EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 303

Communication from the Commission - TRIS/(2022) 00255
Directive (EU) 2015/1535
Notification: 2021/0680/F

Observations from the Commission (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

Observaciones - připomínky - Bemärkninger - Bemerkungen - Märkused - Παρατηρήσεις - Comments - Observations - Osservazioni - Piezīmes - Komentarai - Megjegyzések - Kummenti - Opmerkingen - Uwagi - Observacoes - Komentáre- Pripombe - Huomautuksia - Synpunkter - Коментари - Comentarii.

Sin plazo de statu quo - Doba pozastavení prací se neaplikuje - Ingen status quo frist - Keine Stillhaltefrist - Ooteaeg ei ole kohaldatav - Δεν υπάρχει statu quo - Standstill period does not apply - Pas de délai de statu quo - Termine di status quo non previsto - Bezdarbības periods netiek piemērots - Atidėjimo periodas netaikomas - A halasztási időszak nem alkalmazandó - Il-perijodu ta' waqfien ma japplikax - Geen status quo-periode - Okres odroczenia nie ma zastosowania - Prazo do statu quo não previsto - Perióda pozastavenia neplatí - Obdobje mirovanja ne velja - Ei status quon määräaikaa - Ingen tidfrist för status quo - Не се прилага период на прекъсване - Perioada de stagnare nu se aplică.

(MSG: 202200255.EN)
1. MSG 303 IND 2021 0680 F EN 26-04-2022 26-01-2022 COM 5.2 26-04-2022

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2021/0680/F - S70E

5. article 5, paragraph 2, of Directive (EU) 2015/1535

6. Within the framework of the notification procedure laid down by Directive (EU) 2015/1535 , the French authorities notified to the Commission on 25 October 2021 the draft "Order establishing the list of substances with endocrine disrupting properties referred to in I and II of Article L5232-5 of the Public Health Code and the categories of products presenting a particular risk of exposure referred to in Article L5232-5 of the Public Health Code" ("the notified draft"). According to the notification message, the purpose of the notified draft is to identify the substances with endocrine disrupting properties classified as verified and presumed, suspected, and categories of products presenting a particular risk of exposure to which the obligation to provide information on the presence of endocrine disrupting substances classified as suspected applies.
The notified draft is a follow-up to Article L541-9-1, which was introduced into the Environmental Code by Article 13-II of Law No 2020-105 of 10 February 2020 on combating waste and the circular economy, so-called "AGEC". This article provides that any person placing products on the market for consumers containing substances for which the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) classifies the endocrine disrupting properties as verified or suspected must "provide information to the public by electronic means, in an open, easily reusable and exploitable format by an automated processing system, for each of the products concerned, to identify the presence of such substances in those products". This obligation also applies to certain categories of products with a particular risk of exposure, for substances which endocrine disrupting properties are suspected by ANSES.
Further, Article 2 of Decree No 2021-1110 of 23 August 2021 introduced Articles R5232-19 – R5232-22 in the Public Health Code. Article R5232-19 provides that a joint order of the ministers responsible for health and the environment sets out, on a proposal from ANSES, the list of substances which are classified as stated above and for which AGEC provides the obligations above. The notified draft contains such list and is hence closely linked to the previous drafts notified by France related to AGEC: notifications 2020/832/F, 2020/833/F, and 2021/644/F.

Examination of the notified draft has prompted the Commission to issue the following comments.
1) Chemicals Strategy for Sustainability
Similar comments as sent for notification 2020/833/F may be repeated.
The Commission would like to draw the attention to the actions foreseen by the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment ("CSS" - COM(2020) 667 final of 14 October 2020). In particular, as regards endocrine disruptors, the Commission will "propose to establish legally binding hazard identification of endocrine disruptors, based on the definition of the WHO, building on criteria already developed for pesticides and biocides, and apply it across all legislation". To this end, the Commission will propose to amend the CLP Regulation to introduce hazard identification criteria for endocrine disruptors by the second half of 2022. To this end, several discussions have already taken place with the Member States in a dedicated sub-group of the expert group for REACH and CLP (CARACAL) in which France is very active. In addition, an impact assessment will be carried out and the public consultation to the CLP revision ended on 15 November 2021.
In the light of the observations provided above, with respect to product-specific legislation, the upcoming proposal to establish legally binding hazard identification of endocrine disruptors "across all legislation" will also affect the Cosmetics Regulation .

As regards cosmetic products, on 4 October 2020 the Commission published an Inception Impact Assessment informing citizens and stakeholders that, in the light of the Chemicals Strategy, the Cosmetics Regulation will be subject to a targeted revision and that an impact assessment will be carried out to review some of the provisions of the Cosmetics Regulation. One of the main changes will be the extension of the generic approach to risk management to ensure that cosmetics do not contain chemicals that affect the reproductive or the endocrine system, amongst others, allowing their use only where it is proven to be essential for society. A Commission proposal for the revision of the Cosmetics Regulation is foreseen for the end of 2022.

