food supplements europe

Brussels, 10 August 2017

Comments on the draft Belgian Ministerial decree amending the Ministerial Decree of 19 February 2009 regarding the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations
(TRIS notification number 2017/182/B (Belgium)

Dear Madam, Sir,

Food Supplements Europe would like to offer its assistance by providing the comments attached in order to help ensure that the draft Ministerial Decree mentioned above, notified by Belgium does not create barriers to trade.

We remain at your disposal for any clarification or questions you may have.

Yours sincerely,

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Director Scientific and Regulatory Affairs

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(TRIS notification number 2017/182/B (Belgium)

This Ministerial Decree covers restrictions relating to the use of substances, other than vitamins, minerals and plants and plant preparations in food supplements.

By defining conditions of use for these substances, the possibility is created that products lawfully marketed in other Member States are restricted or prohibited from being marketed in Belgium.

Since the use of other substances in food supplements is not subject to specific EU legislation, national legislation is possible, but only when it is necessary and proportionate and does not hinder trade. Regulation 1925/2006 already covers an EU procedure that allows the setting of conditions of use for substances other than vitamins or minerals that are added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of such substances greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

It is our view that, if necessary based on scientific risk assessment, conditions of use for such substances should be set where necessary via this process and not in national legislation, to effectively protect consumers and ensure the proper functioning of the internal market.

We would like to note that no provision is included in this proposed legislation ensuring the respect of the principle of mutual recognition. Drawing from experience, the Belgian authorities are not applying mutual recognition to products lawfully marketed in another Member State if they do not comply with the national food supplements provisions.

Caffeine

The maximum level of caffeine in food supplements is set at 80 mg/day and it must be indicated that the product is unsuitable for children or pregnant or lactating women.

It is to be noted that food supplements are labelled with a clear daily recommended amount and a statement not to exceed this amount. In addition, the EFSA opinion on the safety of caffeine intake indicates that intakes of 400 mg of caffeine per day and 200 mg per consumption are not of safety concern.[i] In this light, the maximum level of caffeine of 80 mg/day cannot be defended.

We note that this maximum level is based on an advice by the Superior Health Council of 11 January 2012. This recommendation is not based on a risk assessment. In addition, this opinion pre-dates the EFSA opinion relating to the safety of caffeine and has not been updated. It is our view that this opinion is not a valid justification for the setting of this low maximum level.

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Neither can the warning for pregnant or lactating women be justified, as it is formulated as a blank prohibition to use such products in this group of consumers. This is in contradiction with the labelling statement already mandatory under the Food Information Regulation 1169/2011 ('Contains caffeine. Not recommended for children or pregnant women' in the same field of vision as the name of the food, followed by a reference in brackets to the caffeine content expressed per portion as recommended for daily consumption on the labelling).

In addition, four health claims relating to caffeine are currently being considered for adoption by the European Commission. The proposed conditions of use for at least two of these claims cannot be met is the maximum level of caffeine per day is set at 80 mg.

Finally, the Royal Decree of 1 March 1998 on additives, other than colourings and sweeteners, allows the addition of caffeine only to flavoured alcohol-free beverages at a maximum level of 320 mg/l. The addition of caffeine to food supplements therefore does not appear to be allowed and the level in the notified Ministerial Decree would only apply to caffeine from natural sources. This should be clarified. We believe there is no justification not to allow the use of caffeine per se in food supplements.

We would therefore ask the Commission to oppose to both the maximum levels set and the contradictory warning statement. If a maximum level is felt appropriate, risk assessment indicates that a level up to 200 mg per consumption and 400 mg per day is safe. This is in line with the EFSA risk assessment and levels recognised as safe in other Member States (e.g. France: 200 mg)[ii] and most jurisdictions outside the EU.

Lutein

For the reasons explained above, we do not believe it is appropriate to set a maximum level for this substance in food supplements at national level. If a maximum level needs to be established it should be based on a scientific risk assessment.

International risk assessments have shown that an Upper Level of Intake (UL) can be derived from available studies, using the Observed Safe Level (OSL) or Highest Observed Intake (HOI) methodology. The OSL risk assessment method indicates that the evidence of safety is strong at intakes up to 20 mg/d for lutein[iii]. The level proposed in the Belgian draft is therefore too low.

