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Standing Committee on Plants, Animals, Food and Feed

Section *General Food Law*

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SUMMARY REPORT

A.01 Exchange of views and consultation of the Committee on two health claims related to " Coffee C21 and protection of DNA from strand breaks " (Question EFSA No Q-2019-00423) and to " Bifidobacterium animalis subsp. lactis Bi-07 contributes to increasing lactose digestion " (Question EFSA No Q-2020-00024) pursuant to Regulation (EC) No 1924/2006 (Art. 13(5) of Regulation (EC) No 1924/2006)

As provided for in Article 18(1) of Regulation (EC) No 1924/2006, Member States were consulted on two health claims provided for in Article 13(5) of that Regulation, for which the European Food Safety Authority (EFSA) published its opinions.

More specifically, the applications subject to this working document relate to the effects of:

Coffee C21 and protection of DNA from strand breaks

Bifidobacterium animalis subsp. lactis Bi-07 contributes to increasing lactose digestion

The Commission presented the working document and the health claims therein. The delegations raised no comments with respect to the above claims. The matter will be referred for further discussion at expert's level.

A.02 Exchange of views and consultation of the Committee on one health claim related to "Anxiofit-1 and reduction of subthreshold and mild anxiety" (Question EFSA No Q-2020-00032) pursuant to Regulation (EC) No 1924/2006 (Art. 14(1) of Regulation (EC) No 1924/2006)

As provided for in Article 17(1) of Regulation (EC) No 1924/2006, Member States were consulted on one health claim provided for in Article 14(1) of that Regulation, for which the European Food Safety Authority (EFSA) published its opinion on 22 October 2020. More specifically, the application subject to this working document related to the effect of: "Anxiofit-1 and reduction of subthreshold and mild anxiety".

The Commission presented the working document and the health claim therein. The delegations did not raise any comments with respect to the claim per se.

Nevertheless, a few delegations noted that more and more claims are submitted on borderline issues (food vs. medicinal). The Commission reminded the delegations of the importance to assess claims on a case-by-case basis, and decide whether their

wording (or claimed effect) is falling within the scope of Regulation (EC) No 1924/2006. The Commission insisted that a preliminary analysis of the claim is necessary in order to determine whether such a claim should be evaluated within the scope of Regulation (EC) No 1924/2006. Such analysis will have to be carried out on a case-by-case basis by the Member States. Finally, the Commission reminded the delegations of the possibility, through different channels, of exchanging with other Member States and the Commission on borderline applications, before they are officially transmitted to EFSA for a scientific assessment.

The comments expressed during that discussion will be taken into account by the Commission. The claim will be referred for further discussion at expert's level.

A.03 Brexit preparedness.

In view of the end of the transition period provided in the EU-UK Withdrawal Agreement on 31 December 2020 and as part of the Commission's actions to ensure readiness for the UK withdrawal from the Internal Market and the EU Customs Union (among others) at the exception of Northern Ireland that will remain aligned to certain provisions of EU law, the Commission invited Member States to pose questions relating to actions needed to implement the Withdrawal Agreement in the field of food information to consumers, nutrition and health claims, food for specific groups, food supplements, food fortification and natural mineral waters.

The Commission received questions from Belgium, Denmark, Italy and Ireland and provided the following replies:

Belgium posed the question below:

The point was already addressed at the last PAFF GFL but Belgium would very much welcome a reminder (or further clarifications) regarding the indication of the name or business name and address the responsible FBO (Article 9.1.h of Regulation 1169/2011) for food imported from the UK or exported to the UK.

The Commission replied as follows:

According to Article 9(1)(h) of Regulation (EU) No 1169/2011, the indication name or business name and address of the Food Business Operator, who is responsible for the food information, is mandatory. According to Article 8 (1) of Regulation 1169/2011 the FBO responsible for the food information is the operator under whose name or business name the food is marketed, or if that operator is not established in the Union, the importer into the Union market. The requirements of Regulation 1169/2011 also apply for products to be lawfully placed in the market in the Northern Ireland[1].

Therefore, as of 1 January 2021 the foods placed in the Union market have to bear the name or business name and address of a food business operator established in the EU or in Northern Ireland.