As regards REACH, the Commission will propose to "introduce endocrine disruptors (…) as categories of substances of very high concern". As a consequence, the identification of such substances as substances of very high concern ("SVHC") and their inclusion in the candidate list will no longer require scientific evidence that their effects are of equivalent level of concern to other SVHCs. This will further facilitate their possible identification and inclusion on the candidate list. The Commission intends to propose to amend Article 57 of the REACH Regulation to add the SVHC category of endocrine disruptors in 2022, as announced in the Annex to the CSS.
Finally, the Commission will propose to "extend the generic approach to risk management to ensure that consumer products do not contain chemicals that (…) affect the reproductive or the endocrine system" and will "in the meantime, while the generic approach to risk management is not in place, prioritise all the above-listed substances for restrictions for all uses". The Commission intends to propose in 2022 to amend Article 68(2) of the REACH Regulation to extend the generic approach to risk management and to come forward with a prioritisation roadmap in 2021, as announced in the Annex to the CSS.
The Commission trusts that all the above-mentioned processes will not be pre-empted or prejudiced by the lists foreseen by the current notified draft.

2) CLP and REACH
Moreover, the Commission would like to restate the arguments expressed in its comments on notification 2020/832/F.
The Commission is of the view that the notified draft, read in conjunction with the draft notified under reference 2020/832/F, may not be aligned with the CLP Regulation. Pursuant to Article 51 of the CLP Regulation, Member States shall not hinder the placing on the market of substances or mixtures on grounds relating to their classification, if those substances or mixtures comply with the CLP Regulation. The CLP Regulation has Article 114 of the Treaty on the Functioning of the EU ("TFEU") as legal basis and is a maximum harmonisation measure. The Regulation sets the floor and the ceiling for "criteria for classification of substances and mixtures" and harmonises the classification "criteria relating to […] health hazards or environmental hazards" according to Article 1(a) and Article 3 respectively. A requirement to publish certain information on certain substances and mixtures placed on the market if they constitute or contain a substance included in a national list of substances with endocrine disrupting properties could hinder the placing on the market of those substances and mixtures on grounds of their health or environmental hazard, which are kinds of hazard for which the classification is included in the scope of harmonisation of the CLP Regulation. Imposing such a

requirement could therefore be in breach of the free movement clause laid down in Article 51 of the CLP Regulation.
With regard to the REACH Regulation, a total of 219 substances and groups of substances have until now been identified as SVHCs in accordance with Articles 57 and 59 of the REACH Regulation and have been included on the candidate list. For them, the provision of information to consumers has been harmonised under REACH by means of Article 33(2). The Commission notes that, with one apparent exception (the substance cholecalciferol), all substances listed in the notified draft have been identified as SVHCs and included on the candidate list.
Article 33(2) of the REACH Regulation requires suppliers of articles to provide sufficient information to consumers upon request, if the substance is contained in the article in a concentration above 0,1%, to allow safe use of the article. The minimum information to be provided is the name of the substance. REACH does not require information to be provided to consumers on substances identified as SVHCs and included on the candidate list when those substances are not contained in articles (i.e. substances on their own or in mixtures), although the candidate list itself is publicly available on the website of the European Chemicals Agency ("ECHA") in accordance with Article 59(10) of the REACH Regulation. The provision of information to consumers via a public database available via the internet, as foreseen for the substances covered by the notified draft (with the exception of cholecalciferol) read in combination with the draft notified under 2020/832/F, hence both duplicates and goes beyond the harmonised REACH information requirements and therefore infringes Article 33(2) of the REACH Regulation read in conjunction with the free movement clause in Article 128 REACH in so far as substances covered by the notified draft are already identified as SVHCs and subject to Article 33(2) REACH information requirements.
As far as Title VIII and Annex XVII of REACH are concerned, existing restrictions harmonise the conditions which a substance has to comply with to be able to be placed on the market, manufactured or used. To the extent the notified draft, read in combination with the draft notified under 2020/832/F, would have as a result that, for several specific substances already subject to restrictions linked to their endocrine disrupting properties listed in the notified draft, an additional condition of information provision to consumers via a public database accessible via the internet would be imposed in connection with a human health or environmental risk arising from the substance, this would be in breach of those restrictions laid down in Annex XVII REACH read in conjunction with the free movement clause in Article 128 of the REACH Regulation.
The Commission draws the attention of the French authorities to the judgment of the EFTA Court in Case E-9/16 (EFTA Surveillance Authority v Norway) of 14 July 2017 in which the Court ruled that, where an EEA State adopts a national measure restricting the free movement of a chemical substance on the basis of a risk to human health or the environment, the restrictions procedure under the REACH Regulation must be triggered, if not already underway, as a consequence of the obligation on the EEA State to initiate the procedure under Article 69(4) of the REACH Regulation. The Court further held that such national measure will be provisional and cannot be maintained in contravention of the final outcome of the REACH restrictions procedure.
Therefore, if the French authorities proceed to adopt the notified draft, to the extent that it applies to substances which have not been identified as SVHCs and included on the candidate list and which are not subject to restrictions linked to their endocrine disrupting properties, the Commission would expect them to prepare an Annex XV dossier in accordance with Article 69(4) of the REACH Regulation to initiate the REACH restriction procedure without delay, to consider the adopted national measures as provisional and to take into account the final outcome of that REACH restrictions procedure in line with the EFTA Court's ruling in case E-9/16. The Annex XV dossier could also cover substances identified as SVHC and included on the candidate list, but the adopted national measure could not apply to those substances, in the light of Article 33(2) of the REACH Regulation as highlighted above, other than by recourse to the safeguard clause of Article 129 of the REACH Regulation.
The Commission reserves the right to revisit the above-mentioned observations and make any appropriate additional observations when any additional notifications related to the content of this notified draft will be made.
3) Food information and composition
The Commission notes that the notified draft is aimed at supplementing the legal framework including Decree No 2021-1110 of 23 August 2021 on the provision of information enabling to identify endocrine disruptors in a product, which was the subject of a previous notification under Directive (EU) 2015/1535 (notification 2020/832/F).
The Commission takes note that Decree No 2021-1110, which introduces Articles R. 5232-19 to R. 5232-22 in the French Public Health Code, refers in its preamble to notification 2020/832/F and to the Commission notes of 25 January 2021 (request for supplementary information answered by France on 4 February 2021) and 22 March 2021.
Citing as its legal basis, inter alia, Article R. 5232-19 of the Public Health Code, introduced into that Code by Decree No

