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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 16 OCTOBER 2017

(Section *General Food Law*)

CIRCABC Link: *https://circabc.europa.eu/w/browse/e466b53d-c959-48d6-9f18-ac7ee43ef2ec*

A.01 Exchange of views of the Committee on the application of Directive 2009/54/EC on natural mineral water, as regards the definition of natural mineral water.

An exchange of views took place with the Member States on the definition of natural mineral water, with reference to the concept of "original purity".

According to the definition for a 'natural mineral water' provided by Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (hereafter "the Directive"), a natural mineral water must be protected from all risk of pollution in order to preserve its 'original purity'.

Accordingly, the Directive does not provide maximum levels for contaminants in natural mineral waters. Nowadays, due to technological progress in analysis methods, even trace amounts of contaminants can be detected with modern sensitive laboratory methods.

It is therefore not excluded that, even where all conditions set by the relevant legislation are met with a view to preserving the hydro-geological systems and the springs from where the natural mineral water originate, such trace amounts of contaminants could be detected in those waters.

Therefore, with a view to ensuring common application, enforcement and control of the compliance of a natural mineral water with the definition mentioned above, there is a need to agree on a list of substances, together with the parameters and values that could be considered as compatible with the definition of a natural mineral water as laid down in Annex I of the Directive.

To that end, a document providing such technical indications has been drawn up by mutual agreement between the representatives of the Member States, under the coordination of the Commission services.

Most of the Member States which intervened in the exchange of views expressed support to the document submitted for discussion.

Belgium, however, could not follow the approach of this document as regards the presence of metabolites of pesticides. Belgium took the view that all metabolites, and not only certain metabolites, should be taken into account to assess whether a natural mineral water complies with the requirement of original purity. Furthermore, according to Belgium, the use of the guidance document SANCO/221/2000 is not appropriate in the case of natural mineral water to define and assess the relevance of these pollutants, as it is intended to support the review of active substances of pesticides under Regulation (EU) n° 1107/2009 and it does not take into account the specificities of natural mineral water and the requirements laid down in directive 2009/54/EC. Finally, Belgium asked the Commission to take appropriate regulatory initiative to set harmonized criteria to define the original purity of natural mineral water.

France expressed concerns that no common reference exists for the definition of relevant metabolites.

It was concluded that, in view of the very large support to the document, it may be used as a common tool, as explained above, by the national control authorities, and is enclosed as an annex to these minutes.

A.02 Exchange of views of the Committee on the notification of the Swedish National Food Agency's regulations on the enrichment of certain foodstuffs (2017/0181/S) notified to the Commission according to Article 12 of Regulation (EC) No 1925/2006.

On 9 May 2017, the Swedish authorities notified under the procedure laid down in Article 12 of Regulation (EC) No 1925/2006 (addition of vitamins and minerals and of certain other substances to foods) certain mandatory requirements for the enrichment with vitamin D of drinking milk, vegetable and lactose-free products which are intended for use as alternatives to drinking milk, fermented milk, vegetable products which are intended for use as alternatives to fermented milk, margarine, blended spreads, liquid products and products with different fat contents which otherwise correspond to margarine or blended spreads.

During the discussion, some Member States expressed concerns regarding the free circulation and mutual recognition of the food products covered by the measure and asked clarification. It was explained that the Swedish regulation would require organic products from other Member States, and intended to the Swedish market, to be fortified, as otherwise they would be discriminated on that market. However, the organic products from Sweden intended to be marketed in other Member States would not be covered by the fortification requirement and therefore fortified organic products produced in Sweden may not be placed on the market of other Member States.

The Commission should issue its opinion by 9 November 2017.

A.03 Exchange of views of the Committee on the Belgian notification on the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations (2017/182/B) notified to the Commission according to Article 12 of Regulation (EC) No 1925/2006 and Article 45 of Regulation (EU) No 1169/2011.

On 10 May 2017, the Belgian authorities notified a draft Decree amending an existing Ministerial Decree from 2009 regarding the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations. The notified text requires that food supplements containing caffeine, lutein, lycopene and monacolin k shall not be placed on the market unless the daily recommended quantity in the labelling, presentation or advertising complies with the maximum or minimum levels as laid down in the draft Decree. Furthermore, the label of food supplements containing caffeine or monacolin K should include additional warnings.

During the exchange of views, some Member States requested clarification on the justification of the warnings that would be required by the Belgian national measure on the label of food supplements containing caffeine and monacolin K.