Concerning UK requirements for food exported to the UK, you can refer to https://www.gov.uk/food-labelling-and-packaging

[1] Article 5(4) of the NI protocol provides that "the provisions of Union law listed in Annex 2 to this Protocol shall also apply, under the conditions set out in that Annex, to and in the United Kingdom in respect of Northern Ireland." Regulation 1169/2011 is listed in Annex 2 to the Protocol, hence its requirements apply for products to be lawfully placed in the market in Northern Ireland.

Belgium also posed the following question:

Furthermore, as the Directive 2009/54/EC also covers spring water, Belgium would like clarification on the impact of Brexit on trade in spring waters between the EU and the UK. It seems to us that the rules on free movement no longer apply. The notice of 24-04-2020 does not say anything about this aspect.

The Commission replied as follows:

The UK is a third country as of 1/1/2021 and free movement of goods rules do not apply to trade of goods between the EU and Great Britain.

Denmark posed the questions below:

We have a question concerning the requirements for notification of food supplements as foreseen in Directive 2000/46 as well as in other legislations e.g. on infant formula and food for special medical purposes.

Denmark requires notification of food supplements from a country within the EU if you want to market a food supplement in Denmark.

We have notifications of food supplements from UK companies. How are we to consider these notifications after 1 January 2021?

Can we demand that a notification be made by a food business operator responsible for the marketing in the EU and not just a consulting company that represents the UK FBO?

Italy posed the questions below:

Regarding food supplements, foods for special groups and food added with vitamins and minerals we would like to receive clarifications and advice on the following points:

a) How will we deal with UK FBOs that notified directly to Italy the food above mentioned?

Do they have to find an EU FBO to notify the products?

Since a notification requires a fee, do they have to pay again, given the fact that formally it is a new notification and a different FBO?

b) How will we deal with the notified products?

Can they stay on the market?

And if yes, until when?

c) How will we deal with any safety issues which may happen for those products notified by UK FBOs? Can they be subject to a RASFF?

Due to the relevance of the questions posed by Denmark and Italy, the Commission addressed them together as follows:

EU law allows Member States to require the notification for monitoring purposes of food supplements, fortified foods placed in their markets, and requires the notification for foods for specific groups (infant formula and follow-on formula; processed cereal-based food and baby food; food for special medical purposes; and total diet replacement

for weight control). **However, EU law does not regulate the particular notification requirements that should apply.**

According to Article 10 of Directive 2002/46/EC on food supplements, Member States may require the **manufacturer, or the person placing a food supplement on the market** in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product, in order to facilitate efficient monitoring of food supplements.

According to Article 15 of Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods "to facilitate efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex III, Parts B and C, Member States may require **the manufacturer or the person placing such foods on the market** in their territory to notify the competent authority of that placing on the market by providing a model of the label used for the product. In such cases, information on the withdrawal of the product from the market may also be required.

Article 11(1)(d) of Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control empowers the Commission to adopt delegated acts setting the notification requirements for the placing on the market of food for specific groups, in order to facilitate the efficient official monitoring of such food, and on the basis of which food business operators shall notify the competent authorities of Member States where that food is being marketed. As the Commission has not exercised this power yet, Member States may set such notification requirements.

As of 1/1/2021 food originating in Great Britain must comply with notification rules applicable to products originating in non-EU Member States. **The notification rules are national provisions and Member States are responsible for their correct application.**

EU law allows Member States to set specific notification requirements, either from the manufacturer, or from the person placing the product on the market. EU law does not regulate whether the notifier is established in the EU, and thus, it is possible that Member States have enacted divergent provisions in that regard.

We would also like to highlight that the notification and the placing on the market are two distinct and separate acts.

In accordance with the EU law principle of legitimate expectations, notifications submitted by Food Business Operators established in Great Britain before 31/12/2020 shall be processed in accordance with the law applicable at the time of their submission. Without prejudice to any specific national provisions, we would like to note that there is no requirement under EU law for the resubmission of notifications submitted before 31/12/2020.

Please note that any foods that were lawfully placed on the market in the Union or the United Kingdom before the end of the transition period may be further made available on the market of the Union or of the United Kingdom and circulate between these two markets until it reaches its end-user.

The UK is disconnected from RASFF as from 01/01/2021. However, Member States can notify any information of which they are aware, including the information they receive from third countries as usual.

