DATE : Février 2021

NOTIFICATION

Notification Ref : TRIS 2020/833/F and TRIS 2020/832/F

From : SNITEM (Syndicat national de l’industrie des technologies médicales)

**To :** DG Growth, Unit B2 "Prevention of technical barriers”

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**Re :** FRANCE / Potential technical barrier to trade deriving from a draft decree relating to the identification of hazardous substances and the provision of information identifying endocrine disruptors in products

**Date:**  24/02/2021

**Ref.:** FRANCE / Law n°2020-105 of February 10, 2020 relating to anti waste measures and circular economy

Note: unless noted otherwise, all text references in the present notification are from the French Environmental Code.

**1. Basis for notification**

Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services. (**2015 Directive**)

**2. Context**

On February 10, 2020, France adopted [law n°2020-105](https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000041553759/) relating to anti waste measures and circular economy (**2020 Law**).

This piece of legislation 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](https://www.anses.fr/fr/content/note-ast-relative-%C3%A0-la-mise-en-%C5%93uvre-des-dispositions-relatives-%C3%A0-linformation-des) published on November 2nd 2020, 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.

**3. General Issues**

**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 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.

**3.1** Specific comments and recommendations on the draft decree on identification of hazardous substances in products

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

* + 1. 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).
    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 jeopardizes the harmonised European procedure. Among 231 dossiers Annex XV requiring an SVHC identification published so far on [ECHA’s website](https://echa.europa.eu/fr/proposals-to-identify-substances-of-very-high-concern-previous-consultations), 7 substances have been found not to be SVHC (i.e. Cyclododecane, or [trichlorobenzene](https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.001.598));
    3. **A consultation of stakeholders is needed before the lists of hazardous substances is finalized by ANSES followed by a TRIS notification before publication;**
    4. 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;
    5. 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.

**3.2** Specific comments and recommendations on the draft decree on identification 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:

1. 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;**
2. A **definition of the methodology defining criteria and more transparency on the process** followed for listing substances;
3. **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;
4. A **consultation of stakeholders before the lists of EDs is finalized by ANSES followed by a TRIS notification before publication;**
5. 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;
6. 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.

**4. Particularity of medical devices**

**4.1** The rationale of Regulation (EU) 2017/745 on medical devices supersedes the terms of the Draft Decree on the provision of information identifying endocrine disruptors in products

The SNITEM considers that the rationale of [Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02017R0745-20200424&from=EN) (**Regulation**) supersedes that of the 2020 Law and Draft Decree on the provision of information identifying endocrine disruptors in products.

Its position is predicated on the following arguments.

As per its Recital n°1, *“this Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union.”*

The adequate labeling and accompanying information of MDs at the time of their placing on the market therefore forms part of the obligations imposed upon by the Regulation and are verified by notified bodies during the certification process prior to placing the MD on the market. This obligation is complemented by strict rules for manufacturers to comply with whether the information in question appears on the MD itself, label / packaging, or in the IFU (See id., Annex I, Section 23).

In this respect, Section 23.1 of Annex I provides that *“Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following: (a)  the medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.”* (Emphasis added)

While the Medical Devices Directive 93/42/EC had already adopted a risk-based approach to the presence of hazardous substances, focusing on reducing the potential health impact of these substances during the design and manufacture of the device and information to the patient trough labeling requirements ; 2017/745 Regulation considerably strengthened requirements for substances in medical devices. With the entry into application of the Medical Device Regulation (EU) 2017/745 on May 26, 2021, the use of CMR 1A/1B and/or endocrine disrupting substance(s) present in medical device that:

are invasive and come into direct contact with the human body,

(re)administer medicines, body liquids or other substances, including gases, to/from the body, or

transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

will have to be justified through a benefit/ risk assessment as defined by the Scientific Committee on Health, Environmental and Emerging Risks in the guideline published by the European commission and possible only when no other alternatives are possible. The justification will be part of the technical documentation of the device which is assessed by an independent notified body in the certification process prior to deliver the CE mark.

When the justification concludes in favor of the inclusion of the substance in the device, strict information requirements will then apply to the device as specified in section 10.4.5 of Annex I of the regulation. “Where devices, parts thereof or materials used therein [contains CMR 1A/1B and/or endocrine disrupting substance(s) ] in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use. “

As far as MDs are concerned, the SNITEM considers that information requirements intended by Article 13-II are already covered by section 10.4.5 of annex I of regulation 2017/745.

In view of the above however, **the information to users provisions of the Regulation are already strictly defined and any additional requirement would be considered as a barrier of free movement as defined in article 24 of regulation 2017/745**:

*“Except where otherwise provided for in this Regulation, Member States shall not refuse, prohibit or restrict the making available on the market or putting into service within their territory of devices which comply with the requirements of this Regulation.”*

**4.3** The Draft Decree as a barrier to trade

Finally, the French obligation of information applicable to MDs, unlike drugs which are specific excluded from this decree, will create a logistical hardship regarding specific French constraints for MD manufacturers and importers at the EU market level.

The SNITEM considers that such an obligation applicable in France only creates a barrier to trade which is not warranted by compelling environmental considerations.

Besides the economic impact for companies already severely hit by the ongoing crisis, such obligation constitutes a barrier to free trade in violation of article 34 of TFUE in addition to the violation of article 24 of regulation 2017/745.

**5.** Conclusion

In view of the above, the SNITEM holds that MDs should be excluded from the scope of the Draft Decree.