

Glyphosate

SANTE/11051/2016 rev 0

27 June 2016

## Addendum to the Review report for the active substance **glyphosate**

Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on  
27 June 2016

in view of the review of glyphosate in accordance with Article 21  
of Regulation (EC) No 1107/2009

### 1. Procedure followed for the evaluation process

This addendum to the Review Report 6511/VI/99-final of 21 January 2002 has been established as a result of the review of the approval of the active substance glyphosate. The review report is considered to have been amended by means of this addendum as of 27 June 2016.

The renewal assessment, as documented in the *Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate* of the European Food Safety Authority (hereinafter 'the Authority') (EFSA Journal 2015;13(11):4302 [107 pp.]<sup>1</sup>), and the Statement of the Authority *Request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine*" (EFSA Journal 2015;13(11):4303 [13 pp.]<sup>2</sup>), identified several new concerns.

Specifically the Authority concluded that compared to glyphosate, a significant toxicity of POE-tallowamine (CAS No 61791-26-2), a substance frequently used as a co-formulant in plant protection products containing glyphosate, was observed on all endpoints investigated. Additional concerns were highlighted as regards the potential of POE-tallowamine to negatively affect human health when used in plant protection products containing glyphosate. The Authority also considered that a likely explanation for the medical data in humans for plant protection products containing glyphosate is that the toxicity is mostly driven by the POE-tallowamine component of the formulation.

In accordance with Directive 2009/128/EC<sup>3</sup> in conjunction with Article 55 of Regulation (EC) No 1107/2009<sup>4</sup>, Member States should encourage the development and implementation

<sup>1</sup> Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

<sup>2</sup> Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

<sup>3</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71–86).

<sup>4</sup> 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).

of integrated pest management and of alternative approaches or techniques in order to reduce their dependency on the use of pesticides. As plant protection products containing glyphosate are widely used for non-agricultural applications, Member States should ensure that the use of plant protection products containing glyphosate is minimised or prohibited in areas such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities.

Plant protection products containing glyphosate are also used for pre-harvest applications. In certain situations pre-harvest uses to check or prevent undesired growth of weeds are in line with good agricultural practices. Nevertheless it appears that plant protection products containing glyphosate are also used with the intention to control the time point of harvest or to optimise the threshing, although these uses may not be considered within good agricultural practices. Such uses may therefore not be compliant with the provisions of Article 55 of Regulation (EC) No 1107/2009. Member States should therefore pay particular attention to compliance of pre-harvest uses with good agricultural practices when authorising plant protection products.

Given the uncertainties identified in the Authority's review and the consequent doubts whether for all uses currently authorised the criteria laid down in Article 4 of Regulation (EC) No 1107/2009 are still satisfied, the Commission decided to review the approval of glyphosate in accordance with the provisions of Article 21 of the aforementioned Regulation.

The conclusions of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Plants, Animals, Food and Feed and finalised on **27 June 2016** in the format of an addendum to the review report on glyphosate.

The present addendum to the review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the Authority, and the comments and clarifications submitted after the conclusion of the Authority, these documents are also considered to be part of this review report.

## **2. Purposes of this addendum to the review report**

This addendum to the review report has been developed and finalised in support of Commission Implementing **Regulation (EU) No xxx/2016**<sup>5</sup> of [date] amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC<sup>6</sup> and/or Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

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<sup>5</sup> [Reference]

<sup>6</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

### **3. Overall conclusion in the context of Regulation (EC) No 1107/2009**

The overall conclusion as set out in the Review Report 6511/VI/99-final of 21 January 2002 remains unchanged. This conclusion is however subject to compliance with the particular requirements and provisions as set out in that Review Report, as well as with the additional requirements in section 4 of this addendum to the review report, for each glyphosate containing plant protection product for which Member States will grant or review the authorisation.

### **4. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing glyphosate**

The following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, amended or withdrawn, as appropriate, in addition to the issues identified in the Review Report 6511/VI/99-final of 21 January 2002:

Member States must pay particular attention to:

- risks from the use in specific areas referred to in Article 12(a) of Directive 2009/128/EC;
- compliance of pre-harvest uses with good agricultural practices.

Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).