



EUROPEAN COMMISSION

Brussels 16.6.2023

C(2023) 4019 final

Ms Catherine Colonna
Minister for Europe and Foreign Affairs
Ministry for Europe and Foreign Affairs
of France
37, Quai d'Orsay
F - 75351 Paris
France

Subject: Notifications 2023/116-117/F

Draft Order specifying the details relating to the content and the conditions for presenting the information provided for in I and II of Article L. 5232-5 of the Public Health Code

Draft Order on the provision of information to identify endocrine disruptors in a product by means of an application

Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535

Madam,

Within the framework of the notification procedure laid down by Directive (EU) 2015/1535 ⁽¹⁾, the French authorities notified to the Commission on 17 March 2023 the draft “Order specifying the details relating to the content and the conditions for presenting the information provided for in I and II of Article L. 5232-5 of the Public Health Code”, under the reference 2023/116/F, and the draft “Order on the provision of information to identify endocrine disruptors in a product by means of an application”, under the reference 2023/117/F (hereinafter referred to either collectively as “the notified drafts” or individually as “the draft notified under number [the respective notification number]”).

The draft notified under number 2023/116/F concerns a Joint Order of the Ministers responsible for Health and for the Environment specifying the details concerning the

¹) 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 (OJ L 241, 17.9.2015, p. 1).

content and the conditions for presenting information to identify the presence of endocrine disruptors in a product. For certain substances, due to their nutrient character (vitamins, minerals) and their health benefits up to a certain dose (higher safety limits), such as cholecalciferol (vitamin D3), the information on the presence of substances with endocrine disrupting properties will be adapted to indicate that these substances present health benefits according to the precautions for use and dosage specified on the package leaflet or labelling of the product and that in case of doubt the advice of a health professional should be sought.

According to the notification message, the draft notified under number 2023/117/F concerns an Order establishing a list of applications enabling the provision of information on the presence of endocrine disruptors in products.

The notified drafts are follow-up to Article L. 5232-5, which was introduced into the French Public Health Code by Article 13-II of Law No 2020-105 of 10 February 2020 on combating waste and on 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 proven or presumed 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 of which endocrine disrupting properties are suspected by ANSES.

Further, Article 1 of Decree No 2021-1110 of 23 August 2021 introduced Articles R. 5232-19 to R. 5232-22 in the Public Health Code. Article R. 5232-19 specifies that products within the meaning of L. 5232-5 of the Public Health Code, to which the obligation to provide information to identify endocrine disruptors present in them applies, are foods as defined in Article 2 of Regulation (EC) No 178/2002 ⁽²⁾ and substances, mixtures and articles as defined in Article 3 of Regulation (EC) No 1907/2006 ⁽³⁾, with the exception of medicines. Article R. 5232-20 provides that the information concerned must be made available in a dematerialised format, accessible without cost and reusable so as to permit an aggregation. For this purpose, any person placing on the market the products concerned must make the information available either on a dedicated Internet page or by means of an application designated by a joint Ministerial Order. The draft notified under number 2023/117/F designates such an application. Furthermore, a joint Ministerial Order is to specify the details relating to the content and the conditions for presenting the information concerned. The draft notified under number 2023/116/F provides for such details.

²) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

³) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Consequently, the notified drafts are closely linked to the previous drafts notified by France in relation to the AGECE, in particular Notification No 2020/832/F, by which France notified a draft of the above-mentioned Decree No 2021-1110 of 23 August 2021, and Notification No 2021/680/F, by which France notified a draft Order laying down the list of substances with endocrine disrupting properties and categories of products presenting a particular risk of exposure in accordance with Article R. 5232-19 introduced in the Public Health Code by that Decree. France has not yet communicated to the Commission the definitive text of the Order which was subject to Notification No 2021/680/F and has submitted a revised draft of that Order with the draft notified under number 2023/116/F for information purposes.

The examination of the notified drafts has prompted the Commission to issue the following comments.

Food safety and nutrition and health claims made on foods

The fifth and sixth paragraph of Article 3 of the draft notified under number 2023/116/F provide, as regards, respectively, the substances which appear in Table Aa and Table Ba of Annex I to the Joint Order of the Ministers responsible for Health and for the Environment adopted pursuant to Article R. 5232-19 of the Public Health Code, where the product containing the substance concerned is a food as defined in Article 2 of Regulation (EC) No 178/2002 or a medical device as defined in Article 2 of Regulation (EU) 2017/745 ⁽⁴⁾, that the information provided for in I of Article L. 5232-5 of the Public Health Code shall be expressed in the form of the following statement:

“‘contains the substance [insert the name of the substance [...]]: this substance has health benefits when used according to the precautions and dosage specified on the package leaflet or product labelling. If in doubt, seek the advice of a health professional.’”

