

EXECUTIVE DIRECTOR

Parma, 22 NOV 2012
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NOTE TO THE DIRECTOR OF THE SCIENCE STRATEGY AND COORDINATION

Type of the Mandate: Internal Mandate proposed by EFSA to the SCOM Unit for the operation of a Standing¹ Working Group on Guidance Review

Title of the Mandate: Standing Working Group on Guidance Review

The SCOM Unit is requested to manage the administrative and support the scientific activities of the Standing Working Group on Guidance Review. The SCOM Unit will organise the meetings of the Standing Working Group and assist in the production of the scientific outcome in agreement with the respective mandate of the internal Regulatory and Guidance Review Task Force and the mandate described in this document for the Standing Working Group on Guidance Review.

¹ A Standing Working Group is a Working Group of experts created on the basis of a decision of the corresponding Scientific Panel/Committee, 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/Scientific Committee.

MANDATE OF THE STANDING WORKING GROUP ON GUIDANCE REVIEW

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 initiative², EFSA provides scientific opinions on issues falling under its remit.

The Scientific Committee focuses on developing harmonised risk assessment methodologies in fields where EU-wide approaches are not already defined and deals with matters of a horizontal nature. It confirmed during its 56th Plenary Meeting, which took place on 23-24 July 2012, the need for a Standing Working Group on Guidance Review.

In the EFSA Science Strategy 2012-2016³, the Authority has made the commitment to focus on four key strategic objectives:

- i) Further develop excellence of EFSA's scientific activities;
- ii) Optimise the use of risk assessment capacity in the EU;
- iii) Develop and harmonise methodologies and approaches to assess risk associated with the food chain;
- iv) Strengthen the scientific basis for risk assessment and risk monitoring.

The SCISTRAT Directorate, in close cooperation with the RASA and REPRO Directorates, and through the SCOM and EMRISK Units, is developing a guidance review framework for the implementation of activities in relation to the development and harmonisation of risk assessment approaches (objective (iii) of the above-mentioned strategy). The framework shall include three pillars:

- i) Establishing an inventory of regulatory data requirements and guidance documents for risk assessment, which would allow the identification of commonalities and differences in the legislative and data requirements and guidance documents for risk assessment, among the different areas within EFSA's mandate: covering food and feed safety, nutrition, animal health and welfare, plant protection and plant health, and environmental protection.
- ii) Developing and executing a work plan aimed at updating/revision of existing guidance documents and the development of new guidance documents, based on an analysis of the inventory of legislative and data requirements, as well as on trends and developments in risk assessment and the relevant scientific areas for EFSA. This will result in:
 - a. Better harmonisation of the risk assessment methods used within EFSA as well as between EFSA and other scientific advisory bodies carrying out risk assessment at European and/or International level;
 - b. The implementation of new concepts and approaches in EFSA's risk assessment practices.
- iii) The development and implementation of training programmes for experts and staff contributing to the scientific work of EFSA, with a view to ensure the implementation and use of EFSA's guidance documents.

² Regulation (EC) No 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.

³ <http://www.efsa.europa.eu/en/corporate/pub/sciencestrategy12.htm>

As a first step in the development of the guidance review framework, an internal Regulatory and Guidance Review Task Force has been established to make an inventory of the regulatory data requirements and guidance documents for risk assessment (in the form of an EFSA Technical Report), which shall include the identification and analysis of the legislative requirements and guidance documents for risk assessment between the different areas within EFSA's remit. All relevant EFSA Units will be engaged in the development of the inventory of regulatory data requirements and guidance documents to cover the following working areas: chemical and microbiological hazard characterisation, residues and exposure, environmental risk assessment, efficacy / health benefits and import risk assessment.

The EFSA Technical Report on mapping the regulatory data requirements and guidance documents for risk assessment is expected for January 2013.

As a second step, the Standing Working Group on Guidance Review will use the EFSA Technical Report as a starting point to prepare a draft scientific opinion on taking stock of the guidance documents produced by the Scientific Committee and Scientific Panels over the last 10 years since EFSA's inception. The draft scientific opinion should include recommendations for prioritisation of guidance development activities in the period between 2013 and 2015, which would comprise recommendations for the revision of existing guidance and the development of new guidance documents, when needed.

In addition the Standing Working Group on Guidance Review will contribute to the development of training programmes for experts and EFSA scientific staff as, the Authority aims to introduce regular training for new scientific staff and advanced scientific training for experts and more experienced staff contributing to the scientific output of EFSA as of 2013, in line with the EFSA Science Strategy 2012-2016.

This preparatory work will produce a draft scientific opinion that will be presented for possible adoption at the Scientific Committee plenary in July 2013.

Terms of reference:

The objectives of the Standing Working Group on Guidance Review are to perform the following tasks:

- to provide recommendations and set priorities for the review of existing guidance documents, or for the preparation of new EFSA guidance documents. This task will be conducted also considering advices from the LRA Unit when needed or considered appropriate;
- to serve as an expert judgment platform by assisting EFSA in identifying commonalities and differences between guidance documents of different Panels/Risk Assessment bodies;
- to assist the implementation and use of EFSA guidance documents across EFSA;
- to assist in the development and implementation of advanced scientific training programmes for experts of the Scientific Committee, Scientific Panels and EFSA's scientific Units.

In order to fulfil its objectives, the above mentioned Standing Working Group should consist of members with expertise in the various scientific areas covered by EFSA. As such, all EFSA Panels should be represented in the Standing Working Group.

Scope in EFSA's work:

The Standing Working Group will serve as an expert judgment platform for identifying needs for the work plan related to the development and implementation of EFSA's guidance documents. It relates to key strategic objective iii) of EFSA's Science Strategy 2012-2016.

IT impact:

No IT impact foreseen.

Timeline:

The Standing Working Group on Guidance Review will start its activities in December 2012 and end its activities by the end of the term of the Scientific Committee in 2015.

Expected deliverables:

The Standing Working Group on Guidance Review will prepare various documents, including the following:

- a draft scientific opinion to be presented for possible adoption by the Scientific Committee in July 2013 with comments/advice and recommendations;
- a draft scientific opinion in 2014 and 2015, respectively, each of which will provide an evaluation of the implementation of guidance document across EFSA and recommendations for EFSA’s work plan (2015 and 2016, respectively) related to EFSA’s guidance documents.

Declarations of interests for external experts:

The Decision of the Executive Director implementing EFSA’s Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests⁴ 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
No	Guidance Review	0.3	Yes	No	No ⁵	60.000 €/annum	36 months	No	180,000 €

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

⁵ Depending on needs