance were present in a vehicle above 1.5 kg. Is my understanding correct?

A: You are correct. The notification obligation applies if all the criteria mentioned in Art. 7.2 of REACH are met and therefore if the CL substance is present below 0.1% w/w in the article which, in case you have cited under 1.5 kg, no notification is required.

Q25. What does it cost to use the REACH-IT system (including IUCLID 5)?

A: IUCLID 5 can be downloaded free of charge from the ECHA homepage, see Chapter 5.15.

Applicability of IMDS, GADSL etc.

Q26. Does TF-REACH consider using IMDS as a method for collecting information on Candidate List Substances contained in articles for REACH? Or does the TF-REACH have a plan to build another tool?

A: For companies already working with IMDS or other substance reporting systems, it makes sense to use those tools. The prerequisite would be an updated restricted-substance list (e.g. GADSL). Please refer to Chapter 5.9 & 5.10

- Q27.** If IMDS is used for REACH, how is information on “use (purpose of use)” conveyed from DUs to upstream suppliers to meet the requirements of REACH?
- A: IMDS is not the appropriate tool to communicate uses throughout the supply chain. Further information on use communication can be found in Annex L3 “Automotive Industry Recommendation on Exposure Scenarios.pdf”
- Q28.** Tier 1 suppliers often do not have complete information about the constituents of materials they deal with. There is a high probability that the requirements of REACH cannot be satisfied through cooperation with Tier 1 suppliers alone. What does the TF-REACH think about this point?
- A: Communication must go through the whole supply chain, not just Tier 1.
- Q29.** Does TF-REACH think that Candidate List Substances should be controlled company individual or that the GADSL industry initiative can be used?
- A: TF REACH addressed this to GADSL team members. GADSL is covering Candidate List Substances. A process has been developed to guarantee a seamless process- Please refer to Annex N “REACH-GADSL-IMDS FlowChart”
- Q30.** How can we set up a system for implementing REACH with respect to process materials (raw/auxiliary material) in our EEA manufacturing facilities?
- A: If you follow Health, Safety, and Environmental legal requirements in Europe in your facility you will have enough information about your process materials and can make sure your suppliers/importers are aware of REACH. Therefore we recommend using the existing tools in your company. To further optimise your existing processes TF REACH is recommending the use of an electronic data exchange format for SDS communication (EDAS). Please refer to Annex L6 “Position paper EDAS”.
- Q31.** If a supply chain extends into more than one country, is it more difficult to collect sufficient information on the content of Candidate List Substances in my articles?
- A: For data collection it is recommended to use the tools of the Automotive Industry (GADSL & IMDS). To start as early as possible, it is recommended to start your investigations already once the substance is published on the Registry of Intentions (ROI). For further information please refer to Chapter 5.1

Import of substances to the EEA (including Only Representative)

- Q32.** Will a registration under the REACH Regulation be required for substances that are manufactured within the EEA but exported 100% outside of the EEA?
- A: Yes. Article 6 of the REACH Regulation requires a manufacturer of a substance in quantities of more than 1 tonne per year to submit a registration, irrespective of whether this substance will subsequently be exported outside of the EEA. Therefore, substances manufactured in the EEA above this limit that do not meet any of the criteria for exemption from registration in accordance with Article 2 of the REACH Regulation and which are subsequently exported to non EEA countries must be registered. The rationale for this duty is that the exposure resulting from manufacture and any other activity before export could be relevant for workers and the environment in the EEA. Please note that substances which have been registered, exported and then re-imported are exempted from registration and evaluation under certain conditions. See the Guidance on Registration (Section 1.6.4.6 - Re-imported substances). More information on registration obligations can be found in the Guidance on Registration (Section 1.5.2 - Actors in the supply chain with registration obligations).
- Q33.** What are the responsibilities of a non-EEA company who has nominated an OR?
- A: Non-EEA companies have no obligation under REACH. Compliance with REACH must be ensured by their EEA-based importers (i.e. they have to register the substance, provide safety data sheets where necessary, etc.). In order to allow importers to fulfil their obligations, non-EEA companies will however have to provide the necessary information on the substance to the importer.
- If a non-EEA company does not wish the importer to be responsible for obligations under REACH (e.g. if the non-EEA company does not wish to disclose confidential information), it

may appoint an OR. In this case, the OR takes over all obligations of the importers under REACH. (See also ECHA website and Article 8 REACH as well as Q4.)