In addition, we do not believe it is appropriate to set a minimum level for lutein. This minimum level is not based on objective grounds. It is also higher than what is allowed when lutein is used as additive in food supplements, as is permitted by Regulation 1333/2008. To provide legal certainty, it should at least be mentioned that the law does not apply when lutein is used as additive.

Lycopene

For the reasons explained above, we do not believe it is appropriate to set a maximum level for this substance in food supplements at national level. If a maximum level needs to be established it should be based on a scientific risk assessment.

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This has been the case for synthetic lycopene, approved in the EU as novel food by Decisions 2009/348/EC and 2009/362/EC and for lycopene from Blakeslea trispora by Decision 2009/365/EC. The maximum amount specified for food supplements is up to 15 mg per daily dose as recommended by the manufacturer. Still, setting a maximum level in food supplements for lycopene naturally occurring in tomato should also be based on a risk assessment.

International risk assessments have shown that an Upper Level of Intake (UL) can be derived from available studies, using the Observed Safe Level (OSL) or Highest Observed Intake (HOI) methodology.[iv] The OSL risk assessment method indicates that the evidence of safety is strong at intakes up to 75 mg/d for lycopene[v].

The condition of use for lycopene states that only products complying with Regulation (EC) No 258/97 and (EU) 2015/2283 on novel food ingredients shall be permitted. This implies that lycopene first needs to be approved as novel food before it can be used in food supplements. However, the EU Novel Food Catalogue indicates that lycopene has been used to a significant degree before 1997 in food supplements. Therefore, lycopene would need to be approved as novel food only for use in regular foods or in case of synthetic lycopene and lycopene derived from novel source materials. Since the proposed draft only covers food supplements, this is not a valid condition of use and should be removed. The Novel Foods Regulation applies to all foods that fall within its scope anyway.

We would therefore ask the Commission to request this condition of use is deleted.

In addition, we do not believe it is appropriate to set a minimum level for lycopene. This minimum level is not based on objective grounds. It is also higher than what is allowed when lutein is used as additive in food supplements, as is permitted by Regulation 1333/2008. To provide legal certainty, it should at least be mentioned that the law does not apply when lycopene is used as additive.

Monascus purpureus (red yeast rice) or any other source of monacolin K

The condition of use for this compound states that only products complying with Regulation (EC) No 258/97 and (EU) 2015/2283 on novel food ingredients shall be permitted. This implies that the compound first needs to be approved as novel food before it can be used in food supplements. However, the EU Novel Food Catalogue indicates that *Monascus purpureus* has a history of use before 1997 in food supplements. Therefore, it would need to be approved as novel food only for use in regular foods, Since the proposed draft only covers food supplements, this is not a valid condition of use and should be removed.

The law requires an extensive warning statement to be present on products with no transition period. We note that an assessment of the safety of Red Yeast Rice is currently undertaken by EFSA. It would be good to await the outcome of this assessment and measures at EU level instead of divergent national approaches.

We would therefore ask the Commission to ask the Belgian authorities not to proceed with these conditions of use until action at EU level is taken.

Food Supplements Europe 10 August 2017

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[i] EFSA. Scientific Opinion on the safety of caffeine. EFSA Journal 2015;13(5):4102

[ii] Arrêté du 26 septembre 2016 établissant la liste des substances à but nutritionnel ou physiologique autorisées dans les compléments alimentaires et les conditions de leur employ. JORF n°0234 du 7 octobre 2016

[iii] Shao A, Hathcock JN. Risk assessment for the carotenoids lutein and lycopene. Regulatory Toxicology and Pharmacology 45 (2006) 289–298

[iv] Hathcock JN, Shao A. Expanded Approach to Tolerable Upper Intake Guidelines for Nutrients and Bioactive Substances. J. Nutr. 138: 1992S–1995S, 2008.

[v] Shao A, Hathcock JN. Risk assessment for the carotenoids lutein and lycopene. Regulatory Toxicology and Pharmacology 45 (2006) 289–298

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