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ARES(2018)

Dear Ms O'Reilly,

I would like to thank you for your contribution to the public consultation on the transparency and the sustainability of the EU risk assessment in the food chain.

The principles developed in your letter for improving the EU risk assessment model have also guided the Commission in developing the proposal adopted by the College on 11 April 2018.

A full outline of the proposal can be found at the following link on the Commission's website:
https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en

The proposal is founded on four main pillars: increased transparency; additional guarantees on the quality and reliability of scientific studies used in risk assessment; strengthened sustainability of European Food Safety Authority's (EFSA) expertise and governance and improved risk communication.

The Commission fully shares your views regarding the need to ensure that the "public has a right to know on what basis decisions are taken". To this end, the proposal, amongst others, provides that all studies supporting applications for authorisation will be made public proactively and early on in the risk assessment process, with the exception of confidential information and taking into account protection of personal data. They will also be made easily accessible in electronic format. The proposal also strictly defines what type of information can be claimed as confidential and establishes measures for individual examination of the confidentiality request. The already existing

strong provisions ensuring the transparency of EFSA are maintained and in some cases reinforced (e.g. the agenda and minutes of the Working Groups of the Scientific Committee and Panels and supplementary information provided by the applicant will also be made public as you have suggested).

You also stressed in your letter that "safeguards need to be in place to ensure that the applicant's input is factually correct and consists of a representative sample of all relevant data". The Commission supports this principle, and thus four new measures are proposed to increase guarantees on the quality and reliability of studies used in EFSA's risk assessment:

- A Union register of studies commissioned by industry on substances that would be subject to a food law authorisation system is established to ensure that all studies commissioned to support an authorisation, whatever their results, are submitted as part of the relevant request for an authorisation to EFSA.
- EFSA would be able, upon request of a potential applicant, to provide general advice before an application for an authorisation is submitted. For reasons of independence, the general advice provided by EFSA would be limited to the "required content of application for authorisation", namely making clear what relevant provisions (legal provisions, EFSA published guidance) require on the content of applications for authorisations. EFSA will not be entering into the design of the studies to be submitted, which remains the responsibility of the applicant. In addition, the general advice would be provided by EFSA staff, and be completely separate from the work of the experts in the Scientific Panels and its Working Groups, thus fully preserving the independence of the risk assessment carried out by the EFSA Scientific Panels.
- A consultation of third parties and the public is proposed to take place on studies that are submitted by the industry in the applications, to ensure that EFSA has all necessary information for its risk assessment.
- There are controls and audits by the Commission, in cooperation with Member States, to ensure the compliance of laboratories/studies with standards, and
- The Commission can request EFSA to commission additional studies, in exceptional circumstances and for verification purposes, where high controversy may arise.

You also highlight the importance of involving stakeholders and the public in the risk assessment process. The publication at an early stage of the studies and data supporting applications for

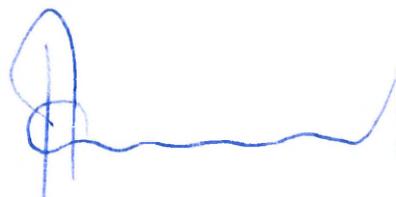
authorisations and the consultation of third parties by EFSA on submitted studies meet your request for providing the legal tools ensuring an "open and transparent EFSA" and pave the way for a meaningful involvement of stakeholders in the risk assessment process.

Furthermore, the new proposal reinforces the risk communication process which is defined in the food safety area as an interactive process involving all relevant parties, i.e. risk assessors, risk managers and stakeholders throughout the risk analysis process, including the explanation of risk assessment findings and the basis of risk management decisions. General objectives and principles of risk communication are set out to ensure accessible, accurate while easy to understand, timely, and transparent information on science and on the decision-making process in the food area. Based on those objectives and principles, the Commission proposes to adopt by means of a delegated act a "General plan" on risk communication.

The long-term independent scientific capacity of EFSA, including a stronger cooperation with Member States, is one of the objectives of the new proposal. Representatives of Member States having experience in risk assessment would constitute the Management Board of EFSA. Member States would also have a role to play as regards the nomination of experts in order to create a pool that will be used to select the independent expertise needed for EFSA's scientific panels. However, the proposed new system maintains the strict rules on excellence and independence for the nomination, selection and appointment of members of the Panels. In addition, the EFSA's Executive Director would have a decisive role in the selection of Panel experts proposed to the Management Board and EFSA would in any case have the possibility to co-opt additional scientists for its Panels, should the right expertise not be available via the Member States' pool.

I believe you share with me the ambition to ensure that EU citizens' expectations on the transparency and safety of the food chain are fulfilled. I trust that the Commission proposal meets your expectations while continuing to provide an independent risk assessment framework supporting safe innovation in the EU food sector.

Yours sincerely,

A handwritten signature in blue ink, consisting of a large, stylized initial 'A' followed by a long, wavy horizontal line that ends in a small vertical stroke.