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**Subject: Notification 2023/375/SE**

**The Swedish National Food Agency's regulations on snus, snus-like products and chewing tobacco**

**Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535 of 9 September 2015**

Sir,

Within the framework of the notification procedure laid down by Directive (EU) 2015/1535<sup>1</sup>, the Swedish authorities notified to the Commission on 15 June 2023 a draft of '*The Swedish National Food Agency's regulations on snus, snus-like products and chewing tobacco*' (hereinafter, 'the notified draft').

According to the notification message, the notified draft aims to ensure that snus-like products are manufactured in a hygienic manner, that the products do not contain dangerous substances as far as possible, and that operators make themselves known to the control authorities and provide them with basic information about their operations.

Examination of the notified draft has prompted the Commission to deliver the following comments pursuant to Article 5(2) of Directive (EU) 2015/1535.

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<sup>1</sup> 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.

## COMMENTS

### (i) References to the EU legal framework applicable to food

The Commission notes that certain provisions of the notified draft seem to apply to the placing on the market of snus-like products requirements that reflect certain provisions of EU food law.

In particular, in Paragraph 2 “Words and Terms” of the notified draft, a reference is made to Regulation (EC) No 1333/2008<sup>2</sup> on food additives, to Regulation (EC) No 1334/2008<sup>3</sup> on food flavourings and to Regulation (EC) No 1935/2004<sup>4</sup> on materials and articles intended to come into contact with food. In Paragraph 4 “Additives” of the notified draft, a reference is also made to Regulation (EC) No 1333/2008 as well as to Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008<sup>5</sup>.

Furthermore, in the notified draft additional references are made in Paragraph 6 “Novel Food” to Regulation (EU) 2015/2283<sup>6</sup> on novel foods and, in Paragraph 9 “Hygiene” to Regulation (EC) No 853/2004<sup>7</sup> on the hygiene of foodstuffs.

The Commission notes that the notified draft does not provide a definition of snus-like products. In the absence of a definition of snus-like products in this draft, it is not clear whether the references to the above-mentioned EU regulations indicate that the Swedish authorities consider snus-like products as food.

In this regard, the Commission notes that, according to Article 2 of Regulation (EC) No 178/2002<sup>8</sup>, ‘*«food» (or «foodstuff») means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans» (first paragraph) and “shall not include (...) (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (...)”* and reminds the Swedish authorities about the need to ensure compliance of the products regulated under the notified draft with this EU definition.

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<sup>2</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, p. 16.

<sup>3</sup> Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, OJ L 354, 31.12.2008, p. 34.

<sup>4</sup> 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.

<sup>5</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council, OJ L 83, 22.3.2012, p. 1.

<sup>6</sup> Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, p. 1.

<sup>7</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1.

<sup>8</sup> 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.

As per the notification message (and taking into account the accompanied impact assessment) snus-like products (with or without nicotine) appear to not contain tobacco, but are nevertheless considered as substitutes or alternatives to tobacco products.

As indicated in the definition of food mentioned above, the primary purpose of food is to be ‘intended to be, or reasonably expected to be ingested by humans’.

Snus-like products, however, are not intended to be ingested, nor chewed or swallowed. Rather, snus-like products are intended to be, or reasonably expected to be absorbed by humans.

Moreover, snus-like products are presented as an alternative to tobacco products. Therefore, the Commission has consistently considered such products not to qualify as foods, including in its reaction to the notification of the basic act to this notified draft (2010/380/SE); hence, the Commission takes the view that EU food law legislation does not apply to such products (including rules on food hygiene).

Accordingly, the Commission invites the Swedish authorities to ensure that:

- the provisions of the notified draft do not equate snus-like products to ‘food’ as defined in Regulation (EC) No 178/2002;
- snus-like products are not perceived by consumers by foods in any possible way by means of the notified draft; and
- the procedures relating to non-compliance with food legislation will not apply to snus-like products as they do not constitute food products (such as notification obligations under the Rapid Alert System for Food and Feed (RASFF) for non-compliance with food additives legislation).

## **(ii) References to food additives approved under EU law**

Furthermore, the Commission would like to draw the attention of the Swedish authorities to the following points concerning approved food additives under EU food law.

Food additives are approved, in line with Article 6(1)(b) of Regulation (EC) No 1333/2008 provided – amongst other requirements - that “*there is a reasonable technological need [in relation to the food] that cannot be achieved by other economically and technologically practicable means*”.

The notified draft provides, in paragraph 4, that approved ‘food additives’ under EU food law can be used in the manufacturing of snus-like products.

The automatic authorisation of approved ‘food additives’ for use in snus-like products would suggest the extension of the possibility to use food additives with products that do not constitute food. As the use of these food additives has been found to have a technological need only in relation to foods, they have been approved only for use in food, on the basis of Regulation (EC) No 1333/2008.

Given the automatic application of such a provision, the Commission would like to invite the Swedish authorities to clarify how they intend to ensure that ingredients that increase palatability or have colouring properties – which may be approved food additives but

only following an assessment for a technological need in relation to food – are not used in snus-like products, which are substitute products to tobacco products.

In this context, the Commission would like to ask the Swedish authorities to provide in their draft law additional details on the use of food additives in these products, concerning, in particular, the level of exposure for users. Although these products cannot be considered as food, they make use of the same substances used as food additives.

The Commission invites the Swedish authorities to take the above comments into account.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

Yours faithfully,

For the Commission

Kerstin Jorna  
Director-General

Directorate-General for Internal  
Market, Industry, Entrepreneurship  
and SMEs