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Scientific advice on human nutrition

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ABSTRACT

Over its first three mandates the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) has provided scientific advice on a range of issues related to human nutrition. The scientific outputs adopted over this time are summarised within the six main areas within the remit of the Panel: (i) tolerable upper intake levels for nutrients; (ii) safety of novel foods; (iii) food allergens; (iv) dietetic products; (v) population reference intakes for nutrients; and (vi) nutrition and health claims on foods. The scientific advice of the Panel was provided mainly in response to requests from the European Commission and applications for authorisation of novel foods, health claims and for exemption from allergen labelling. The outputs of the Panel have been extensively used by the European Commission and Member States in the implementation of European Union (EU) policy and legislation. In addition, some of the scientific opinions assess key elements of the evidence on nutrition in obesity and other diet related diseases and are an important source of scientific advice for policy makers who wish to address these important issues in public health. Throughout the different areas of its work, the Panel has placed considerable focus on consultation with stakeholders. In the area of health claims in particular, EFSA has had continuing consultation with stakeholders in developing extensive guidance for applicants. This article summarises the nature of the advice provided by the Panel, its regulatory context and how it is applied in the implementation of EU policy and legislation.

KEY WORDS

Nutrition, scientific advice, NDA Panel.

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INTRODUCTION

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was established in mid 2003 by Article 28 (4e) of Regulation (EC) No 178/2002[3] as one of the Scientific Panels of the European Food Safety Authority. Since then, the NDA Panel has been responsible for providing scientific advice on issues related to human nutrition, including (i) tolerable upper intake levels for nutrients; (ii) safety of novel foods; (iii) food allergens; (iv) dietetic products; (v) population reference intakes for nutrients; and (vi) nutrition and health claims on foods.

The work plan of the NDA Panel has been determined mainly by requests for advice from the European Commission and applications for authorisation of novel foods, health claims and for (temporary) exemption from allergen labelling. In addition, a number of guidance documents on substantiation of health claims on foods have been developed in consultation with stakeholders.

Much of the work on developing scientific opinions and guidance documents was carried out in working groups consisting of NDA Panel members, as well as additional independent experts, supported by staff of the EFSA Nutrition Unit.

This article summarises the nature of the advice provided by the Panel, its regulatory context and how it is applied in the implementation of EU policy and legislation. Since its inception, the Panel has issued more than 650 scientific outputs which can be retrieved from the following website: http://www.efsa.europa.eu/en/publications/efsajournal.htm

1. TOLERABLE UPPER INTAKE LEVELS FOR NUTRIENTS

The NDA Panel adopted scientific opinions on Tolerable Upper Intake Levels (UL) for 12 vitamins and minerals in 2004 and 2005. This was a continuation of the work on UL previously carried out up to April 2003 by the Scientific Committee on Food (SCF). These opinions were provided at the request of the European Commission for advice on the safety of vitamins and minerals to support the implementation of harmonised EU legislation for food supplements and fortified foods, and particularly to assist with the setting of maximum limits for micronutrients in these products. All opinions (34 on UL for individual nutrients as well as an opinion on principles for establishing UL) were published in a special compilation in 2006 (SCF and EFSA, 2006).

More recently, a scientific opinion on UL for omega-3 long-chain polyunsaturated fatty acids (Docosahexaenoic acid (DHA), Eicosapentaenoic acid (EPA), Docosapentaenoic acid (DPA)) and revised opinions on UL for calcium and vitamin D were adopted by the Panel in response to a request from the European Commission in the context of establishing conditions of use for authorisation of health claims on these nutrients.

The UL opinions are comprehensive evaluations of possible adverse health effects of individual nutrients at intakes in excess of dietary requirements and, where possible, establish Tolerable Upper Intake Levels (UL) for different population groups. In addition to the immediate regulatory applications, these scientific opinions represent a valuable scientific reference on the safety of nutrients which will be used by scientists and policy makers for many years.

[3] 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. OJ L 31, 1.2.2002, p. 1–24.

