



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for food sustainability responsible for Directorates D, E, F and G

Brussels,
SANTE/E4/NT/gb/(2022)4721368

Dear Prof. Dr. Jäckel, Prof. Dr. Jany, and Dr. Louis,

Subject: Your letter of 18 May 2022 on the current discussion of more advanced nonselective herbicide technologies in Europe, focus on Surfactants used in Glyphosate Based Herbicides

Thank you for your above-mentioned letter to President von der Leyen, Executive Vice-President Timmermans, and Commissioners Kyriakides, Sinkevicius and Wojciechowski, who asked me to respond on their behalf. In your letter you comment on the necessity to fully investigate the toxicity of glyphosate-based formulations and call of the Commission to initiate an investigation programme on the safety of surfactants in glyphosate-based herbicides.

First, please let me emphasise that the protection of human and animal health, of the environment, and the promotion of scientific research are among our highest priorities. The European Union regulatory framework for plant protection products (PPPs) is among the most stringent in the world. Regulation (EC) No 1107/2009¹ provides that only active substances and PPPs containing them that fulfil the criteria set in this regulation can be authorised for use. All approvals and authorisations are limited in time and must be periodically reviewed so that new scientific and technical developments are fully taken into account.

Regulation (EC) No 1107/2009 sets out a two-step process with the approval of active substances at EU level (following a comprehensive scientific assessment that includes data on the active substance and at least one formulated products), and the authorisation of formulated products by Member States. Before granting product authorisations, Member States must indeed assess the properties of the specific product formulations

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

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Commission Regulation (EU) No 284/2013² requires that the detailed composition of each PPP is submitted to the competent authorities and that for each formulated PPP the applicant provides data that should allow the assessment of all relevant effects of any co-formulants and certain tests must be conducted with the formulated products themselves. Furthermore, Member States may request additional data on each co-formulant or on the product itself, if deemed necessary. Lastly, the mutual recognition and the zonal authorisation procedures imply that Member States peer-review each other's assessments of PPPs.

Please be also informed that Annex III to Regulation (EC) No 1107/2009³ (as amended by Commission Regulation (EU) 2021/383⁴) lists all co-formulants which are not accepted for inclusion in PPPs – thus corresponding to the first category of substances for which you call in your letter. Those include polyethoxylated tallowamines, whose presence in formulations containing glyphosate had raised concerns over potential negative effects on human health. The Commission is in the process of preparing an Implementing Regulation setting up a process by which Member States can propose further co-formulants to be examined and possibly added to this Annex III and the draft Regulation is currently under discussion with Member States at the Standing Committee on Plants, Animals, Food and Feed. The draft will be subjected to public consultation in due time.

Let me also recall that the process for the possible renewal of approval of glyphosate (currently expiring on 15 December 2022) is ongoing and it is premature to speculate about whether this active substance will remain approved in the future or not. Detailed and up-to-date information on the renewal process is available at our dedicated website⁵.

Once again, let me emphasise that the safety of consumers, human and animal health, protection of the environment, scientific research and technological development, and sustainable and competitive agriculture, are all goals of highest importance for the Commission and its services and we will continue to work towards achieving them.

Yours sincerely,

Claire Bury

² Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁴ Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products (OJ L 74, 4.3.2021, p. 7).

⁵ https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en