

Parma, 6 August 2012
Ref.: NDA/WG Dietetic
Products/jk

NOTE TO THE DIRECTOR OF SCIENTIFIC EVALUATION OF REGULATED PRODUCTS

Type of the Mandate: Internal Mandate proposed by EFSA to the Nutrition Unit for the operation of a Standing Working Group¹ on Dietetic Products

Title of the Mandate: Standing Working Group on Dietetic Products

In accordance with Title II of the Executive Director Decision concerning the selection of members of the Scientific Committee, Scientific Panel and external experts to assist EFSA with its scientific work², the external scientific experts providing the required expertise could be invited on:

- *an ad hoc basis for a single meeting or for the duration of the work on a specific mandate or project, or*
- *on a longer term when the required expertise is needed for more than one mandate or project.*

When a working group of experts is required for more than one mandate, it is called a Standing Working Group.

The Nutrition Unit is requested to manage the administrative and support the scientific activities of the Standing Working Group on Dietetic Products (formerly called WG on Infant Formulae). The Nutrition Unit will organise the meetings of the Standing Working Group and assist in the production of the scientific outcomes in agreement with the respective mandates addressed by the Standing Working Group.

¹ A Standing Working Group is a Working Group of experts created on the basis of a decision of the corresponding Scientific Panel, designed to coordinate discussions and provide scientific contributions on specific related mandate(s), for a set period of time within the three years mandate of the Panel.

² <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

MANDATE OF THE STANDING WORKING GROUP ON DIETETIC PRODUCTS

Background:

The European Food Safety Authority (EFSA) is the keystone of European Union risk assessment regarding food and feed safety, animal health and welfare, nutrition, plant protection and plant health. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent and transparent scientific advice and clear communication on existing and emerging risks associated with the food chain. On request from the European Commission, European Parliament or Member States or on its own initiative³, EFSA provides scientific opinions on issues falling under its remit.

The Panel on Dietetic Products, Nutrition and Allergies (NDA Panel), which deals with questions related to dietetic products, nutrition and food allergies as well as associated subjects such as novel foods, confirmed during its 48th Panel Plenary Meeting the continued need of the ongoing Standing Working Group on Dietetic Products (formerly called WG on Infant Formulae) in order to assist the Panel in issuing opinions falling in particular under the framework of Directives 2009/39/EC, 2006/141/EC, 2006/125/EC, 1999/21/EC, and 1999/21/EC or any subsequent or implementing legislative measures thereof.

Terms of reference:

The objective of the Standing Working Group on Dietetic Products is to perform the following preparatory work for consideration by the Scientific Panel in relation to requests falling in particular under the framework of Directives 2009/39/EC, 2006/141/EC, 2006/125/EC, 1999/21/EC, and 1999/21/EC or any subsequent or implementing measures thereof:

- Preparation of draft opinions related to foodstuffs intended for particular nutritional uses under the framework of Directive 2009/39/EC or any subsequent or implementing legislative measures, including assessment of safety and suitability of substances added to infant formulae and follow-on formulae (Directive 2006/141/EC), of processed cereal-based foods and of baby foods (weaning foods) (Directive 2006/125/EC), of foods for energy-restricted diets for weight reduction (Directive 96/8/EC), and of foods for special medical purposes (Directive 1999/21/EC).
- Assistance in relation to any other request related to infant nutrition or foods intended for population groups with particular nutritional needs.
- As appropriate, assistance to develop draft guidance documents. All guidance documents drafted by the WG shall undergo a public consultation after endorsement by the NDA Panel.

In order to fulfil its objectives, the above mentioned Standing Working Group should consist of members with long-standing experience in safety (risk) assessment and/or suitability assessment in particular of foods intended for infant nutrition and expertise in the following scientific areas: infant nutrition/paediatrics, human nutrition, nutrient requirements, human medicines, food allergy/intolerance, metabolic diseases, and clinical immunology.

Scope in EFSA's work and outsourcing programme: The Standing Working Group will assess the available relevant scientific information and data provided to EFSA by Member States and stakeholders,

³ Regulation (EC) N°178/2002 of the European Parliament and 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.

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as well as those submitted through the applicants' dossiers or through public calls for data. As appropriate, EFSA will outsource collation or analysis of scientific information in order to support the scientific work of the Standing Working Group.

IT impact: No

Timeline: At the onset of a new Panel mandate (during an inaugural meeting) there is a need to confirm the continued need for all ongoing Working Groups. There is also a need for the Panel Chair to appoint a chair and vice-Chairs of all Working Groups. It is the task of a newly appointed or re-confirmed Chair of a Standing Working Group in collaboration with the respective Head of Unit to select members of the Working Group following the procedure as laid down in the Executive Director Decision 2011⁴.

Scheduled Standing WG meetings in the 3 months period following the inaugural meeting will be conducted by experts selected during the previous Panel mandate.

Expected deliverables (e.g. scientific output, scientific article):

Scientific contribution(s), which will be submitted for consideration to and possible adoption by the NDA Panel.

Declarations of interests for external experts (only if applicable):

The Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests⁵ will be followed while setting up and operating this Standing Working Group.

Production of scientific outputs			Consultation Mechanisms			Resource and Timing Impact			
Panel	Standing Working Group	EFSA Staff/annum	Network meetings	Workshops Seminar	Public Consultation	Financial Resources/annum	Duration of execution	IT Costs	Total cost
NDA	Dietetic Products	1 (FTE)	No	No	Yes ⁶	14.000 € /annum	36 months	No	42.000 €

SIGNED

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⁴ <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

⁶ Depending on needs