2. SAFETY OF NOVEL FOODS

Novel foods and food ingredients are defined as those which have not hitherto been used for human consumption to a significant degree within the European Union (in practice before 15 May 1997). Regulation (EC) No 258/97[4] of January 1997 lays out detailed rules for the authorisation of novel foods and novel food ingredients. The scientific aspects of information necessary to support applications for putting novel foods and novel food ingredients on the European market were addressed by recommendations of the Scientific Committee on Food (SCF) and implemented by the European Commission through Commission Recommendation 97/618/EC[5], and this guidance provides the basis for scientific evaluation of novel foods by the NDA Panel.

Applications for authorisation of novel foods are assessed by Member States in the first instance. Following an initial (favourable) assessment by the competent Authority of the Member State in which the application to market the novel food is first presented, there is the opportunity for other Member States to comment on the evaluation report. If there are comments and objections of a scientific nature raised by other Member States, the European Commission may request the NDA Panel to deliver a scientific opinion on the safety of the novel food.

To date, 37 scientific opinions on novel foods have been adopted by the Panel. These opinions serve as the scientific basis for EU Decisions on authorisation of the novel foods[6] under Regulation (EC) No 258/97.

3. FOOD ALLERGENS

Directive 2000/13/EC[7] on food labelling requires the mandatory labelling of ingredients present in foodstuffs, including all known allergens, in order to provide consumers with better information and to protect the health of those suffering from food allergies or intolerances. In response to a request from the European Commission, the NDA Panel in 2004 provided advice on the scientific basis for the identification of foods, food components and food ingredients which induce food allergies and food intolerance for labelling purposes. This relates to cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and dairy products including lactose, nuts, sesame seeds, celery, mustard, and sulphite at concentration of 10 mg/kg and above.

Given the possibility that certain derivatives of foods, which are known to contain allergens, may not trigger an allergic reaction, this same legislation also provides for possible exemption from their mandatory declaration in the ingredient lists of food labels. In response to a request from the European Commission, the NDA Panel evaluated 29 applications received concerning these derivatives and provided scientific advice regarding the likelihood of their triggering adverse reactions following their consumption by susceptible individuals under the conditions specified by the applicant. In advance of receiving these requests, the NDA Panel carried out a stakeholder consultation with experts from industry.

On the basis of the Panel's advice, the European Commission established a list of derivatives for which labelling exemptions were granted as laid down in Annex IIIa of Directive 2000/13/EC[7].

[4] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1–6.

[5] 97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 253, 16.9.1997, p. 1–36.

[6] http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm

[7] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. OJ L 109, 6.5.2000, p. 29–42.

4. DIETETIC FOODS

In the framework of Directive 2006/141/EC[8], which specifies the composition of infant formulae and follow-on formulae, the NDA Panel provided advice on four nutrients/substances with respect to their safety and suitability of use in such formulae, i.e. fructooligosaccharides, lutein, whey protein partial hydrolysates and goat milk protein. The NDA Panel also provided scientific advice on thresholds of lactose that may be tolerated by people who are lactose intolerant or suffer from galactosaemia. In the light of a revision of Directive 2006/125/EC[9] on cereal-based foods and baby foods, the NDA Panel also provided advice on the request of the European Commission about the suitable age for the introduction of complementary foods into infants' diets in the EU.

5. POPULATION REFERENCE INTAKES FOR NUTRIENTS

The scientific advice on Population Reference Intakes (PRIs) for nutrients is important as the basis of EU action in the field of nutrition. For example, such advice has in the past been used as the basis of nutrition labelling. The SCF report (SCF, 1993) on nutrient and energy intakes dates from 1993 and it was considered that there was a need to review and update these earlier recommendations to ensure that the EU action in the area of nutrition is underpinned by the latest scientific advice.

In this context EFSA was requested to consider the existing population reference intakes for energy, micro- and macronutrients and dietary fibre in the light of new evidence.