For the warning on food supplements containing caffeine, Belgium explained that, while Regulation (EU) n° 1169/2011 requires that a warning should appear on the label of food with added caffeine, their measure would extent that requirement, in the case of food supplements, in case where caffeine is naturally present in an added ingredient, such as botanical extract.

In the case of monacolin K from red yeast rice, Belgium recalled that an assessment of the safety by EFSA is ongoing, and that the warning envisaged is justified under public health protection, pending the outcome of the safety assessment.

Annex III point 4.2 of Regulation (EU) No 1169/2011 requires foods other than beverages, where caffeine is added with a physiological purpose to bear the statement 'Contains caffeine. Not recommended for children or pregnant women'.

The Commission reminded that this point was discussed in the past in the Working Group on the Regulation (EU) No 1169/2011 on the provision of food information. During that discussion it was generally agreed that this requirement is not limited to cases where the caffeine is added as such but it also applies to any other case where an ingredient containing caffeine is added with a physiological purpose. This would be the case for a food with guarana extract, which contains a high level of caffeine. However, chocolate, which contains low amounts of caffeine, would not be considered a source of caffeine with a physiological purpose when added as an ingredient.

The Commission should issue its opinion under the procedure of Article 45 of Regulation (EU) n°1169/2011 by 20 December 2017 and, under the procedure of Article 12 of Regulation (EC) n°1925/2006, by 20 March 2018.

A.04 Exchange of views of the Committee on the Italian notification on Vegetable substances and preparations allowed for use in food supplements (2017/276/I) notified to the Commission according to Article 12 of Regulation (EC) No 1925/2006 and Article 45 of Regulation (EU) No 1169/2011.

On 28 June 2017, the Italian authorities notified a draft Decree regulating the use of substances and plants preparation in food supplements. Apart from the modification of the lists of plants or plants preparation included in the annex and pursuant to Article 12 of Regulation (EC) n° 1925/2006, some warnings should also be included on the labelling of foodstuffs containing certain varieties of plants.

In presenting its draft measure, Italy explained that its objective is to set a list of vegetable substances and preparations allowed for use in food supplements, that would mirror the corresponding list adopted by Belgium and France, so that a common list (known as "Belfrit list") would apply in those three countries.

During the exchange of views, several Member States took the opportunity of that discussion to reiterate their request for EU harmonisation of the list of botanicals used in food supplements.

The Commission should issue its opinion under the procedure of Article 45 of Regulation (EU) n°1169/20011 by 27 December 2017 and, under the procedure of Article 12 of Regulation (EC) n°1925/2006, by 27 March 2018.

A.05 Exchange of views and consultation of the Committee on three health claims related to "Condensyl® and sperm DNA damage" (Question EFSA No Q-2016-00665), to "Erythritol sugar-free hard confectionery and reduction of dental plaque and dental caries" (Question EFSA No Q-2017-00002) and to "'Lactobacillus fermentum CECT 5716 and Staphylococcus load in milk" 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 three health claims provided for in Article 14(1) of that Regulation, for which the European Food Safety Authority (EFSA) published its opinions in May/July 2017.

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

- Condensyl® and sperm DNA damage
- Erythritol sugar-free hard confectionery and reduction of dental plaque and dental caries
- Lactobacillus fermentum CECT 5716 and reduction of Staphylococcus load in breast milk

The Commission presented the working document and the health claims therein. No comments were raised by the delegations. The matter will be referred for further discussion at experts' level.

A.06 Exchange of views and consultation of the Committee on seven health claims related to "Stablor® and reduction of visceral fat while maintaining lean mass" (Question EFSA No Q-2016-00319), "Curcumin and normal functioning of joints" (Question EFSA No Q-2016-00856), "A fixed carbohydrate:protein ratio ≤ 1.8 and body weight" (Question EFSA No Q-2016-00436), "Vibigaba and blood cholesterol" (Question EFSA No Q-2017-000300), "Vibigaba and blood pressure" (Question EFSA No Q-2017-00031), "Vibigaba and reduction of body weight in the context of an energy-restricted diet" (Question EFSA No Q-2017-00032) and "Vibigaba and long-term blood glucose concentration" (Question EFSA No Q-2017-00033).

Member States were consulted on four health claims submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, for which the European Food Safety Authority (EFSA) published its opinions in February/May/June/July 2017.

