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EFTA SURVEILLANCE AUTHORITY

EFTA SURVEILLANCE AUTHORITY DECISION

of 19 December 2018

adopting the opinion of the EFTA Surveillance Authority concerning a notification by Norway of a draft regulation on the addition of other substances than vitamins and minerals to foods

THE EFTA SURVEILLANCE AUTHORITY,

Having regard to the Act referred to at point 54zzzu of Chapter XII of Annex II to the EEA Agreement,

> *Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods* ("Regulation No 1925/2006"), and in particular Article 12 thereof,

as adapted to the EEA Agreement by point 4(d) of Protocol 1 to the EEA Agreement and Article 1(2) of Protocol 1 to the Surveillance and Court Agreement.

Whereas:

On 28 June 2018, the EFTA Surveillance Authority ("the Authority") received a notification from Norway (Doc No 1043295), concerning a draft regulation on certain other substances than vitamins and minerals, amending the Norwegian Regulation No 247 of 26 February 2010 on the addition of vitamins, minerals and certain other substances to foods ("the draft regulation").

The notification was made under Directive 98/34/EC *of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations*[1], under Regulation (EU) No 1169/2011 *of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers*[2] and under Regulation No 1925/2006.

[1] Act referred to at point 1 in Chapter XIX of Annex II to the EEA Agreement.
[2] Act referred to at points 54zzzt, 54zzzu and 86 in Chapter XII of Annex II to the EEA Agreement.

It follows from Article 11(2)(b) of Regulation No 1925/2006 as adapted that if EEA EFTA States, in the absence of EEA provisions, consider it necessary to adopt new legislation on the prohibition or restriction on the use of certain other substances in the manufacture of specified foods, they are to notify the Authority in accordance with the procedure in Article 12 of that regulation. Pursuant to Article 12(2) of Regulation No 1925/2006 as adapted, the Authority is to give an opinion on the notified measures.

1. Description of the draft regulation

The draft regulation introduces a revised procedure for the addition of other substances than vitamins and minerals ("other substances") to foods and food supplements, and provides in particular that:

- Substances which are on a list contained in its Annex 3 can be added to foods, subject to the conditions of use specified in that annex, in particular the permitted levels;

- For substances which are in Annex 3 but which do not satisfy the conditions in the Annex, operators are to notify the addition to the Norwegian Food Safety Authority (NFSA). The notified addition can be used six months after the addition has been submitted, or three months after if the notification contains data that has already been approved in another EEA State, and provided that the NFSA has not laid down an individual decision prohibiting or setting other restrictions on the addition;

- For other substances which are not listed in Annex 3, the addition of such other substances to foods is only permitted if the NFSA has authorised it. The NFSA shall take a decision on applications for authorisation within six months, or three months if they contain data that has already been approved in another EEA State.

Annex 4 of the draft regulation specifies the information to be provided in applications for notifications and authorisations.

The draft regulation also foresees that the NFSA is to amend the list in Annex 3 as necessary immediately after having completed notification or authorisation processes.

2. Assessment

Regulation No 1925/2006 defines "other substance" in Article 2(2) as a "*substance other than a vitamin or a mineral that has a nutritional or physiological effect*". It sets out in Article 8 a procedure to be followed by the European Commission if it decides to include a substance in Annex III as a substance prohibited, restricted or under scrutiny (two substances were included in Annex III pursuant to this procedure).

Recital 2 in the preamble to Regulation No 1925/2006 provides that *"[i]n the absence of specific Community rules regarding prohibition or restriction of use of substances or ingredients containing substances other than vitamins or minerals under this Regulation or under other specific Community provisions, relevant national rules may apply without prejudice to the provisions of the Treaty".*

Furthermore, according to Articles 11(2)(b) and 12 of Regulation No 1925/2006 as adapted, if an EEA EFTA State, in the absence of EEA provisions, considers it necessary to adopt new legislation that restricts the use of certain other substances in the manufacture of specified foods, it must notify the Authority and the other EEA States of the envisaged measures and give the reasons justifying them.

In the absence of harmonisation at EEA level, national measures concerning the addition of other substances to foods and food supplements are subject in particular to Articles 11 and 13 of the EEA Agreement.