Scientific opinions have been adopted, following public consultation, on general principles for setting dietary reference values for nutrients, on dietary reference values for carbohydrates and dietary fibre, protein, water, and fats, and a scientific opinion on energy requirements has been endorsed by the Panel for public consultation.

The PRI opinions comprise detailed reviews of the functions and health effects of individual nutrients in order to establish dietary requirements and to derive dietary reference values, such as population reference intake, adequate intake, recommended intake range, for different population groups. These scientific opinions represent a valuable scientific reference on the health effects of nutrients, including the evidence for the role of nutrition in obesity and diet related disease.

The Panel was also asked to provide guidance on the translation of nutrient-based dietary advice into guidance, intended for the European population as a whole, on the contribution of different foods or categories of foods to an overall diet that would help to maintain good health through optimal nutrition (food-based dietary guidelines). The Panel has adopted an opinion in 2009 on establishing food-based dietary guidelines, following public consultation.

The Panel provided advice in 2009 on the labelling regarding reference intakes for energy and total fat, saturated fat, carbohydrate, sugars and salt to assist the European Commission in developing new legislation on food labelling (Regulation (EU) No 1169/2011[10]).

[8] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. OJ L 401, 30.12.2006, p. 1–33.

[9] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version). OJ L 339, 6.12.2006, p. 16–35.

[10] 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, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18–63.

6. NUTRITION AND HEALTH CLAIMS

Regulation (EC) No 1924/2006[11] on nutrition and health claims made on foods specified a number of significant tasks for EFSA, including providing advice on nutrient profiles and on the scientific substantiation of health claims.

Article 4 of the Regulation foresees that the European Commission shall establish specific nutrient profiles that foods or certain categories of foods must respect in order to bear nutrition and health claims. At the request of the European Commission, and following consultation with stakeholders through a scientific colloquium in 2007, the NDA Panel adopted an opinion on nutrient profiles in 2008. The Panel's advice addressed the criteria that could be used for setting nutrient profiles, as well as the choice of nutrients and the advantages and disadvantages of different types of schemes. This advice served as a basis for the development of a nutrient profile scheme by the European Commission which is the subject of ongoing discussions with stakeholders.

The NDA Panel has carried out assessments of the scientific substantiation of health claims under the Regulation (EC) No 1924/2006 since 2007. Of all the areas within the remit of the Panel, the assessment of the scientific substantiation of health claims has proven to be the most challenging in terms of workload and complexity. To date, the Panel has adopted scientific opinions on applications under the individual authorisation procedure for:

- 62 health claims submitted under Article 13.5 (health claims based on newly developed scientific evidence and/or which include a request for the protection of proprietary data) and
- 93 health claims submitted under Article 14 (60 on claims for development and health of children and 33 on reduction of disease risk claims).

The Panel's advice is used as the basis for authorisation decisions by the European Commission and the Member States (with scrutiny by the European Parliament), the outcomes of which are published in the EU Register of Nutrition and Health Claims made on foods[12]. To date (July, 2012), 19 claims submitted under the individual authorisation procedure have been authorised, 77 non-authorised and the remainder are pending a decision on authorisation.

The Regulation also provided for so called 'general function claims', defined under Article 13.1 of the Regulation, to be assessed and authorised by a different procedure than that for other claims. Out of the 4 637 claims submitted to EFSA by the European Commission between July 2008 and March 2010, the NDA Panel completed evaluations of 2 758 claims by June 2011 (331 claims were withdrawn and 1 548 claims on 'botanicals' have been placed on hold by the European Commission pending further consideration on how to proceed with these). As a result of these evaluations a total of 341 opinions were adopted by the NDA Panel between June 2009 and June 2011 and published in six series. These opinions have provided the basis for the European Commission to establish a first list of 222 permitted health claims under the Art. 13(1) procedure in 2012[12].

In 2012, the Panel also completed further assessments for a number of 'general function claims'. These included 74 claims relating to microorganisms which were considered by the Panel to be insufficiently characterised and 17 claims for which the evidence provided during the initial submission was not sufficient for substantiation. These assessments were based on additional data submitted by Member States and will be used by the European Commission and the Member States for amendment of the list of permitted health claims. Two of the claims were considered to be substantiated, i.e. prunes and normal bowel function and alpha-cyclodextrin and a lower rise in blood glucose after meals.