Ireland posed the question below:

The UK mandatory fortification requirements for flour were notified to the EU Commission as required under Regulation (EC) 1925/2006 and are accordingly included in the associated Community Register. Can this flour produced in the UK (excluding Northern Ireland) be placed on the EU market after the end of the transition period?

The Commission replied as follows:

No. The UK is a third country as of 1/1/2021 and free movement of goods rules do not apply to trade of goods between the EU and Great Britain.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning a draft order notified by Romania as regards information on the surface treatment of fruit and vegetables with pesticides

On 18 November 2019, the Romanian authorities notified simultaneously both under Directive (EU) 2015/1535 (TRIS Notification 2019/565/RO) and Article 45 of the Regulation (EU) No 1169/2011 (FIC Regulation) a national draft order regarding the requirement for economic operators to inform consumers about the post-harvest surface treatment of fruit and vegetables with pesticides, justified in terms of protection of public health and consumer protection.

On 17 December 2019, the Commission communicated in TRIS that it will assess the notified draft against the FIC Regulation rules. On 6 February 2020, the Commission invited the Romanian authorities to provide clarifications on the notified order. The Romanian authorities replied on 5 March 2020. On 5 June 2020, the Commission notified to Romania a negative opinion concluding that the Romanian Authorities failed to justify under at least one of the grounds of Article 39(1) of the FIC Regulation and in particular in terms of protection of public health and protection of consumers. The draft Commission Implementing Decision is a follow up to the Commission's Negative Opinion as provided in Article 45(4) of the FIC Regulation.

Romania presented the notified draft order and explained that it is justified on grounds of the protection of public health and the protection of consumers. The provisions of the draft order aim to ensure that consumers in Romania are better informed regarding the treatment that fruit and vegetables have undergone and are given information on how to handle those foods in such a way that they do not impact their lives or their health. Therefore, the Romanian authorities consider it necessary that in case the operator apply a post-harvest surface treatment on fruit and vegetables with pesticides in order to preserve their freshness, the consumers should be informed thereof through the labelling or by placing of this information in the vicinity of the products. Romania responding to a question from a delegation further clarified that they have not found during the official controls that the use pesticides and maximum residue levels are not in conformity with the EU law.

The Commission presented the draft Implementing Decision which concludes that based on the harmonized Union requirements on authorisation and use of plant protection products and on their maximum residue levels in fruit and vegetables, which include a thorough scientific assessment of the safety of the plant protection products, and in view of the enforcement and surveillance rules to be respected by the competent authorities of the Member States, there is no justified need for additional national mandatory requirements concerning food information or labelling as regards residues

of pesticides on grounds of the protection of public health and the protection of consumers.

One delegation raised concerns on the wording of recitals 9 and 10 of the draft Implementing Decision and asked whether the notified draft is appropriate to be discussed in the PAFF Committee on Phytopharmaceuticals – Pesticides Residues. The Commission clarified that these two recitals just state the legal framework on the authorisation of plant protection products and on the level of pesticide residues and that it does not consider necessary to have a discussion at the PAFF Committee on Phytopharmaceuticals – Pesticides Residues.

One delegation while supported the draft Implementing Decision, expressed its sympathy to the Romanian order in terms of consumer information policy taking into account that fresh fruits and vegetables are exempted from providing a list of ingredients. The Commission clarified that pesticides residues are not considered as ingredients and the food information rules for prepacked and non-prepacked fresh fruits and vegetables on this matter are the same.

One delegation expressed that view that if there should be any need in the future for the provision of information on the post-harvest treatment of fruit and vegetables with pesticides, such discussion should take place at EU level and not at national level.

Following a question from a delegation, the Commission clarified that REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues has been completed and there has not been any particular issue or request on labelling.

Finally, the Commission informed the delegations of its intention to obtain the vote on this draft Implementing Decision by written procedure.

Vote taken by written procedure: favourable opinion

M.01 Outcome of the written procedure vote of the PAFF meeting of 5 October 2020

One Member State asked to be informed on the outcome of the written procedure vote that was taken for point B1 of the previous PAFF meeting held on 5 October 2020. The Commission clarified that will inform in writing all Member States on the outcome of the vote for this point.