2021-1110, the notified draft sets out the lists of a) substances with verified and presumed endocrine disrupting properties (Article 1 and Table A of Annex I) and b) substances with suspected endocrine disrupting properties (Article 2 and Table B of Annex I). Furthermore, it sets out the categories of products presenting a particular risk of exposure referred to in Article L. 5232-5 II of the Public Health Code, i.e. those for which the obligation to provide information as referred to in paragraph I of that Article also applies to substances of which the ANSES qualifies the endocrine disrupting properties as suspected (Article 3 and Annex II of the notified draft). Whilst a number of substances are listed as having verified or presumed endocrine disrupting properties in Table A of Annex I to the notified draft, no substances are listed as having suspected endocrine disrupting properties in Table B of that Annex, and the list of product categories presenting a particular risk of exposure in Annex II reads: "Not applicable".
The provision of food information to consumers is an area where the harmonised provisions of Regulation (EU) No 1169/2011 on the food information to consumers apply. Since, as it is understood, Decree No 2020/1110 and the notified draft apply to foodstuffs in general, they also extend their effect to areas where the placing on the market or use of certain foods or food improvement agents is harmonised at EU level with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, such as novel foods falling within the scope of Regulation (EU) 2015/2283 on novel foods , food additives falling within the scope of Regulation (EC) No 1333/2008 and flavorings falling within the scope of Regulation (EC) No 1334/2008 .
In its comments issued on 22 March 2021 on notification No 2020/832/F the Commission pointed to Article 38(1) of Regulation (EU) No 1169/2011 and invited the French authorities to notify their draft following the relevant procedure, i.e. in accordance with Article 114(5) of the TFEU. Under that provision, if, after the adoption of a harmonisation measure at EU level, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it is required to notify the Commission of the envisaged provisions as well as the grounds for introducing them.
The Commission takes note of the adoption of Decree No 2021-1110 on 23 August 2021. The Commission is not aware of any prior notification of the provisions of that Decree in accordance with Article 114(5) of the TFEU.
In the absence of a notification, as required by Article 38(1) of Regulation (EU) No 1169/2011, read in conjunction with Article 114(5) of the TFEU, of Decree No 2021-1110 based on which the notified draft would be adopted, the Commission invites the French authorities to take the necessary steps to remedy this situation. The respect of that notification requirement is essential to ensure that the acts having their legal basis in Articles R. 5232-19 to R. 5232-22 of the Public Health Code, such as the notified draft, are lawfully adopted.
The Commission is concerned that the Decree No 2021-1110 and the notified draft may affect EU harmonised rules, by going beyond the applicable provisions of Regulation (EU) No 1169/2011 and can be potentially creating additional burden for food business operators and traders of such products that contain one or more of the substances listed in the notified draft in view of their marketing in France.
In the light of the provisions of the notified draft, establishing a national list of substances with endocrine disrupting properties, and their impact on the EU harmonized provisions, the Commission invites the French authorities to clarify in the notified draft the rationale of their regulatory approach.
4) Food contact materials
As the notified draft is intended to apply to “materials and objects intended to come into contact with food”, the French authorities are invited to ensure that the provisions of the notified draft do not interfere with the full and correct application of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food , in particular the provisions on labelling laid down in Article 15 of that Regulation. In this context, the Commission notes that a number of substances, of which the use in plastic materials and articles intended to come into contact with food is authorised, subject to certain conditions, by Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food , adopted under Regulation (EC) No 1935/2004, appear in the list of substances with verified and presumed endocrine disrupting properties laid down in Table A of Annex I to the notified draft.
5) Plant protection products and biocidal products
The Commission recalls its comments of 22 March 2021 on notification 2020/832/F regarding the draft which was in essence adopted as Decree No 2021-1110. As explained in those comments, insofar as Article R. 5232-19(1) to (3) introduced in the French Public Health Code makes, for the purposes of providing publicly available information on proven, presumed or suspected endocrine disrupting properties, certain plant protection products, biocidal products or their active substances subject to national rules depending on the outcome of the evaluation and identification of such

