EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and Biocides

Brussels,
SANTE/E4/MW/df (2017) 6114587

Dear Petitioner,

Subject: Your petition on glyphosate - Ares(2017)5153873

Thank you for your petition addressed to Commissioner Andriukaitis in which you express your concerns about the renewal of approval of glyphosate. Your message was passed to me as my unit is responsible for the glyphosate file. Commissioner Andriukaitis asked me to reply on his behalf.

I understand that there is fear and concern about glyphosate and exposure to it from food and other sources, and the impact on the environment, as well as misunderstanding regarding the process for approval of active substances in the European Union.

The EU has the most stringent regulatory systems for pesticides in the world, ensuring the highest safety standards for human and animal health and the environment, underpinned by sound science. The system comprises two distinct steps: first an evaluation and approval of active substances at EU level, and second authorisation of plant protection products containing approved substances by the Member States. The relevant procedures, which also apply in the case of glyphosate, are described on the European Commission's website: http://ec.europa.eu/food/plant/pesticides/index_en.htm.

The Commission has and will continue to remove active substances from the market for which it cannot be demonstrated that the strict approval criteria enshrined in the legislation are satisfied. It is never the case that substances are allowed to be placed on the market and used when there are safety concerns for human health or the environment.

The same holds for other substances used in plant protection products. In August 2016[1] the Commission amended the conditions in the existing approval of glyphosate, to ban the co-formulant POE-tallowamine in glyphosate-based products and to reinforce scrutiny of pre-harvest uses of glyphosate, as well as to minimise the use in specific areas (e.g. public parks and playgrounds).

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1313

As to the potential effects of glyphosate on human health, on 15 March 2017, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) reached by consensus an agreement that there is no justification for a classification of glyphosate as carcinogenic, nor as toxic for reproduction or mutagenic.

This Opinion of ECHA is shared by many other regulatory bodies, both inside and outside the EU, including authorities in Canada, Australia, New Zealand and Japan as well as the FAO-WHO Joint Meeting on Pesticide Residues.

The classification of a substance is based solely on the hazardous properties of the substance. It does not take into account the likelihood of exposure to the substance and therefore does not address the risks from exposure. The risks from exposure to glyphosate were however assessed by the European Food Safety Authority (EFSA) in its conclusion[2] on glyphosate, which confirm that no unacceptable effects on human or animal health and the environment are expected when glyphosate is used properly.

The EU pesticides legislation[3] makes it clear that plant protection products can only be authorised by the Member States if it has been demonstrated that they have no unacceptable effects on the environment, including the contamination of water bodies and the impact on non-target species, including insects, and on biodiversity. Accordingly, the assessment of glyphosate took into account the predicted levels of glyphosate in soil, water and air and a full risk assessment was undertaken for non-target organisms. This evaluation showed that glyphosate can be used without deleterious effects on the environment. However, it must be highlighted that Member States have an obligation to carefully consider each glyphosate-containing product that is or is to be authorised on their territories, taking into account national conditions (for example, agronomic and climatic conditions) to ensure that all uses are fully considered. The protection of the environment is a cornerstone of EU legislation and the assessment schemes in place ensure that the latest scientific and technical knowledge is taken into account to achieve the high standards of protection sought within the Union.

The safety of European consumers as regards pesticide residues in food products is ensured through Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin[4]. Maximum Residue Levels (MRLs) are the highest levels of pesticide residues that are legally tolerated in or on food and feed and are set to ensure that food products containing residues below these limits are safe for consumers. MRLs are based on the residue levels expected when a pesticide is used according to good agricultural practice and are well below the level that would be necessary to protect human health and are therefore highly protective for consumers. These MRLs apply to food products

---

2 EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302. See also http://www.efsa.europa.eu/en/corporate/pub/glyphosate151112.

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. 1–50.

4 OJ L 70, 16.3.2005, p. 1–16.

regardless of their origin, i.e. whether they are produced in the EU or imported from third countries.

Every year, EFSA publishes an annual report on pesticide residues in food summarising the results of a coordinated multiannual control programme of the Union and of the overall control activities (reported as national control programmes). In the most recent report from 2015, published by EFSA in April 2017[5], it was found that 96.9 % of 5,329 samples analysed did not contain any measurable glyphosate residues and in only 0.09 % of samples, the MRL was exceeded.

Various allegations have been made about the credibility and reliability of the EU assessment of glyphosate, most notably in the context of the so-called 'Monsanto Papers'. In response to these allegations the Commission asked the agencies involved in the assessment of the substance at EU level – EFSA and ECHA, to indicate whether such allegations, even if true, would have an impact on their conclusions. The agencies confirmed at two occasions, in June and August 2017, that this was not the case. In addition, in September 2017, articles appeared in a number of European press outlets casting doubt on the integrity of the EU assessment of glyphosate, in particular the content of the renewal assessment report (RAR) submitted to EFSA by the German Federal Institute for Risk Assessment (BfR), which had conducted the first evaluation of glyphosate. The Commission took these allegations seriously and asked the BfR and EFSA to respond. The two bodies issued statements strongly refuting these allegations. The statements can be found on their respective websites. Therefore, given the thorough scrutiny of all available information, there are currently no grounds to question the EU assessment of glyphosate.

Taking into account the conclusion of EFSA, the opinion of ECHA and other legitimate factors and considering the approval criteria laid down in the EU pesticides legislation, the Commission has made a proposal to Member States to renew the approval of glyphosate for a period of five years.

Details about the Commission's proposal and the ongoing discussions with Member States can be found on the following dedicated webpage: https://ec.europa.eu/food/plant/pesticides/glyphosate_en.

Yours sincerely,

pp A. Billoch

Klaus Berend
Head of Unit

[5] European Food Safety Authority, 2017. The 2015 European Union report on pesticide residues in food. EFSA Journal 2017;15(4):4791