[11] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.
[12] Available from http://ec.europa.eu/nuhclaims/index.cfm?event=register.home

Because of the scientific and technical complexity of health claims, EFSA has placed considerable focus on consultation with stakeholders and in developing extensive guidance for applicants[13]. In addition to detailed guidance for preparation and presentation of applications (adopted in 2007), guidance on the general principles employed by the Panel for scientific substantiation of health claims were developed in 2009 and updated twice since then, with the most recent revision published in 2011. This guidance document covers issues such as the totality of available scientific evidence, selection of pertinent studies for substantiation of health claims, wording of claims, the extent to which a food needs to be characterised for the claimed effect, claimed effects which are considered beneficial physiological effects, definition of a risk factor for the development of a human disease, compliance/eligibility issues for health claims, and procedural aspects.

Following public consultation, the NDA Panel has also finalised six guidance documents on scientific requirements for substantiation of health claims related to:

- gut and immune function
- antioxidants, oxidative damage and cardiovascular health
- appetite ratings, weight management and blood glucose concentrations
- bone, joints, skin and oral health
- nervous system, including psychological functions
- physical performance.

These guidance documents define a range of claimed effects that are considered beneficial physiological effects under the Regulation and address the types of human studies, outcome measures and study groups considered appropriate for scientific substantiation of different claims.

7. FUTURE CHALLENGES FOR THE NDA PANEL

Since its establishment in 2003, the mandate of the NDA Panel has evolved to take account of new EU legislation, including labelling of foods with respect to allergens, nutrition labelling, and nutrition and health claims. Over that time, the work of the Panel has developed with a greater emphasis on applications, for example, on health claims and novel foods and exemptions for allergen labelling. In addition to on-going requests from the European Commission for scientific advice across the different areas of the Panel's remit, it is expected that the workload on assessment of health claims applications under the individual authorisation procedure will continue to remain at a significant level with assessments of increasing complexity. Assessment of those 'general function claims' on 'botanicals' that have been placed on hold by the European Commission would also be a significant challenge for the Panel if the European Commission requests these assessments. For novel foods, the proposal for the revision of the Regulation (which was not adopted in 2011) is the subject of on-going consideration. Under this proposal, EFSA would carry out the assessment of all applications for authorisation of novel foods which will require close collaboration with Member States in this work.

The challenge for the Panel will be to continue to provide independent scientific advice of high quality in a timely manner. This will also require a continued strong focus on consultation and dialogue with stakeholders, including applicants for authorisations.

CONCLUSIONS

Over its first three mandates, through 46 plenary and over 250 working group meetings, the NDA Panel has provided over 650 scientific outputs within the six main areas in the remit of the Panel: (i) tolerable upper intake levels for nutrients; (ii) safety of novel foods; (iii) food allergens; (iv) dietetic products; (v) population reference intakes for nutrients; and (vi) nutrition and health claims on foods.

[13] Available from http://www.efsa.europa.eu/en/nda/ndaguidelines.htm

Of these areas, the assessment of the scientific substantiation of health claims has proven to be the most challenging for the Panel in terms of workload and complexity.

The scientific advice of the Panel was provided mainly in response to requests from the European Commission and applications for authorisation of novel foods, health claims, or for temporary exemption from allergen labelling.

The outputs of the Panel have been extensively used by the European Commission and Member States in the implementation of EU policy and legislation. In addition, some of the scientific opinions (e.g. on population reference intakes and health claims) assess key elements of the evidence on nutrition in obesity and other diet related diseases and are an important source of scientific advice for policy makers who wish to address these important issues in public health.

Throughout the different areas of its work, the Panel has placed considerable focus on consultation with stakeholders. In the area of health claims in particular, EFSA has had continuing consultation with stakeholders in developing extensive guidance for applicants.

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