# CEFIC REPLY TO THE TRIS NOTIFICATION 2020/832/F and 2020/833/F

## To identify and manage Endocrine Disruptors, regulatory actions deemed necessary should be taken at EU level, in the form of a Regulation, across all EU Member States. Such approach would lead to consistency on all actions and measures across the European Internal Market. Cefic is concerned on the introduction of French national measures which are not aligned with the European actions foreseen under the Chemicals Strategy for Sustainability and that could jeopardise the good functioning of the internal market.

### Background:

#### On 22 December 2020, France notified the European Commission, via the TRIS Notification system, two draft Decrees which lay down the conditions governing the application of the legislative provisions related to the creation of a list of hazardous substances and the implementation of the obligation to provide information which identified the presence of Endocrine Disruptors (EDs) in products (notification number TRIS 2020/832/F and TRIS 2020/833/F).

General Considerations

1. **The introduction of new national mandatory requirements, not aligned with European requirements, 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. Finally, these requirements would lead to legal uncertainty due to the lack of clarity on the scope of these requirements, the lists of substances and the methodology for their adoption and update.
2. Industry asks for harmonisation and alignment of any national initiative with the soon to be taken decisions related to the Green Deal and especially to the Chemical Strategy for Sustainability (CSS), that encompasses multiple legislative actions on various topics, including Endocrine Disruptors. Moreover, any fragmented approach at national level, especially when aiming at identifying hazardous substances and endocrine disruptors, appears in contradiction with the ‘one substance one assessment’ principle that the European Commission promotes in the CSS. We understand France otherwise supports actions proposed by the European Commission under the CSS, particularly the proposal to address Endocrine Disruptors under the CLP (Classification, Labelling, Packaging Regulation) which, once implemented, will result in labelling and listing of EDs (under Annex VI to CLP). The Commission intends to launch a legislative proposal amending CLP in 2021.
3. Cefic considers that the differentiation of rules on the same subject at European level and at Member States level, such as measures to strengthen consumer information on the presence of hazardous substances in products proposed by these Decrees, would also likely create considerable burden for the industry, along with fragmentation within the EU internal market and confusion of consumers and users of chemicals who will get some information at national level and possibly different information at European level. It is therefore essential to the efficiency and success of the European policies related to chemicals 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.
4. In addition, the REACH Regulation, the cornerstone of chemicals policy, already foresees tools to identify and communicate on any hazardous substances, in particular SVHC (thus including endocrine disruptors). These tools include a review by an independent scientific committee (the MSC Committee) which evaluates any proposed classification of a substance as SVHC and provides its opinion. While for REACH the process is well established and transparent, in the case of the French Decrees it seems that such a scientific and independent review has not been nor is envisaged to be implemented.

SPECIFIC COMMENTS ON THE DECREE UNDER REFERENCE TRIS 2020/833/F ON THE IDENTIFICATION OF HAZARDOUS SUBSTANCES IN WASTE-GENERATING PRODUCTS

* 1. Regarding the presence of hazardous substances in products, the requirements stated in the French Decree (Notification Reference TRIS 2020/833/F), on information to consumers go beyond the requirements included in the REACH Regulation in three areas:

1. The French Decree foresees the obligation for companies to inform consumers on the presence of SVHCs in products, while REACH states that this information to consumers should be given on demand and not on a mandatory basis (Article 33.2).
2. The French Decree extends the obligation to inform consumers on the presence of substances which, not being SVHCs, have a comparable concern but are not listed in the Candidate List, without explicitly referring to the Article 57 of REACH, which describes the criteria to identify SHVCs. This reference is of utmost importance as it provides clarity on how substances are to, or are not to, be identified as SVHCs. In fact, there have been cases in the past where substances have been proposed to be classified as SVHCs but such classification was not confirmed by RAC under the current European procedure (i.e. Cyclododecane or Trichlorobenzene). This new requirement introduced by the French Decree jeopardizes the harmonised European procedure which is supported by independent expert advice. The REACH process to identify any substance as SVHC is clear, transparent and allows stakeholders to participate in the discussion and to provide any comments or evidence. Therefore, any proposed list of hazardous substances advanced at national level should also envisage such stakeholder engagement, followed by a TRIS notification of the list before publication.
3. The concentration thresholds for application of information requirements foreseen by the French Decree are not in line with the European ones. Reference to concentration thresholds is essential for regulatory compliance and legal security of the system, for the producer as well as the control agency.

SPECIFIC COMMENTS ON THE DECREE UNDER REFERENCE TRIS 2020/832/F ON THE PROVISION OF INFORMATION IDENTIFYING ENDOCRINE DISRUPTORS IN A PRODUCT

Concerning the Decree under TRIS notification Reference 2020/832/F, which addresses the issue of open data to the public on endocrine disruptors, including the creation of an ED database, Cefic highlights that any evaluation of a substance regarding their possible endocrine disruption properties should be done following harmonised criteria defined at European level.

Any evaluation performed at Member State level, following a different set of criteria (including different categories) would lead to substances being classified differently in each Member State with consequences that would distort the European internal market (e.g blacklisting). Consumers and users would find different information in France and on the ECHA website for the same substance. How can they make sense of it? This does not only undermine REACH but also runs counter to the principles of the CSS: policy coherence, streamlining of EU legislation on chemicals and “one substance, one assessment” to coordinate and harmonise the work of different agencies.

Furthermore, any evaluation of a substance at Member State level should follow a clear and transparent methodology together with the process of establishing a list of substances having ED properties. This process should also envisage the participation of stakeholders before any list is finalised, followed by a TRIS Notification before publication.

As stated above, Cefic asks for a harmonisation of the obligations in France with European regulations concerning thresholds for application of any information requirement. Reference to concentration thresholds is essential for regulatory compliance and legal security of the system, for the producer as well as the control agency. Such thresholds apply across all endpoints and ED should not be an exception.

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|  |  | For more information please contact:  Sylvie Lemoine, Executive Director, Cefic,  +32.2.436.93.80 or syl@cefic.be.  About Cefic Cefic, the European Chemical Industry Council, founded  in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 16% of world chemicals production. |