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

- Stablor® and reduction of visceral fat while maintaining lean mass
- Curcumin and normal functioning of joints
- A fixed carbohydrate:protein ratio ≤ 1.8 and reduction of body weight
- Vibigaba and maintenance of normal blood cholesterol
- Vibigaba and maintenance of normal blood pressure
- Vibigaba and reduction of body weight in the context of an energy-restricted diet
- Vibigaba and maintenance of long-term blood glucose concentration

The Commission presented the working document and the health claims therein. No comments were raised by the delegations. The matter will be referred for further discussion at experts' level.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

This draft Commission Regulation was submitted to the Standing Committee in accordance with Article 18(5) of Regulation (EC) No 1924/2006. It aims at refusing to authorise the use of one health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, pursuant to Article 13(5) of Regulation (EC) No 1924/2006. More specifically, the application subject to this draft measure relates to the effects of *Lactobacillus plantarum* 299v and an increase of non-haem iron absorption.

The European Food Safety Authority (EFSA) gave an unfavourable opinion to this health claim and accordingly it should not be authorised. The Commission presented the draft and the health claim therein.

There were no comments or observations by the delegations in the substance of the draft measure.

Vote taken: Favourable opinion.

M.01 Request from the Netherlands - Concentrated acetic acid in food stores

The NL raised an AOB point concerning the sales of concentrated acetic acid in food stores. In the Netherlands, it was found that highly concentrated acetic acid is sold in food stores as food. Concentrated acetic acid products are used in Surinam and Eastern-European cuisines. The instructions for use state that 50 ml of the contents diluted with water to 1 liter equals 1 liter of vinegar. The label of this particular product contains several warnings: "dangerous when used undiluted", "causes burns", "do not inhale vapours", "when in contact with eyes rinse with ample water", "keep away from children". Also, the product is fitted with child-proof fastenings and a hazard pictogram and a hazard statement indicating corrosive properties is placed on the label. The Dutch Food and Consumer Product Safety Authority intends to take measures on the basis of Regulation (EC) 178/2002[1] Article 14 because a risk assessment has shown that concentrated acetic acid products with concentrations of 80% are directly toxic when ingested and that it also possesses other hazardous properties when inhaled or when the product comes into contact with the skin. Concentrations as low as 12% may have adverse effects when ingested. Products with concentrations up to 10% are not deemed hazardous when ingested or when it comes into contact the skin.

The NL asked other Member States whether they have information of such products on their market and whether any national rules or regulations apply to these products.

PL, FR and BE consider such products to be a chemical and not food.

In LT and LV, there are national rules on the marketing of acetic acid as food. It can be sold in food stores provided that the concentration is up to 9% and 10% respectively.

SV also allows the marketing of such products as foods under national food law, with concentrations of 24%; such products contain warning labels and instructions of use.

In UK, there are no such products in food stores. However, they had a similar issue with another product (liquid alcohol) used in patisserie. In that case, the UK authorities asked for warning labels.

In Finland, there used to be national legislation governing the marketing of highly concentrated acetic acid as food accompanied with warnings. Following accession to the EU, this national legislation was abolished and such products would now be considered chemicals and not food.

The NL authorities thanked the Member States for their contributions and they will consider further how to deal with such products.

The Commission underlined that Member States are responsible for ensuring the proper implementation of food law in their territories, while the primary responsibility is to ensure compliance with food law requirements remain the responsibility of food business operators. Member States should be careful in the handling of such products in light of the risk assessment findings.

[1] 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

M.02 Request from Belgium - Food supplements intended to infants and young children

Belgium asked for an exchange of views on the classification of food supplements for infants and young children.

Belgium explained that the categorization as baby food or as food supplement has a big impact in the domain of additives, pesticides, or contaminants. Furthermore, as infants and young children are vulnerable groups, a clarification on this aspect is of high importance.

The issue of whether food supplements for infants and young children (e.g. vitamin D drops) can fall under the definition of baby foods, provided in Article 2(2)(f) of Regulation (EU) No 609/2013 was discussed in the last EG meeting of 12 June 2017.

It was highlighted in that meeting that Member States remain responsible for the classification of products in their role of enforcers of EU law. It means that national control authorities are competent to decide, on a case-by-case basis taking into account all the characteristics of the products, whether a given product falls within the definition of food (and not e.g. medicinal products), and if so, to which specific category of food it belongs.

During the discussions, Member States that intervened agreed that this type of products cannot be classified as baby foods. The majority of the Member States which expressed views noted that the products are indeed classified as food supplements for infants and young children, while some others indicated that they classify such products as medicinal.

