WORKING DOCUMENT:
Final Orgalime response to ECHA call for input on their task to develop a database on articles containing Candidate List substances under the Waste Framework Directive

09/10/2018

QUESTION 1. Article-centric approach: ECHA proposes a "article-centric approach" to implement the new notification obligations under the Waste Framework Directive. Do you find this as an appropriate way forward?

Orgalime response to QUESTION 1:
The European Technology Industries represented by Orgalime welcomes that ECHA is seeking the views of its stakeholders on a first draft scenario it has developed to implement its new duties of setting up a database of articles that contain Candidate List substances and make available this information to waste treatment operators and consumers. We also welcome ECHA's work to develop a workable and practical scenario for this new database. Considering the objectives of the database described in the draft scenario document, it is understandable that looking into this new proposed article-centric approach forms part of such a scenario building. However, **neither the legal provisions of Article 9.1 of the revised Waste Framework Directive in combination with Articles 7(2) and 33(1) of the REACH Regulation nor the practical implementation by companies providing the information do support an article-centric approach**.

- From the **legal perspective:**
  - **Article 9.1a** of the revised Waste Framework Directive requires ECHA "*to establish a database for the data to be submitted to it pursuant to point (i) of paragraph 1"* which is "*the information pursuant to Article 33(1) of REACH*".
  - **Article 33(1)** of REACH states that this information means "*sufficient information, available to the supplier, to allow the safe use of the article, including, as a minimum, the name of that substance".*
  - **Article 7(2)** of REACH as described in ECHA's draft scenario document is entirely "substance-centric" meaning that an EU producer or importer of articles containing a Candidate List submits only one notification per each Candidate List substance for all articles containing that substance.
  - In addition, Article 9.1a of the revised Waste Framework Directive stipulates that *"ECHA shall provide access to that database to waste treatment operators. It shall also provide access to that database* ***to consumers upon request***." This raises the issue of legal compatibility with the REACH Regulation because according to Article 33(2) of REACH, any supplier of an article containing SVHCs shall provide the consumer with *"sufficient information only on request by a consumer*". Can ECHA take over the role of the supplier and make this information available to consumers? Can ECHA act on behalf of the supplier to

fulfill the requirements of Article 33(2)? Will additional requests to the supplier by the consumer still be necessary? We believe this is an important issue that needs to be clarified legally before implementing the database.

- **From the practical side of article suppliers:**
  - **The companies' internal logistic systems** including IT systems, possible data management systems, internal procedures, etc **are currently substance-centric** in order to allow compliance with various chemicals and substances regulations such as the REACH Regulation 1907/2006 but also sector specific legislation notably the RoHS Directive 2011/65/EU.
  - Changing from the current "substance-centric approach" to the proposed new "article-centric approach" would create **significant consequences in terms of administrative burden and costs, which have not been impact assessed**. This is why, Orgalime advocated for an impact assessment and expressed its serious concerns that the proposal for such a complex database, which was not part of the initial European Commission proposal for the revision of the Waste Framework Directive and was introduced at the very last stage of the negotiations, has not been subject to an impact assessment. These expected significant additional administrative burden and costs are of particular concern to SMEs that are facing severe financial and human resource constraints. According to ECHA's draft scenario document, SME's are particularly vulnerable in this respect.
  - In addition, if the database will be **requesting information on SVHCs in general, this will have a very significant impact on the industry** considering the need to identify SVHCs in each and every article in that case.

- **From the perspective of waste treatment operators**, we challenge that it will be feasible for them to identify and separate the articles one by one to remove SVHCs from the waste treatment processes.

For all these reasons, <u>Orgalime strongly recommends ECHA not to implement the proposed article-centric approach</u>.

In addition, we have the following **other issues of concern:**

- The proposed article-centric scenario appears to pursue a full bill of materials and not only SVHCs, thus going beyond the legal scope and not respecting European property rights and confidential business information.

- In general, in both approaches (article-centric or substance-centric) double postings of data will still occur. The article-centric approach may reduce the number of double posting to a certain extent but will not be fit to avoid double postings of data. In addition, it would mean a substantial reshuffling in the roles and responsibilities of different actors in the supply chain, which are in our view not covered by the current legal mandate established by the Article 9 of the revised Waste Framework Directive. For example, how would the concept of article identifier apply for articles in mechanical industries that have been welded together? We argue against different notification systems for the different roles in the supply chain, as some actors such as private companies can play multiple roles: importer, assembler, retailer, etc.

