POSITION PAPER

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Orgalim comments on the French draft decrees on the identification of hazardous substances and the provision of information identifying endocrine disruptors in products

Executive summary

Orgalim, representing Europe's technology industries, does not support the provisions of these French draft decrees. Orgalim fears that the decrees will be a considerable burden for industry and create more confusion and fragmentation within the EU internal market, with very limited positive effects on the health of EU citizens and the environment.

Regulation of substances should take place at European level, for EU Member States to compete on a level playing field and reap the full benefits of the Internal Market, while delivering on health and environmental factors. It is essential to the efficiency and success of the Green Deal and the new EU Circular Economy Action Plan that requirements are developed on a harmonised basis, across all EU Member States. Orgalim calls on all Member States to refer to existing European procedures and Article 57 of REACH Regulation for the definition of hazardous substances. Moreover, regarding the Substances of *Very High* Concern in Products (SCIP) database, Orgalim has serious concerns about the workability, proportionality and value of these national provisions. We therefore call on France to first conduct a study on the overlap with future EU legislation as well as the usefulness, feasibility, proportionality and impact of these new requirements.

1. Background

French Law No 2020-105 of 10 February 2020[1] concerning the reduction of waste and the promotion of the circular economy provides for the possibility of extending and strengthening the information requirements established at EU level on the presence of hazardous substances in products. Article 13 of this law provides for the use of several Council of State decrees to set the implementing rules for the identification of hazardous substances and the provision of identifying endocrine disruptors in a product placed on the market.

Article 13-I of this law relates to consumer information on the environmental characteristics of waste-generating products and states that a decree will determine "the definition of environmental qualities and characteristics, the procedures for establishing them, the categories of products concerned and the procedures for informing consumers". According to this article, another decree will identify the hazardous substances referred to, after consulting the French Agency for food, environmental and occupational health safety (ANSES). This first decree has not yet been adopted.

In an opinion published on November 2nd 2020[2], ANSES stated that the list of Substances of *Very High* Concern established under REACH regulation is relevant to form the basis of this list and further opinions are needed to specify what other substances should be included. These additional opinions are still pending.

[1] Legal text available here
[2] Published opinion available here

Article 13-II of this law aims to provide the public with information on the presence of endocrine disruptors in products and requires a decree of Council of State to lay down the modalities of application of this article. Article 130 of the French Circular Economy Law states that Article 13 will come into force on 1 January 2022.

Draft decrees notified under notification numbers TRIS 2020/833/F and TRIS 2020/832/F lay down the conditions governing the application of the legislative provisions related to the list of hazardous substances and the implementation of the obligation to provide information identifying endocrine disruptors in products.

These draft decrees raise concerns regarding the deadline for application and the consistency with EU regulations, notably considering that several dispositions have to be laid down by Ministerial orders.

2. General comments and recommendations

The introduction of new national mandatory requirements, not aligned with European requirements, will create competitive distortion and jeopardise the level playing field within the EU and the good functioning of its market. Furthermore, these additional obligations will increase the complexity of information gathering along the value chain for companies placing products on the French market. In addition, potential labelling requirements, not in line with EU obligations, would be likely to affect the free circulation of goods within the EU. Moreover, regarding the Substances of *Very High* Concern in Products (SCIP) database, we have serious concerns about the workability, proportionality and value of these national provisions. We therefore call on France to first conduct a study on the overlap with future EU legislation as well as the usefulness, feasibility, proportionality and impact of these new requirements. Finally, these provisions would lead to **legal uncertainty due to the lack of visibility on the scope of these requirements, the lists of substances and the methodology for their adoption and update.**

Industry asks for harmonisation of the French obligations with the decisions that will be taken soon at EU level in the context of the Green Deal and the EU Circular Economy agenda (e.g. Sustainable Product Initiative, Ecodesign revision and Chemicals Strategy for Sustainability). The Chemicals Strategy for Sustainability is an umbrella for multiple separate legislative actions on various topics. One of the 'legacy topics' to be included concerns endocrine disrupters under the CSS block: **"Simplifying and consolidating the legal framework: One substance, one assessment"**. Fragmented approaches at the national level, identifying hazardous substances and endocrine disruptors, are likely to contradict the 'one substance one assessment' principle that the European Commission promotes in this strategy. Additionally, there are plans for a **REACH revision by 2022**, to extend the generic approach to risk management to ensure consumer products do not contain chemicals that cause cancers or gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative and toxic. **The harmonisation and alignment with the CSS** activities are crucial to **avoid separation of rules on the same subject between the EU and the Member States.**

The parliamentary debates have shown a willingness to strengthen information for consumers regarding the presence of hazardous substances in products. We consider that the separation of rules on the same subject between the EU and the Member States would be likely to create a considerable burden for the industry, together with more confusion and fragmentation within the EU Internal Market and the Member States' markets. Due to the enormous effort that such provisions would entail regarding the French market, industrial companies might refrain from expanding business areas to include products for French consumers, for example specially designed products produced in small quantities. **It is therefore essential to the efficiency and success of the Green Deal and the new EU Circular Economy Action Plan that requirements are developed on a harmonised basis, across all EU Member States, and are proportionate to ensure the effective ongoing operation of the Internal Market.**

Moreover, because of the broad definition of consumer products, these requirements would lead to **legal uncertainty as regards the scope of application.**

Furthermore, the evaluation of substances should be based on the processes established under REACH and carried out by ECHA's bodies (RAC and SEAC) created for this purpose.

It is also vital for the operators and for authorities to **ensure that such national requirements can be implemented, and that the operators can access the information on the presence of hazardous substances or endocrine disruptors along the supply chain,** even if it is supra-national or global. This would be especially important for endocrine disruptors or hazardous substances for which the information may not be mandatory in the supply chain at EU and global level and therefore not available for downstream users. These new requirements, limited to France, would increase the complexity regarding the exchange of information along the supply chain.

3. Specific comments and recommendations on the draft decree on identification of hazardous substances in waste-generating products

Regarding hazardous substances, the requirements on information to consumers go beyond the REACH regulation on the following points:

- Bullet The law foresees an obligation to inform consumers on the presence of SVHC in products, whereas REACH states that information to consumers should be given on demand (Article 33.2);
- This obligation also extends to informing consumers of the presence of substances having a comparable concern to SVHC, but not listed on Candidate List. However, **the text is not explicitly referring to Article 57 of REACH for identification criteria**. Furthermore, instances have occurred whereby substances have been proposed for identification as SVHC but have not been confirmed after discussion under the European procedure. This new requirement jeopardises the harmonised European procedure. Among 231 dossiers Annex XV requiring an SVHC identification published so far on ECHA's website, seven substances have been found not to be SVHC (i.e. Cyclododecane, or trichlorobenzene);
- **A stakeholder consultation is needed before the list of hazardous substances is finalized by ANSES, followed by a TRIS notification before publication;**
- For substances that are not subject to harmonised mandatory traceability in the European territory, **a period of 18 months is necessary from the publication of the lists of substances (and their updates)**. This is a minimum period of time for companies to collect this information within their supply chains, which are often European or globalised, assuming that the communication is dematerialised;
- In addition, **this draft decree does not mention the threshold for application of information requirements**. Industry asks for a harmonisation of the obligations in France with European regulations. The reference to a concentration threshold is essential for regulatory compliance and legal security of the system, for the producer as well as the control agency.

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