The Commission understands from the revised draft of the Joint Ministerial Order to be adopted pursuant to Article R. 5232-19 of the Public Health Code, submitted by France with the notification for information purposes, that the statement concerned would at this stage apply to foods and medical devices containing the substance cholecalciferol.

The Commission recalls that Article 14(1) of Regulation (EC) No 178/2002 prohibits the placing on the market of food if it is unsafe having regard to the factors listed in Article 14(3) of that Regulation. Under Article 14(2)(a) of that Regulation, food is deemed to be unsafe if it is injurious to health having regard to the factors listed in Article 14(4) of that Regulation.

The Commission invites the French authorities to clarify in the notified draft how they ensure food safety in accordance with Article 14 of Regulation (EC) No 178/2002 taking into account the statement set out in the fifth and sixth paragraph of Article 3 of the draft notified under number 2023/116/F.

Moreover, the statement set out in the fifth and sixth paragraph of Article 3 of the draft notified under number 2023/116/F may create confusion as regards its relationship with Regulation (EC) No 1924/2006 on nutrition and health claims made on foods ⁽⁵⁾, as it

⁴) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁵) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

refers to the relationship between a constituent of a food and health. Article 2(2)(5) of Regulation (EC) No 1924/2006 defines “health claim” as meaning “*any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health*”. Under Article 3 of that Regulation, health claims may be used in the labelling, presentation and advertising of foods placed on the market in the Union only if they comply with the provisions of that Regulation. Under Article 10(1) of that Regulation, health claims are prohibited unless they comply with the general requirements in Chapter II and the specific requirements in Chapter IV of that Regulation and are authorised in accordance with that Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof.

Consumers may perceive the statement set out in the notified draft as an authorised claim, although it does not fall in the scope of Regulation (EC) No 1924/2006. The Commission therefore invites the French authorities to amend the wording of the statement set out in the fifth and sixth paragraph of Article 3 of the draft notified under number 2023/116/F, to ensure coherence with Regulation (EC) No 1924/2006.

Food contact materials

Based on the earlier related Notification No 2021/680/F the Commission understands that the notified drafts are intended to apply to “*materials and objects intended to come into contact with food*”. In addition, Article 2 of the draft notified under number 2023/116/F provides that the making available of the information concerned applies to the entire product and its primary packaging or sales packaging. The French authorities are therefore invited to ensure that the provisions of the notified drafts 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⁽⁶⁾, in particular the provisions on labelling laid down in Article 15 of that Regulation.

Plant protection products and biocidal products

The Commission recalls its comments of 22 March 2021 on Notification No 2020/832/F regarding the draft which was in essence adopted as Decree No 2021-1110 and those of 26 January 2022 on Notification No 2021/680/F.

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⁽⁷⁾ and Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products⁽⁸⁾. In particular, by merely referring to the assessment conducted by ANSES as

⁽⁶⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

⁽⁷⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁽⁸⁾ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

regards the endocrine disrupting properties (proven, presumed or suspected) of the substances concerned, Article L. 5232-5 of the Public health Code, which the notified drafts aim to implement, could give rise to legal uncertainty since the assessment of endocrine disrupting properties for substances used in plant protection products and biocidal products is to be carried out, in accordance with the relevant provisions of Regulations (EC) No 1107/2009 and (EU) No 528/2012, by the European Food Safety Authority, the European Chemicals Agency or the Commission. Legal uncertainty is even more likely considering that the scientific criteria for the determination of endocrine-disrupting properties in the context of biocides and of plant protection products are set out, respectively, in Delegated Regulation (EU) 2017/2100 ⁹⁾ and in Annex II to Regulation (EC) No 1107/2009, where there is no classification of endocrine disrupting properties as “proven”, “presumed” or “suspected” as such. The related provisions of the notified drafts could hinder the effective functioning of the internal market contrary to the aims of the Regulations concerned.

The French authorities are also invited to clarify whether and how the notified drafts are intended to apply to treated articles which are defined in Article 3(1)(l) of Regulation (EU) No 528/2012 and are subject to harmonised rules on their placing on the market and labelling as laid down in Article 58 of that Regulation.

The French authorities are therefore invited to ensure that the criteria to be applied for pesticides and biocides under the French law comply with the EU harmonised criteria for those substances without prejudging any further discussions at the EU level.

The French authorities are reminded of their obligation to notify any future amendments of the notified drafts or other related measures 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.

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.

Yours faithfully,

For the Commission

Thierry Breton
Member of the Commission

⁹⁾ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).