It was concluded that such products should not be classified as baby food. Furthermore, it is underlined that the food supplement legislation does not provide the possibility of presenting food supplements under specific sub-categories, for example intended for specific groups of consumers, as such practice could be misleading. The recommended use of the food supplement concerned should take place within the instruction for use, in accordance with Article 27 of Regulation (EU) n°1169/2011.

Annex to the minutes of the

PAFF meeting of 16 October 2017

Point A.01: Exchange of views on a

DOCUMENT PROVIDING INDICATIONS FOR COMPETENT AUTHORITIES AND FOOD BUSINESS OPERATORS ON COMPLIANCE OF NATURAL MINERAL WATER WITH THE DEFINITION LAID DOWN BY ANNEX I TO DIRECTIVE 2009/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 18 JUNE 2009 ON THE EXPLOITATION AND MARKETING OF NATURAL MINERAL WATERS[1]

This document was developed in collaboration between the experts of the Member States under the technical coordination of the Commission services. It has not been adopted or endorsed by the European Commission. Any views expressed in this document may not in any circumstances be regarded as stating an official position of the Commission. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex I to Directive 2009/54/EC or any case law developed with regard to these provisions. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

Note: This document is an evolving document and may be updated to take account of the experience of the competent authorities or of information provided.

BACKGROUND AND OBJECTIVES

According to the definition for a 'natural mineral water' provided by Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (hereafter "the Directive"), a natural mineral water must be protected from all risk of pollution in order to preserve its *'original purity'*.

Accordingly, the Directive does not provide maximum levels for contaminants in natural mineral waters. Nowadays, due to technological progress in analysis methods, even trace amounts of contaminants can be detected with modern sensitive laboratory methods.

It is therefore not excluded that, even where all conditions set by the relevant legislation are met with a view to preserving the hydro-geological systems and the springs from where the natural mineral water originate, such trace amounts of contaminants could be detected in those waters.

1 OJ L 164, p. 45.

Therefore, with a view to ensure common application, enforcement and control of the compliance of a natural mineral water with the definition mentioned above, there is a need to set an agreed list of substances to be taken into account, together with the parameters and values that could be considered as compatible with the definition of a natural mineral water as laid down in Annex I of the Directive.

This document has been drawn up by mutual agreement between the representatives of the Member States, under the coordination of the Commission services. The indications given in this document have no legally binding effect. National rules may continue to be applied, in compliance with Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), on the territory of the Member State in which the natural mineral water is exploited.

The aim of this document is to provide indications to Member States' control authorities and to food business operators with regards to the compliance of a 'natural mineral water 'with the definition laid down by Annex I to the Directive, in particular the requirement for 'original purity' of a natural mineral water at source.

The aim is to ensure a clear common approach throughout the EU in the assessment of whether a 'natural mineral water' complies with the definition laid down by the Directive, thereby ensuring that the primary purposes of the Directive i.e. to protect the health of consumers, to prevent consumers from being misled and to ensure fair trading, are met.

This document may be used as a tool by operators exploiting natural mineral water springs and by national control authorities, including where they set multi-annual national control plans in accordance with Regulation (EC) No 882/2004.

It does not apply to spring waters as defined by the Directive.

THE LEGISLATIVE FRAMEWORK RELATED TO THE DEFINITION OF A 'NATURAL MINERAL WATER'

i. Definition

The primary purpose of the Directive is to protect the health of consumers, to prevent consumers from being misled and to ensure fair trading.

Annex I of Directive 2009/54/EC on the exploitation and marketing of natural mineral waters provides a definition for a *'natural mineral water'* as follows:

> *"'Natural mineral water' means microbiologically wholesome water, within the meaning of Article 5, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits.*
>
> *Natural mineral water can be clearly distinguished from ordinary drinking water:*
>
> *(a) by its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects;*
>
> *(b) by its original purity,*
>
> *both characteristics having been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution."*

Unlike for other categories of drinking waters, no parameters or values for anthropogenic substances have been laid down by the Directive for natural mineral waters, as they must have the highest level of quality, as reflected by the concept of 'original purity' included in the definition.

This is because at the time of adoption of the Directive, i.e in 1980, standard laboratory analytical methods could not detect very low levels of anthropogenic substances and this was considered to be satisfactory for measuring the absence of man-made contaminants in natural mineral waters and thus compliance of the natural mineral water with the requirement for 'original purity'.