QUESTION 2. Challenges: what would be, in your view, the main challenges to implement the proposed scenario?

Orgalime response to QUESTION 2:

We expect the following **main challenges if implementing the proposed new article-centric approach:**

- **Will the expected very significant additional burden placed on article suppliers bring a real added value to the protection of the environment and/or human health?** According to a recent position of EURIC, the European Recycling Industries' Confederation, "*the existence of the database will not change the treatment processes of end-of-life articles covered by a sector-specific directive"* - including WEEE - which already includes particular "*requirements on the removal of components and fluids containing hazardous substances".* In addition, EURIC confirms that the database "*will not solve the issues linked to the legacy substances in material flows"* for recyclers. Therefore, **Orgalime questions the proportionality of the database and reiterates its call for an impact assessment.**

- The **protection of European Intellectual Property Rights regarding confidential business information on products is crucial** for the competitivity of European companies. We are seriously concerned about the proposed clear identification of all components of an article that would require publishing the construction and other technical files as well as the list of suppliers if unique ID identifier depends on the manufacturer. These should also be considered as confidential business information. Furthermore, the draft scenario document mentions that "*ECHA intends to make all the data received on articles publicly available on its website*" and that "*ECHA does not expect to collect confidential business information*". How can the confidentiality about the sourcing of articles be managed and secured? As far as we understand from the section 3. *Information requirements* of the accompanying technical supporting document, the name of the articles suppliers / companies submitting data to the database will be publicly available for any complex object (as ID identifier of articles available for a complex object). We also question whether it is legal to make such information publicly available and whether it is compliant with the new recent EU General Data Protection Regulation (GDPR). The proposed clear identification of all components of an article that would require publishing the construction and other technical files as well as the list of suppliers will create a major disadvantage for the European industry compared to non-EU manufacturers

- We also see the following **further challenges:**
    - How would a **level playing field** between EU produced and imported articles be ensured? We suggest that articles imported directly by consumers through e.g. online web shops from non-EU countries should also be included in the new database.
    - **Data management** will be very challenging:
        - Double posting of data for the same product (e.g. a screw being used in multiple industries/articles with each manufacturer having their unique identifier (ID) and related likely misunderstandings will also limit the value of the database in terms of improving the traceability of substances in material streams. In the case of multiple suppliers for a single article and differences in composition for the same article, we wonder whether traceability will be feasible for the final complex article. How could a unique ID apply for similar articles be provided by different suppliers and assembled in complex objects? Should a unique ID for the final complex article be developed it will depend on the different suppliers.

        - Flexibility of the database system in terms of uploading data: just making use of pull down menus would mean that for certain articles it may not be possible to upload data (if not included) and would require a global alignment of terminology (e.g. for the garden machinery sector, “turf equipment” is used in the US versus “lawn & garden equipment” in the EU).If allowed to use free text, unique ID’s would not work, and would risk including wrong data due to miss-typing.
        - Language to be used and related (translation) costs. The database must be available in all EU languages. An article supplier for example in Spain will likely upload the information to the database in his language, but due to the free movement of goods, said article may then be present in waste streams of France, Greece and Finland. Therefore, waste operators and consumers across the EU should be able to have access to this information without language barriers.
    - Article 9(2) of the of the revised Waste Framework Directive stipulates that “*the European Chemicals Agency shall establish a database […] and maintain it*”. In our opinion, the **maintenance** of this future possible database will be crucial and it has been made clear by the legislator that this maintenance of the database must be carried out by ECHA. This raises the important question of legal responsibility over the content of the database. That also results in many other questions related to e.g. content checks, plausibility checks, deletions of data (if an SVHC is no longer present in the product), management of updates, or the use of data by market surveillance authorities (see also our response to QUESTION 4).

- These implementation challenges will not only occur for companies but also for authorities and their enforcement activities, e.g. how to secure the same level of understanding and the same way to deal with the article-centric approach? Harmonised implementation is expected to be at risk.

Duty holders (article suppliers)

QUESTION 3. The legal text requires any supplier of an article containing a Candidate List substance to notify ECHA. Are there needs and practical means to tailor the notification system for the different roles in supply chains?

