Update from the European Commission’s Working Group meeting on health claims, 19th December 2016

There was discussion on a number of health claims including an update on the caffeine claims, on the use of the term “Probiotic” on foods, on claims made on sports food and young child formulae, and an update on the REFIT evaluation of Regulation 1924/2006 on nutrition and health claims made on food. Your views are invited in relation to items 1, 8, and 9 in particular.

1. Follow-up discussion on the health claims related to caffeine following the objection of the European Parliament Article 13(3) of Regulation (EC) No 1924/2006

The Commission explained that the draft Regulation authorising four positive health claims on caffeine (and rejecting a fifth claim) previously received a favourable opinion by qualified majority vote (Standing Committee April 2016) but was subsequently rejected by the European Parliament due to concerns regarding adolescents consuming energy drinks high in sugar and caffeine. The Commission was keen for a solution regarding the fifth claim regarding the effect of caffeine on perceived exertion/effort during exercise which was to be rejected (via the Recitals in the draft Regulation) as it exceeds the limit of 3 mg/kg body weight recommended by the EFSA as a safe caffeine intake. Member States considered options and the Commission is likely to take forward a proposal to reject the high intake claim.

One Member State considered it unfortunate that the very valid concerns regarding the consumption of energy drinks high in sugar by adolescents has been linked to the health claims on caffeine and questioned the evidence base for the European Parliament’s concerns, particularly in light of EFSA’s

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1 The EP objection is on the grounds that the health claims on caffeine are not compatible with the aims of the legislation as:

a) According to the draft measure, the claims on alertness and concentration shall not be used on food targeting children, including adolescents. However, adolescents represent the biggest group of consumers of energy drinks.

b) While the Commission has still not set nutrient profiles, as required under the Health Claims Regulation, the health claims on caffeine could be used on energy drinks, which have a high sugar content.
Opinion on the safety of caffeine (published May 2015). In response, the Commission asked Member States to submit information regarding caffeine claims on energy drinks on their market.

If you are able to provide information regarding caffeine in energy drinks to assist the UK with this submission, please email your information to our mailbox nutritionlegislation@dh.gsi.gov.uk by 31 January 2017.

2. Discussion on a draft Commission Regulation authorising a health claim related to lactitol and maintenance of normal defecation Article 13(5) of Regulation (EC) No 1924/2006

EFSA gave a positive opinion on the health claim submitted by DuPont Nutrition BioSciences ApS via the UK Competent Authority. The scope of the authorisation of the claim on lactitol has now been aligned with the authorisation of lactitol as a novel food, and in both cases authorisation relates to food supplements only.

Member States were in agreement that it is unnecessary to have a warning statement for lactitol as authorisation is restricted to food supplements where additional information on dosage would already be supplied (as there is a requirement under the food supplements Directive for a warning not to exceed the recommended daily dose). In addition, consumers are unlikely to consume lactitol supplements without understanding the potential effects.

There was a query regarding the wording of the conditions of use referring to consumption of the 10g of lactitol in a single portion; EFSA agreed to check. The draft Regulation authorising the health claim will be presented for an opinion at Standing Committee (no vote, consultation procedure).

3. Discussion on a draft Commission Regulation refusing to authorise certain health claims made on foods related to low-fat fermented milk with a combination of fructooligosaccharides and live Lactobacillus rhamnosus GG (ATCC 53103), Streptococcus thermophilus (Z57) and Lactobacillus bulgaricus (LB2), and defence against reactivation of Herpes simplex virus in the orolabial epithelia, to FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of prandial blood glucose responses and V0137 and ‘a reduced loss of cognitive function Article 13(5) of Regulation (EC) No 1924/2006

The three health claims received negative opinions from EFSA as a cause and effect relationship had not been established between the consumption of the food constituent and the effect. No comments were received during the 30 day consultation period and the draft Regulation will be presented for a vote at Standing Committee.

4. Discussion on a draft Commission Regulation authorising a health claim made on foods and referring to the reduction of disease risk, related to Monacolin K and maintenance of normal blood LDL-cholesterol concentrations Article 14(1)(a) of Regulation (EC) No 1924/2006

The health claim relates to a low 2mg concentration of Monacolin K, and the Commission indicated its intention to proceed with authorisation as it would be disproportionate to do otherwise (as a claim
relating to 10mg Monacolin K is on the market). The Commission has issued a mandate for EFSA to make a full safety assessment of Monacolin K.