Q34. Are EFTA member states included in the scope of REACH?

A: Iceland, Liechtenstein, Norway and Switzerland are members of the European Free Trade Agreement (EFTA). The EFTA Convention established a free trade area among its Member States in 1960. Iceland, Liechtenstein and Norway entered into the Agreement on the European Economic Area (EEA) in 1992, which entered into force in 1994. Therefore, the EEA is composed of Iceland, Liechtenstein, Norway and the 27 EU Member States. As soon as REACH is implemented by the EEA EFTA-States (which means EFTA States covered by EEA agreement), imports from Norway, Iceland and Liechtenstein will be considered as intra-Community trade for the purposes of REACH. EFTA is preparing a proposal for an EEA Joint Committee Decision, incorporating the Regulation and establishing the conditions for the EEA EFTA participation in the EU Chemicals Agency. EFTA is targeting to have the Regulation incorporated by 1 June 2008. Therefore, an importer of a substance from an EEA country would not be required to register the substance under REACH and would simply be regarded as a DU. However his supplier in the EEA/EFTA States will have to register the substance as a manufacturer under REACH with all associated obligations like any other manufacturer within the EEA. Importers of a substance from Switzerland (a non EEA country belonging to EFTA but not to EEA) will have the same obligations under REACH as any other importer. Examples: A formulator purchasing his substances in Germany or Iceland will be considered as a DU. A formulator purchasing his substances in Switzerland or Japan will be considered as an Importer.

Q35. When did REACH come into force in Norway, Iceland and Liechtenstein?

A: Above mentioned countries had implemented the REACH legislation by inclusion into the EEA Agreement on 05 June 2008.

Q36. What about non-automotive products like machinery or tools which are exported to the EEA?

A.: REACH concerns all imported products independent of their usage in the EEA. In general the exporter has no legal obligation. Under REACH, the importer within the EEA is responsible to fulfil all requirements. Exporters only have to fulfilled obligations stipulated and delegated in related contracts such as to deliver the information about CL-Substances or the fulfil the REACH Notification obligations of Article 7.2 REACH. In general it is to say that vehicle manufacturers and most of their suppliers shall avoid to become an importer. Instead they are recommended to ask the exporter to announce an "OR" who will take over all duties under REACH.

Q37. Is packaging material included with the article from outside EEA subject to REACH?

A.: In most cases, packaging is considered an article under REACH and thus has to comply with all Article related REACH obligations (Art. 7.1 "Registration of substances in articles", Article 7.2 "Notification", Art. 33 "Communication of CL-Substances" and Art 67 "Restriction").

Exposure Scenarios and Safety Data Sheets

Q38. What is the Automotive Industry proposal to handle SDS?

A: Please refer to Annex K (SDS-Matrix), Annex L6 (EDAS-position paper) and Chapters 5.5 and 5.6.

Q39. What is the recommendation for collecting and checking exposure scenarios?

A: Please refer to Annex L3 (Automotive Industry recommendation on Exposure Scenarios) and chapters 5.5 and 5.6.

Q40. Is there a mechanism for conveying information on "use" to upstream suppliers?

A: Communication within the supply chain is key for REACH compliance. The Automotive Industry TF REACH is recommending the use of generic Exposure Scenarios to check and communicate uses. For further details please refer to Annex L3 - Automotive Industry Recommendation on Exposure Scenarios.pdf.

Waste

Q41. Is a waste treatment operator a DU under REACH?

A.: The treatment of waste material itself is not a use of a substance or mixture and, therefore, the operator is not a DU under REACH.

Q42. How is chemical control in REACH linked to waste control?

A: For all hazardous substances above 10 tonnes / year, a Chemical Safety Report (CSR) and a Chemical Safety Assessment (CSA) have to be prepared. This risk assessment has to take into account all ways (including waste streams) in which the substance could contaminate the environment. "Waste" by it self is exempt from REACH and need not be registered.