However, technological progress in analytical methods has made it possible to detect even trace levels of such contaminants, for which there is no associated health risk, but that could, beyond given levels, question the quality of the natural mineral water concerned. This presents certain difficulties for food business operators when ensuring compliance with the purity and quality requirements for natural mineral waters and for control authorities in the Member States when verifying that compliance.

ii. Safety and quality criteria

A 'natural mineral water' must comply with specific safety and quality criteria that are laid down by the Directive and by other relevant pieces of EU legislation.

In particular, it must comply with the microbiological requirements that are defined by Article 4 of the Directive, and with the chemical parameters and values for certain constituents that are naturally present in natural mineral waters as laid down in Commission Directive 2003/40/EC of 16 May 2003[2].

Commission Directive 2003/40/EC was adopted on the basis of Article 12 of the Directive; it provides a list of certain constituents that may be present in the natural state in certain natural mineral waters because of their hydrogeological origin and that may present a risk to public health above a certain concentration. Annex I thereof lays down maximum limits for these natural constituents and Annex III lays down limits for residues resulting from the use of ozone enriched air, that is permitted for the separation of iron, manganese, sulphur and arsenic in natural mineral waters.

A natural mineral water may not be subject to any treatment other than those authorised by the Directive or by Commission Directive 2003/40/EC. Furthermore, any treatment must not modify the natural mineral water's composition with regard to its essential constituents or it microbiological characteristics.

Regarding contaminants, Article 12 of the Directive enables the Commission to adopt methods of analysis, including methods of detection, to verify the absence of pollution of a natural mineral water. However, those tools are not adapted to the continuous progress and increase in sensitivity of laboratory methods.

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[2] Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentrations limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters (OJ L 126, p. 34))

It is therefore necessary to set, on a common understanding and for a limited list of anthropogenic substances in natural mineral waters, guidance values to be used by the Member States' control authorities and by food business operators in their operations.

Those guidance values are set at the lowest possible level, so that the presence of the substances concerned up to those levels would not put into question the quality of the natural mineral water with regard to the requirement laid down by the definition of a 'natural mineral water' that it must be clearly distinguished from ordinary drinking water.

SPECIFIC PARAMETERS

For the purpose of assessing compliance of a natural mineral water with the requirement for 'original purity' as laid down in the definition in Annex I to the Directive, the following specific parameters and their values should be taken into account:

Parameter	Guidance value
Polynuclear aromatic hydrocarbons (PAHs)	0.01ug/L for individual substances[3]
Volatile organic compounds (VOCs)	1.0ug/L for individual substances [4]
Trihalomethanes (THMs)	1ug/L for individual substances
Pesticides	0.1ug/L for the sum of all individual pesticides and their relevant metabolites[5] [6]; 0.03ug/L for aldrin, dieldrin, heptachlor and heptachlor epoxide [7] Member States may set individual limits for those pesticides considered to be relevant in the local, regional or national context.

[3] As fluoranthene and naphthalene may be formed naturally in the environment and may therefore be detected at high levels than the guidance value, hydrogeological assessments are required on a case-by-case basis to clarify that any natural origin does not affect the original purity of the natural mineral water.

[4] Certain VOCs may be found naturally in the environment. Therefore a case-by-case hydrogeological assessment may be required if higher levels of these substances are found in a natural mineral water.

[5] As defined in the Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances regulated under Council Directive 91/414/EEC, http://ec.europa.eu/food/plant/docs/pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr.pdf.

[6] Member State authorities may establish lists of pesticides considered to be relevant at local, regional or national level for the purpose of assessing compliance of the natural mineral water with the parameter of 0.1ug/L for the sum of all individual pesticides.

[7] A case-by-case hydrogeological investigation and analysis of the causes may be required if higher levels of any pesticide and/or its metabolites are detected in a natural mineral water.

Member States agree that:

- the presence of the above substances below the corresponding guidance value does not affect the level of quality of the natural mineral water concerned in a way that would make it incompatible with the definition of natural mineral water by reference to the concept of "original purity";

- in cases where a specific natural mineral water does not comply with the above guidance values, the competent authorities may assess on a case-by-case basis what action to take, taking into account relevant factors such as hydrogeological variations and potential shortcomings in the protection of the spring or the aquifer. The operator exploiting the spring must investigate the cause of the pollution and take appropriate measures to eradicate it;

- as hydrogeological variations may occur at a local or regional level, it is the responsibility of the Member States' competent authorities to assess on a local, regional or national level whether additional criteria are to be included when assessing the compliance of a natural mineral water with the definition laid down by the Directive. This is because certain local factors may influence the presence of other substances and this is best dealt with at a local level.