5. **Follow-up on the positions received from Member States on health claims made on foods and referring to children's development and health** Article 14(1)(b) of Regulation (EC) No 1924/2006

The Commission received written submissions from Member States in the summer regarding their views on health claims targeting children. Although there was strong support for the prohibition of claims targeting children 0-3 years, this was not feasible with the current rules. There was strong support to prohibit claims on mandatory nutrients. The Commission was considering an action plan to deliver this objective which could involve a new recital in the legislation to ban claims in mandatory nutrients in follow-on formulae and an amendment to the DHA claim which was previously voluntary. The Commission was requested to take account of developments in Codex in their action plan.


Given that further consideration is needed on the applications for “cough drop” as a generic descriptor, the Commission proposed that the draft Regulation authorising the use of the term “tonic” as a generic descriptor in relation to tonic water, and “Biscotto salute” in relation to a biscuit will progress to a vote at Standing Committee. Minor amendments regarding “tonic” were noted, including some translation terms.

7. **Exchange of views on Natural Mineral Water (NMW) and the use of nutrition and health claims**

The Commission presented a Working Document on the application of Regulation 1924/2006 on nutrition and health claims to Directive 2009/54/EC on natural mineral water (NMW). The conclusions from a recent ECJ preliminary ruling were that the two legal texts should work in parallel and only where there is a conflict does the Directive prevail (as Regulation 1924/2006 applies without prejudice to Directive 2009/54/EC). The Regulation applies to NMW but the specific indications/claims in the Directive prevail if there is any contradiction, and a case by case assessment will be appropriate to come to a decision.

8. **Exchange of views on sports food and nutrition and health claims related aspects**

The Commission presented a Working Document seeking Member States’ views on labelling aspects of sports foods following the application of the Regulation 609/2013 on foods for specific groups (20th July 2016) rendering sports foods as “normal” foods which have to comply with general food law i.e. rules on general food labelling, food supplements, fortified foods, and health claims made on foods. There was general support for a uniform implementation of the rules regarding the name/designation of sports foods under Regulation 1169/2011 on food information for the consumer (EU FIC, Article 17) although Member States’ indicated a requirement for detailed descriptions, and one Member State indicated an industry Code could be helpful in this respect. A number of Member States called for a definition of sports foods.
There was more concern regarding the use of abstract pictures of cyclists, runners, etc. on sports foods, which a number of Member States considered to be health claims, or alternatively could be construed as *instructions for use* or *marketing appropriate use* indications under EU FIC, but the key issue was to ensure such pictorials are not misleading. There was a short discussion on the industry’s protein labelling initiative (arising from the industry’s concern regarding “protein spiking”) which industry has recently amended to delete the option of naming added amino acids which contribute to the total protein content as it could be construed as a health claim. Member States indicated that use of the voluntary label may go beyond consumer information and could indicate that a particular type of protein was nutritionally superior and this may need some consideration by EFSA. Member States suggested that the industry should consider submitting a “high quality protein for sports people” health claim application.

The Commission requested views on amending the current approach to permitting nutrition claims (which relates to the beneficial effect on the general population) to allow nutrition claims on foods which would be contrary to beneficial nutrition for the general population (e.g. a claim for high in sodium). There was some support in principle for reviewing the approach. Some Member States pointed out that nutrition claims for sodium were not necessary as nutrition labelling is available and businesses can voluntarily indicate the sodium content. It was considered by some Member States that nutrition claims for sodium and carbohydrates in sports foods would be confusing for the general population and send a mixed message regarding public health initiatives to reduce sugar and salt in the diet.

Member States were invited to submit written comments on sports foods. If you are able to provide information to assist the UK with this submission, please email your information to our mailbox nutritionlegislation@dh.gsi.gov.uk. There is no clear timetable for Commission action so no deadline for comments.

9. *Exchange of views on the application of horizontal rules of EU food law to young-child formulae*

The Commission presented a Working Document and referred to an industry paper outlining their views on the regulatory changes necessary in relation to labelling and composition aspects of Young Child Formulae (YCF) following the application of the Regulation 609/2013 on foods for specific groups (20th July 2016) rendering YCF foods as “normal” foods which have to comply with general food law. Ten Member States had always considered YCF as normal foods so there are minimal changes to enforcement. Seventeen Member States considered them to be dietetic foods and one Member State did not have them on their market. The majority of Member States indicated that the key issue was the need for specific Nutrient Reference Values (NRVs) and significant amounts for young children for the addition of vitamins and minerals to foods for young children and for health claims. Member States also raised enforcement concerns with the term “growth” and “growing-up”, and use of the term “milk” when it isn’t.

Written responses on the Working Document and industry paper were requested by mid-January. Member States were asked to consider requirements for NRVs for children e.g. the age range of children and whether NRVs should be set for all vitamins and minerals or only certain ones (e.g. iron, vitamin D and iodine).
If you are able to provide information regarding requirements for NRVs for children to assist the UK with this submission, please email your information to our mailbox nutritionlegislation@dh.gsi.gov.uk by 16 January 2017.

