efsa
European Food Safety Authority

ACTING EXECUTIVE DIRECTOR

Parma, 10.3.2014
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NOTE TO THE HEAD OF SCIENCE STRATEGY AND COORDINATION DEPARTMENT

Type of the Mandate: Internal Mandate proposed by EFSA to the SCER Unit for the establishment of a standing WG[1] on genotoxicity.

Title of the Mandate: Standing Working Group on the interpretation of genotoxicity data in the overall risk assessment.

The SCER Unit is requested to manage the administrative and scientific activities of the Standing Working Group on genotoxicity. The SCER Unit will organise the meetings of the Standing Working Group and will assist in the production of the scientific draft outputs 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.
http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

MANDATE of the standing working group on interpretation of genotoxicity data in the overall risk assessment

Background:
In the context of the evaluation/re-evaluation of regulated products, EFSA's scientific panels perform sometimes scientific assessments of the same active ingredients/substances, either simultaneously or following the completion of the assessment by another Unit.

Conducting assessments of the same active ingredient/substances across EFSA Units/Panels raises practical difficulties which are mainly associated with the following:

- The re-evaluation is conducted under different legal frameworks with different data requirements (e.g. feed versus food additives)
- Different legal deadlines applied for different uses of the same ingredients/substances
- The dataset available for the assessment of the same active ingredient/substances in one Panel may be different from the data set available in another Panel. The sharing of the data between Panels performing assessment of the same active ingredients/substances would allow a more complete assessment, but some information may be covered by data protection/confidentially clauses.

The analysis of some cases for the evaluation of food/feed ingredients/substances in the last few years (e.g Allura Red, Brilliant Black etc..) highlighted the necessity to come up with possible proposals in order to better address the issue of assessment of the same active ingredients/substances that are ongoing in EFSA either simultaneously or following the completion of the assessment by another Panel. In some instances, the different interpretation of the Scientific Committee guidance on genotoxicity testing strategies (EFSA, 2011[2]) has been advocated as the reason that leads to different evaluation of the same genotoxicity data.

In order to avoid conflicting opinions across Panels, especially in the case when there is different interpretation of the same genotoxicity data, the Scientific Committee confirmed during its 66th Plenary Meeting the need of a Standing Working Group on genotoxicity. This Standing Working Group will deal with ad hoc questions and its derivatives.

Terms of reference:
The aim of this assignment is to establish a Scientific Committee Standing WG (SWG) for genotoxicity to:

- Provide support to the different EFSA Units/Panels in the evaluation of genotoxicity data sets/scientific literature for assessments where different views have been expressed in the respective Panels or within the same Panel,
- Provide advice on the interpretation of equivocal genotoxicity test results,
- Provide advice on the interpretation of the genotoxicity data e.g. in the light of the genotoxicity testing strategy opinion (EFSA, 2011[3]).

The support will be in a form of an *ad hoc* overall conclusion to be considered by the Unit/Panel that has requested the advice. The request should be put forward by the Chair(s) of the Panel(s) in time before finalisation of the opinion.

In order to fulfil its objectives, the above mentioned SWG should consist of members with expertise in genotoxicity/mutagenicity data interpretation. Ideally, EFSA panels dealing with chemical risk assessments should be represented in the SWG. In any case, a broad representation of EFSA panels will be reflected in the composition of the SWG.

[2] http://www.efsa.europa.eu/en/efsajournal/pub/2379.htm

IT impact:

No

Timeline:

The Standing WG on genotoxicity will be established upon approval of the mandate. The SWG will start working as soon as the first request for provision of advice will be sent to the SC from any EFSA panel/unit.

The SC standing WG on genotoxicity will be in place until the end of the mandate of the present Scientific Committee, therefore until July 2015. It is expected that about 4-6 meetings will be held from the approval of the mandate until July 2015, depending upon the *ad hoc* questions that will be put forward to the standing WG by the panel chair(s).

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

The standing WG on genotoxicity will provide support in form of advice to the requesting panel/unit, that will be considered by the requested Panel(s) in the finalisation of the output(s).

Publication plan (if applicable):

Not applicable

Production of scientific outputs			Consultation Mechanisms			Resource and Timing Impact			
Panel	WG	EFSA Staff	Network meetings	Workshops Seminar	Public Consultation	Other Financial Resources (excl. Art.36, Procurement)	Duration of execution	IT Costs	Total cost (incl. Art.36, Procurement)
NO	yes	0.1	No	no	No	0 €	12	NA	25.000 €

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