In this regard, the EFTA Court stated that: "*In the absence of harmonisation of rules, when there is uncertainty as to the current state of scientific research, it is for the Contracting Parties to decide what degree of protection of human health they intend to assure, having regard to the fundamental requirements of EEA law, notably, the free movement of goods within the European Economic Area.*", and it further noted: "*Measures taken by a Contracting Party must be based on scientific evidence; they must be proportionate, non-discriminatory, transparent, and consistent with similar measures already taken*".[3]

In addition, it follows from the case-law of the Court of Justice of the European Union (CJEU) that national legislation which makes the addition of a nutrient to a foodstuff lawfully manufactured and/or marketed in other EEA States subject to prior authorisation is not, in principle, contrary to EEA law, provided that certain conditions are satisfied; in particular:

- such rules must make provision for a procedure enabling economic operators to obtain the authorisation to market foodstuffs with nutrients in amounts exceeding those authorised, and to have the nutrient included on the national list of authorised substances;

- an application to obtain the authorisation to market those foodstuffs may be refused by the competent national authorities only if those foodstuffs pose a genuine risk to public health.[4]

It appears from the notification and related information that the list of Annex 3 of the draft regulation includes substances and permitted levels considered to be safe by the NFSA on the basis of risk assessments carried out by the Norwegian Scientific Committee for Food Safety (VKM) and the Norwegian Institute of Public Health for these substances.

Secondly, the Authority notes that operators may apply for the addition to foods and food supplements of substances listed in Annex 3 at higher levels than those foreseen in that annex, subject to a notification procedure, where operators can market the product at the end of the applicable period, provided NFSA has not adopted an individual decision.

The draft regulation foresees shorter deadlines for the processing of notifications or authorisations of products legally placed on the market in other EEA States.

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[3] Judgment of the EFTA Court of 5 April 2001, Case E- 3/00, *EFTA Surveillance Authority v. Norway*, [2000-2001] EFTA Ct. Rep. 73, paragraphs. 25 and 26.

[4] See for example: Judgment of 5 February 2004, Case C-24/00 *Commission v. France*, ECLI:EU:C:2004:70, paragraphs 25, 26 and 27; Judgment of 27 April 2017, Case C-672/15, *Noria Distribution SARL*, ECLI:EU:C:2017:310, paragraphs. 22- 23.

The draft regulation also establishes an obligation for NFSA to amend the list in Annex 3 as necessary immediately after having completed the processes of notifications and authorisations.

The Authority underlines that, according to the case-law mentioned above, notifications or applications to obtain the authorisation to add other substances may be refused by the competent national authorities only if those substances pose a genuine risk to public health.

Finally, the draft regulation provides in its Annex 4 that, for notifications and applications for authorisations, "*it must be documented that the substances(s) sought for inclusion in Annex 3 is not a novel food(s), i.e. has been on the market prior to 15 May 1997, cf. Regulation No 1215 of 25 July 2017 relating to novel foods*".

The Authority understands from this sentence that the draft regulation does not apply to novel foods, while this is not expressly mentioned in the main text of the draft regulation.

The Authority further notes that this sentence may raise some questions of interpretation in light of the definition of novel food in Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods[5], which (for example) also includes food used exclusively in food supplements within the EU before 15 May 1997 where it is intended to be used in foods other than food supplements.[6]

Moreover, the list in Annex 3 of the draft regulation includes the substance lycopene in the food supplement category. This substance is on the EU list of novel foods authorised to be placed on the market within the EU established by Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017[7] for the food supplements category and with maximum levels which are different from those set in Annex 3 of the draft regulation. While the Authority understands that this does not entail consequences for lycopene as a novel food since novel foods are not subject to the procedures of the draft regulation, this might entail some questions of interpretation.

The Authority therefore invites the Norwegian Government to consider these potential questions of interpretation.

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[5] 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, act referred to at points 86 and 124 in Chapter XII of Annex II to the EEA Agreement.

[6] Regulation (EU) 2015/2283 provides in its Article 3(2)(a) in relevant parts that: "'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:
[…] (ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
- a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or
- they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;
(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC".

[7] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 *establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods*, act referred to at point 124b in Chapter XII of Annex II to the EEA Agreement.

In light of the above, it would appear that the draft Norwegian regulation on the addition of other substances than vitamins and minerals to foods and food supplements would not result in an unjustified restriction in the marketing of the products concerned.

HAS ADOPTED THIS DECISION:

1. In accordance with the procedure laid down in Article 12 of Regulation (EC) No 1925/2006, the EFTA Surveillance Authority delivers a positive opinion on the draft Norwegian regulation on certain other substances than vitamins and minerals.

2. This decision is addressed to Norway.

Done at Brussels, 19 December 2018

For the EFTA Surveillance Authority,

Bente Angell-Hansen President	Frank J. Büchel College Member	Högni Kristjánsson Responsible College Member

For Carsten Zatschler
Countersigning as Director,
Legal and Executive Affairs

This document has been electronically authenticated by Bente Angell-Hansen, Catherine Howdle.