

Parma, 25<sup>th</sup> September 2014

**MANDATE OF THE STANDING WORKING GROUP ON GENOTOXICITY OF THE PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS**

**Title of the charter “safety evaluation of Flavourings - evaluation of existing substances” (FIP-04\_A):  
Operational activities of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing  
Aids Standing Working Group on Genotoxicity<sup>1</sup> (September 2014-June 2017).**

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 work<sup>2</sup>, 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 FIP Unit is requested to manage and support the administrative and scientific activities of the Standing Working Group on Genotoxicity. The FIP Unit will organise the meetings of the Standing Working Group and assist in the preparation of scientific outputs in agreement with the respective mandates addressed by the Standing Working Group. The Head of Unit will ensure coordination with work programs of other units so that when Working Groups of other Panels/Scientific Committee assess overlapping substances or organisms the Standing Working Group is provided with applicable information and data from other Panels/Scientific Committee.

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<sup>1</sup> 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.

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

## MANDATE OF THE STANDING WORKING GROUP ON GENOTOXICITY OF THE PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS

### 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 initiative<sup>3</sup>, EFSA provides scientific opinions on issues falling under its remit.

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), which deals with questions on the safety of use of materials in contact with food, enzymes, flavourings and processing aids, confirmed during its 48<sup>th</sup> Panel Plenary Meeting (inaugural meeting of the CEF Panel mandate 2014-2017) the need of a Standing Working Group on Genotoxicity related to the evaluations of applications on flavourings and source materials for use in food subject to an evaluation mentioned in article 9 of Regulation (EC) No 1334/2008<sup>4</sup> following the Common Authorisation Procedure laid down by Regulation (EC) No 1331/2008<sup>5</sup>. These applications also include the evaluation of the existing flavouring substances from the evaluation programme laid down in Regulation (EC) No 1565/2000<sup>6</sup> and the applications on smoke flavourings under Regulation (EC) No 2065/2003<sup>7</sup>. In addition this may include also evaluations concerning certain substances naturally present in foods mentioned in Article 6 or other issues such as interpretation decisions by the Commission which may require consultation of EFSA as foreseen in Regulation 1334/2008.

### Terms of reference:

The objective of the Standing Working Group on Genotoxicity is to perform the following preparatory work for consideration by the CEF Panel:

1. To carry out safety assessments of genotoxicity of flavouring substances used in or on food as required under the applicable European Regulations (see above).

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<sup>3</sup> 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.

<sup>4</sup> Regulation (EC) N°1334/2008 of the European Parliament and the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) N°1601/91, Regulation (EC) N°2232/96 and (EC) N°110/2008 and Directive 2000/13/EC. OJ, L 354, 31.12.2008, p. 34-50.

<sup>5</sup> Regulation (EC) N°1331/2008 of the European Parliament and the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ, L 354, 31.12.2008, p. 1-6.

<sup>6</sup> Regulation (EC) N°1565/2002 of the European Parliament and the Council of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) N° 2232/96 of the European Parliament and the Council. OJ, L 180, 10.7.2000, p. 8-16.

<sup>7</sup> Regulation (EC) N°2065/2003 of the European Parliament and the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods. OJ, L 309, 26.11.2003, p. 1-8.

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**DEPARTMENT OF SCIENTIFIC EVALUATION OF REGULATED PRODUCTS – FOOD INGREDIENTS AND PACKAGING UNIT**

2. To deliver draft scientific opinions on the flavouring substances examined.
3. To contribute to possible revision of draft guidance document(s) for presentation of an application for safety assessment of flavourings substances.
4. To advise on genotoxicity matters within the remit of the CEF Panel.

In order to fulfil its objectives, the above mentioned Standing Working Group should consist of members with expertise in the following scientific areas: genotoxicity, carcinogenicity, metabolism, general toxicology and risk assessment. Additional expertise might be required for specific applications/mandates. Upon request from EFSA, hearing experts might be invited to meetings of the Standing Working Group to clarify outstanding issues.

**Scope in EFSA's work and outsourcing programme:** The Standing Working Group will assess the available relevant scientific information submitted through the applicants' dossiers and data provided to EFSA by stakeholders, the Commission and Member States or through public calls for data. As appropriate, EFSA will outsource collation or analysis of scientific information in order to support the scientific assessment 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 2014<sup>8</sup>.

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 contributions, which will be submitted for consideration to and possible adoption by the CEF 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 Interests<sup>9,10</sup> will be followed while setting up and operating this Standing Working Group.

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<sup>8</sup> <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

<sup>9</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf> (applicable until 29 September 2014)

<sup>10</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf> (applicable as of 30 September 2014)