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Question regarding the term “diet” or “dietetic”

With the repeal of Directive 2009/39/EC on foodstuffs intended for particular nutritional uses, a Member State explained that it is unclear how to handle the use of the term “diet” or “dietetic” in the labelling and marketing of foods. There has been a case where a meal replacement product is marketed with the term “Diet” as part of the product name and asked whether this be regarded as an unspecific health claim that should be accompanied by a related authorised health claim. Alternatively it could be considered that the reference to “diet” should be restricted to total diet replacement for weight control in order not to mislead consumers.

There was general agreement that the term “dietetic” should no longer be used to describe foods as the concept has been abolished and foods should now fall under foods for specific groups or under general foods where they are regulated by general food law (which would include health claims and food information for the consumer legislation).

There was general agreement that the term “diet” is an unspecific health claim that would need to be supported with an authorised health claim (e.g. meal replacement claim or reduced energy claim). It did not appear to be necessary to restrict the term “diet” to only total diet replacement for weight control foods.

Question regarding front of pack nutrition systems

A Member State is discussing implementing a front-of-pack (FoP) nutrition scheme and has considered the approaches used in other Member States. A question was asked regarding a colour coding and scoring scheme, based on coloured dots. A red dot indicates that a product should be consumed rarely, while a green dot indicates that the product should be consumed daily or in greater quantity. All colors are presented at the same time, but the dot corresponding to the score is bigger than the others. This system is often presented as falling under Regulation 1169/2011 on food information for the consumer (EU FIC). However, it was queried whether it should be considered as falling under Regulation 1924/2006 on nutrition and health claims made on food. The classification has important consequences, as systems under 1924/2006 may only be developed by Member States and have to be notified, while systems under 1169/2011 do not need to be notified and can also be developed by operators, provided they comply with Article 35 and 36.

The Commission agreed that the colour dot system is not an additional form of information falling under EU FIC. Such a system would be a voluntary national initiative within scope of Directive 2015/1535/EU and would need to be notified under the TRIS procedure (Technical Regulations Information System). It was unclear how it could be notified under Regulation 1924/2006 on health claims as the red scale
would not comply with 'beneficial' nutrition and health claims (unlike the Keyhole system which applies to ‘healthy’ foods).

**Question regarding the use of the nutrition claim “Energy-free” and the term “zero calories”**

A Member State had recently become aware of a number of businesses making use of the conditions of use relating to the “energy-free” nutrition claim, but rather than claiming that their products are “energy-free” they are claiming that their products are “zero calories”. A small number of consumer complaints have been received about the use of the term “zero calories” as they consider that the “zero calories” claim is misleading as the products do not contain zero calories; they actually contain ~3 calories per 100ml. Consumers have been advised that the products in question meet the conditions of use for the EU authorised “energy-free” nutrition claim and that “energy-free” drinks tend to have this very small number of calories because it is virtually impossible for any drink to have no calories, unless it is water. Member States were in agreement that use of the term “zero calories” is equivalent to use of the “energy-free” claim, provided there is compliance with the conditions of use for the claim.

**Question regarding the nutrition claim "NO ADDED SUGARS"**

A Member State referred to the conditions of use of the claim “with no added sugars” and stated that the claim cannot be used for products which contain food used for its sweetening properties. Sweeteners are regarded as food by Regulation 178/2002 and they are used for their sweetening properties. Therefore a strict legal interpretation of the conditions of use prevents products containing sweeteners to use the claim "with no added sugars". However, this interpretation is contested by some businesses and views were requested from Member States and a written position from the Commission on how the conditions of use should be interpreted.

The Commission advised that it was for Member States to interpret the legislation and if a Commission position was requested it would need to seek a legal opinion from DG Health. The Commission understood why some Member States took a strict approach for legal certainty, but appreciated why others took a more pragmatic approach. The Member States who took a pragmatic approach indicated that their interpretation was that it was never the intention of the "with no added sugars" claim to exclude sweeteners. The strict interpretation would result in the removal of a whole category of food and drink from the market and would be an unwelcome set back to industry action on sugar reduction and the obesity crisis in Europe.

The Commission advised that if there was a real problem on the internal market then Member States would need to submit evidence and proposals to address the issue.

**Update on use of the term “probiotic”**

Although the Commission had met with the industry and had sympathy for the impact on marketing for the sector, there were no clear solutions. One approach would be to draft a Delegated Act but it was
likely that the European Parliament would reject such an approach. To resolve the issue would demand significant resources, and it was currently not a priority.

Update on REFIT evaluation of the Regulation
The on-line survey/questionnaire has been sent to the Member State Competent Authorities (19th December) and should be completed within 8 weeks. A separate questionnaire has been sent to industry via trade associations.

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