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AFNUM COMMENTS ON THE FRENCH DRAFT DECREES ON THE IDENTIFICATION OF HAZARDOUS SUBSTANCES AND THE PROVISION OF INFORMATION IDENTIFYING ENDOCRINE DISRUPTORS IN PRODUCTS

1. BACKGROUND

French Law No 2020-105 of 10 February 2020[1] against waste and for the circular economy provides for the possibility of extending and strengthening the information requirement 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 is related to the information of consumers on the environmental characteristics of in 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" and another decree will identify the hazardous substances referred to, after opinion of the French Agency for food, environmental and occupational health safety (ANSES). This first decree has not yet been adopted.

By 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.

Article 13-II of this law aims to provide the public with information on the presence of endocrine disruptors in products and require 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.

The draft decrees notified under notification number 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 identiying endocrine disruptors in products.

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

2. GENERAL COMMENTS AND RECOMMENDATIONS

The introduction of new national mandatory requirements, not aligned with European requirements, will install competitive distortion, 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. Finally, these requirements 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 a harmonisation of the French obligations with the decisions that will be taken soon at EU level in the context of the Green Deal (e.g. Sustainable Product Initiative and Chemicals Strategy for Sustainability). The Chemical Strategy for Sustainability is an umbrella for multiple separate legislative actions on various topics. One of the topics that's going to be included are the so-called 'legacy topics', and this

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

concerns endocrine disrupters under CSS block: **"Simplifying and consolidating the legal framework: One substance, one assessment".** Fragmented approaches, at the national level, to identify 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 on **REACH revision by 2022**, in order to extend the generic approach to risk management to ensure consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative and toxic. **The harmonization and alignment with the CSS** activities is crucial to **avoid a separation of rules on the same subject between the EU and the members states**.

The parliamentary debates have shown a willingness to strengthen consumer information compared to the REACH Regulation. We consider that the separation of rules on the same subject between the EU and the Member States would be likely to create considerable burden for the industry, more confusion and fragmentation within the EU internal market and the Member States markets. **It is therefore essential to the efficiency and success of the Circular Economy, that requirements are developed on a harmonised basis, across all EU Member States, and proportionate, to ensure the effective ongoing operation of the internal market.**

Furthermore, REACH processes to identify SVHC (including ED) include a **review by an independent scientific committee**, the RAC committee. This committee evaluates the proposal and gives his opinion. In both of these decrees it seems that such a scientific and independent review is missing. We regret that a similar committee is not foreseen for the application of these measures.

It is also vital for the operators as for authorities to **ensure that such national requirements can be implemented, and that the operators can get 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 is likely to be not mandatory in the supply chain at EU and global level and therefore not available for downstream users.

3. SPECIFIC COMMENTS AND RECOMMENDATIONS ON THE DRAFT DECREE ON IDENTIFICATION OF HAZARDOUS SUSBTANCES IN PRODUCTS

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

a. The law foresees an obligation to inform consumers of the presence of SVHC in products, whereas REACH states that information to consumers should be given on demand (article 33.2).
b. 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 jeopardizes the harmonised European procedure. Among 231 dossiers Annex XV requiring an SVHC identification published so far on ECHA's website, 7 substances have been found not to be SVHC (i.e. Cyclododecane, or trichlorobenzene);
c. A consultation of stakeholders is needed before the lists of hazardous substances is finalized by ANSES followed by a TRIS notification before publication;
d. For substances that are not subject to harmonised mandatory traceability on 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;
e. In addition, **this draft decree doesn't 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.

4. SPECIFIC COMMENTS RECOMMENDATIONS ON THE DRAFT DECREE ON THE PROVISION OF INFORMATION IDENTIFYING ENDOCRINE DISRUPTORS IN PRODUCTS

Regarding the issue of open data to the public on EDs, which includes the creation of a data base on EDs, Industry asks for:

a. An evaluation of the criteria used by ANSES for the identification of EDs in 3 categories as foreseen by the law (known/presumed/suspected). **A harmonisation with the criteria defined at EU level is essential;**
b. A **definition of the methodology defining criteria and more transparency on the process** followed for listing substances;
c. **Mentioning in the decrees 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;
d. A **consultation of stakeholders before the lists of EDs is finalized by ANSES followed by a TRIS notification before publication;**
e. The legal provisions of this text to **specify the scope in accordance to the notice** of this decree that states that these information requirements apply to consumer products only;
f. According to the notice part of the decree many product categories are exempted. Art. 1 of the draft decree is only exempting medicines and foodstuffs as defined in Article 2 of Regulation (EC) No 178/2002. It seems to be a discrepancy and it should be made clear by the French government also in the Article section that the above mentioned products are exempted.