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Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods]
- General approach

I. INTRODUCTION

1. On 12 April 2018, the Commission transmitted to the European Parliament and to the Council a proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain¹ amending several Directives and Regulations, and in particular Regulation (EC) No 178/2002 on general food law, which *inter alia* establishes the European Food Safety Authority (EFSA).

¹ 8518/18.

2. The proposal aims at:
 - ensuring that scientists and citizens have access to key safety related information being assessed by EFSA at an early stage of the risk assessment,
 - ensuring that EFSA has access to the broadest relevant scientific evidence possible related to a request for authorisation,
 - increasing the guarantees of reliability, objectivity and independence of studies used by EFSA in its risk assessment,
 - better involving Members States in EFSA's governance structure and scientific panels in order to support the sustainability in the long-term of EFSA risk assessment without touching on its independence,
 - strengthening the risk communication between the Commission/EFSA/Members States and public/stakeholders.

3. The proposal is accompanied by a legislative financial statement, which sets out the estimated financial impact of the measures proposed², and by a Commission staff working document (Synopsis report) covering the feedback from citizens and national authorities, groups and organisations ('stakeholders') following an open consultation³.

4. No impact assessment has been carried out by the Commission for this proposal. In its introductory explanatory memorandum, the Commission specified that "*no impact assessment was carried out for this initiative, as the measures that are to be introduced by the proposal will mainly concern the transparency and the way the Commission as risk manager and the EFSA as risk assessor will gather and manage the evidence needed to perform their tasks on the basis of unchanged criteria. Such measures are therefore not expected to have significant socio-economic and environmental impacts that are clearly identifiable ex ante*".⁴.

5. The draft regulation is based on Articles 43(2), 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

² 8518/18, page 44.

³ 8518/18 ADD1.

⁴ 8518/18, page 8.

6. On 11 December 2018 the European Parliament plenary voted ⁵ a number of amendments on the proposal but not its legislative resolution, thereby leaving open the possibility to reach an agreement at first-reading agreement between the two institutions.
7. The Economic and Social Committee delivered its opinion on 19 September 2018⁶ and the Committee of the Regions delivered its opinion on 10 October 2018⁷.
8. One national parliament has delivered an opinion on the application of the principles of subsidiarity and proportionality.⁸

II. STATE OF PLAY IN COUNCIL

9. Given the horizontal nature of the proposal, an *ad-hoc* Working Party on General Food Law was established by the Permanent Representatives Committee on 30 May 2018.
10. At the last meeting⁹ of the ad hoc Working Party on General Food Law on 12 October 2018, the Presidency compromise text received a very broad support from delegations.

⁵ Following the vote, the rapporteur, Ms Renate Sommer (EPP, Germany), resigned. Her decision might have an impact on the calendar of negotiations.

⁶ [NAT/732-EESC-2018-02522](#).

⁷ [CDR 2837/2018](#).

⁸ <http://www.ipex.eu/IPEXL-WEB/dossier/document/COM20180179.do#dossier-COD20180088>

⁹ The *ad hoc* Working Party on General Food Law met on 26 June 2018, 6, 16 and 26 July 2018, 7, 12 and 24 September 2018, 1 and 12 October 2018.

11. The Counsellors/Attachés (AGRI-EFSA, AGRI - Veterinary Matters, AGRI - Phytosanitary Matters, Foodstuffs) confirmed this support at their last meeting on 6 December 2018¹⁰.
12. On 12 December 2018, the Permanent Representatives Committee (Part 1) confirmed the agreement on the compromise text as amended during the meeting to include the modifications proposed by two delegations in Article 1 paragraph 9 of the proposal (and in the corresponding recital).

III. CONCLUSION

The Council is therefore invited to adopt the general approach as set out in addendum 1 to this note.

¹⁰ The Counsellors/Attachés met on 14 November and 6 December 2018.