Orgalime response to QUESTION 3:

- We agree with the following description of duty holders outlined in the draft scenario document:
  “*Supplier of articles under Article 3(33) of REACH can be:*
    - *the producer of articles, if they place articles on the market;*
    - *the importer of articles as such or in complex objects, because import is deemed to be placing on the market;*
    - *the “assembler” that places articles (incorporated in complex objects) on the market;*
    - *the distributor (including retailers, internet sellers);*
    - *any other actor in the supply chain placing articles on the market (e.g. second-hand goods store).*

  A company may have one or more roles”.

- A mechanism to aggregate suppliers and reduce subsequent notifications to the database would be desirable for the workability of the database. However, as outlined

in our above response to question 1, this would not be compatible with the existing legal framework established by the Article 9 of the revised Waste Framework Directive in combination with the Articles 7(2) and 33 of REACH.

- In addition, the notification requirements of Article 7(2) REACH are different from the communication requirements of Article 33 REACH. The notification obligation applies if the substance is present in those articles in quantities totaling over one tonne per producer or importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w). Hence why companies whose articles do not fulfill the above criteria do not fall under this requirement of "notification". If this needs to be applied for all articles containing SVHC's then the legal text of REACH must first be reviewed.
- Furthermore, the "unique identifier" seems a really difficult concept to implement. Experience shows that a given article may have different identifiers even within one company depending on for example the workshop in which it is used.

QUESTION 4. Data submitter needs: do data submitters have specific needs, which the Agency would have to take into account when designing the database and its data submission interface?

Orgalime response to QUESTION 4:

- To ensure fair competition and a level playing field between EU produced and imported articles, **Member States must be equipped with the financial and human resources to follow-up any requirement by proper enforcement activities** e.g. via the verification of data submitted and of the verification of submitting entity.
- **Management and reliability of data:**
    - We suppose that any article / product / complex product manufactured in EU (and potentially also imported) is integrated in the database in the interest of improved supply chain traceability. This implies that the amount of data managed by the database will be very high. Not all articles in complex articles will have substances of very high concern (SVHCs). Therefore, there will be gaps and missing article identifiers for manufacturers when submitting data to the database.
    - The data transfer must be practicable. This includes the question of responsibility. Who is responsible for the data transfer? The first distributor?
    - Who takes over the deletion of data, if an SVHC is no longer present in the product? Risk of outdated data. How do market surveillance authorities handle these "misinformation"?
    - Other considerations to be taken into account e.g. when an SVHC is added. This information will not be included in the original version of the product submitted to the database. Also, when a producer has phased out an SVHC from its product, new identifiers will be needed. How will the waste treatment operators deal with these situations when SVHCs are added or deleted?
    - We question how waste treatment operators will make the difference between articles with the same ID produced at different times and with different composition (with or without SVHC)? Shall a unique ID identifier be given each time the composition of an article changes (change in raw materials suppliers for instance)?
    - As not all companies have in place detailed traceability mechanisms for every change in an article, we would very much welcome recommendations from ECHA for suppliers of complex articles about when to report changes of data in the database.
    - Obligations cannot be retroactive for article suppliers. It should be clarified that the information must be submitted to ECHA only for new SVHCs (as from the

date on which the data supply obligation becomes effective). A retroactive obligation for substances already identified as SVHC for already delivered products would not be justified in particular because the information on SHVC content in material purchased in the past is not provided by raw materials suppliers, so the information would not be available to article manufacturers.
- A data submitter located outside the EU must be allowed.
- The new database will need an interface to be able to upload the existing information from existing standards; e.g. for our sector IEC 62474 (Material Declaration for Products of and for the Electrotechnical Industry) and IPC 1752A (Data Exchange Standards)). To avoid duplication, we consider it extremely important that information/datasets from existing standards and systems can be easily transferred onto the database. Therefore, it is important to investigate the compatibility of the database with existing standards and common practices. The affected industries should be consulted.
- In our view, it is not enough to define an EU-wide format for data transmission. Rather, an international format for data transmission would have to be developed.

Users of the database (waste operators and consumers)

QUESTION 5. User needs: do the expected users of the database have specific user needs, which the Agency would have to take into account when designing the database and its dissemination?

Orgalime response to QUESTION 5:

- We reiterate our concerns regarding the proportionality of the new database and reiterate our call for an impact assessment considering the recent statement of waste treatment operators that "*the existence of the database will not change the treatment processes of end-of-life articles covered by a sector-specific directive"* - including WEEE – *"which already includes particular "requirements on the removal of components and fluids containing hazardous substances*". In addition, recyclers confirm that the database "*will not solve the issues linked to the legacy substances in material flows*" for them.
- As there was no impact assessment for this new database, its environmental benefits, and the benefits for waste treatment operators and consumers in particular, have not been demonstrated. In addition, we would appreciate evidence demonstrating that the proposed database will fulfill specific needs of consumers or waste treatment operators.