properties under a national procedure which is applicable to such products or their active substances, this approach interferes with the harmonised procedure applicable to the evaluation of endocrine disrupting properties under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products ("the Biocidal Products Regulation").
The related provisions of the notified draft could similarly hinder the effective functioning of the internal market contrary to the aims of those Regulations. Whilst the Commission notes that the list of substances in Table A of Annex I to the notified draft appears not to lead to discrepancies with those Regulations, given that one of the substances is considered to have endocrine disrupting properties under Regulation (EU) No 528/2012, and the other substances are not biocidal and pesticide specific substances, the French authorities are reminded of their obligation to respect the EU legislative framework on endocrine disrupting properties for pesticides and biocides and to notify any future amendments of the lists set out or referred to in the notified draft to the Commission in accordance with Article 5(1) of Directive (EU) 2015/1535 insofar as they contain technical regulations as defined in Article 1(1)(f) of that Directive.
6) Medical Devices Regulation
For the identification of hazardous substances ("substances which are carcinogenic, mutagenic or toxic to reproduction" ("CMR") and "substances having endocrine-disrupting properties" ("ED")), Regulation (EU) 2017/745 on medical devices ("Medical Device Regulation") relies on the CLP Regulation and on the REACH Regulation or the Biocidal Products Regulation.
Section 10.4 of Annex I of Medical Device Regulation includes a list of requirements applying to certain categories of medical devices which contain, in a concentration above 0.1% weight by weight (w/w), substances that are:
• CMR of category 1A or 1B, in accordance with Part 3 of Annex VI to the CLP Regulation ; or
• that have endocrine disrupting properties and are identified either in accordance with Article 59 of the REACH Regulation or in accordance with those criteria that are relevant to human health of the criteria established in the delegated act adopted by the Commission pursuant article 5(3), first paragraph, of the Biocidal Products Regulation.
Those categories of medical devices shall include a justification for the presence of endocrine disruptors (the admissible justifications being specified in section 10.4.2 of Annex I to the Medical Device Regulation).
In accordance with the Medical Device Regulation such medical devices, their parts or materials containing ED substances in a concentration above 0,1 % weight by weight (w/w), have to 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 (see Section 10.4.5 of Annex I to the Medical Device Regulation). 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.
In addition, this information has to be made publically available through the European database on medical devices (Eudamed) .
Law No 2020-105 established in France the obligation to provide information to the public for any person placing products on the market containing substances having verified or suspected endocrine disrupting properties. Since the notified draft sets up a national list with such substances without making specific reference to the criteria set up in REACH, those national provisions could put an additional obligation on products from other Member States containing one or more of the substances listed in the notified draft, that would therefore need to be labelled, notwithstanding the concentration level in such products. In addition, the information required pursuant to the Public Health Code shall be published on a national public internet website. These latter requirements could therefore create a technical barrier for medical devices containing one or more of the substances listed in the notified draft, when they are placed on the market from other Member States, in particular owing to the fact that the list of verified and suspected endocrine disrupting substances notified by the French authorities does not seem to be identical to the EDs identified as substances of very high concern pursuant to REACH Regulation, to which specifically the Medical Device Regulation makes reference regarding those substances.
Since the notified draft appears to require stricter labelling and information obligations for certain category of medical devices and, this regardless of the concentration of ED that they may contain as referred in section 10.4 of Annex I to the Medical Device Regulation, such national rules could create additional obligations for manufacturers and traders of medical devices importing such devices from other Member States of the Union and potentially limit the free circulation of such devices within the EU market. The Commission therefore asks the French authorities to clarify in the notified draft

the rationale for these requirements.
The Commission invites the French authorities to take the above comments into account.
The Commission furthermore reminds the French authorities that once the definitive text has been adopted, they are required to communicate it to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

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