QUESTION 6. Information requirements: besides the substance name, which additional information should be submitted to support safe use and end-of-life stage of articles?

Orgalime response to QUESTION 6:

- Sub-articles (components) of complex products are often deeply integrated, assembled or joint together into the final article with no exposure under reasonable and foreseeable conditions of use. As the objective of the Article 33 of REACH is to allow the safe use of articles, it would therefore in our opinion **not be necessary to require a complete breakdown of a complex article into all of its components.**
- The database should be targeted to the given users and f**ocus only on limited information required and necessary for waste treatment operators and consumers, which have** different needs. The design of the new database should be adapted to these different needs. As there was no impact assessment for this new

database, its environmental benefits, and the benefits for waste treatment operators and consumers in particular have not been demonstrated.

- As there was no impact assessment for this new database, its environmental benefits, and the benefits for waste treatment operators and consumers in particular have not been demonstrated. **The information to be submitted must be based solely on the legal background of the Waste Framework Directive and the REACH Regulation**. Furthermore, it should be taken into account that the voluntary submission of data should not render the database unworkable and ultimately useless for consumers and waste treatment operators.
- The **protection of European Intellectual Property Rights regarding confidential business information of products is crucial**. See details in our above response to QUESTION 2.

QUESTION 7: Are there any **further comments** or feedback you would like to share with ECHA on the draft scenario?

Orgalime response to QUESTION 7:

- The timing to respond to this consultation is very short.
- The implementation deadlines of 5 January 2020 and 5 January 2021 for ECHA and suppliers of articles are extremely challenging considering the complexity involved and the number of articles and complex articles to be included.
- Is there a mechanism foreseen to evaluate whether the below objectives of the database to support the circular economy will be achieved?
    1. Decrease hazardous waste generation by supporting the substitution of substances of concern in articles, placed on the EU market;
    2. Allow authorities to monitor the use of substances of concern in articles and initiate appropriate actions over the whole life-cycle of articles;
    3. Provide information to further improve waste treatment operations.
- In the draft scenario document, ECHA indicates that one of the objectives of this database is to "*allow authorities to monitor the use of substances of concern in articles and initiate appropriate actions over the whole life-cycle of articles*" and to "*provide information to further improve waste treatment operations*". Information to authorities regarding the use of substances of concern is already managed by the registration and notification procedures (Article 7 of REACH). The uses of a substance across the supply chain are also indicated in REACH registration files. The scope of the database should be limited to Candidate List substances (SVHCs). The draft scenario uses the terms *"substances of concern (in articles)",* "*hazardous substances (in articles)"* and Candidate List substances and is inconsistent. We reiterate that the legal background needs to be considered (Waste Framework Directive and the REACH Regulation).
- We remind that the proposal for this new overly complex database introduced at the last moment has not been subject to an impact assessment. In particular, there was no impact assessment for the proposed draft scenario with the new "article-centric approach". Furthermore, future uses of the database and a wider scope with additional information to be included will also require impact assessment and stakeholder consultation.
- Furthermore, this proposal overlaps with the ongoing work on the interface between chemicals, products and waste legislation. We remind that the European Commission announced a "*feasibility study, addressing representative sectors, on the use of different information systems, innovative tracing technologies and strategies which could enable relevant information to flow along article supply chains and reach recyclers*" by the end of 2019.

- The transposition and implementation of the database by the Member States should be fully harmonised.
- The implementation of this database by SME's should be prioritised, considering that a lot of them are involved in complex and/or international supply chains.
- For the relevance of the database, it is important to know what waste treatment operators will do with the given information.
- The mixing of references to different legal provisions (Articles 7(2) & 33 of REACH and Article 9 of revised Waste Framework Directive) makes it difficult to understand to which Article an information or requirement is linked to.
- Many outstanding questions about the database need to be discussed in technical working groups in the next months. To do this, all relevant stakeholders should be involved in a transparent and open process.

Orgalime remains available to provide the relevant expert input to your activities from its perspective of a major downstream user and article manufacturer under the REACH Regulation 1907/2006/EC and the target industry of the sector specific Waste Electrical and Electronic Equipment Directive 2012/19/EU (WEEE).