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Brussels, 21 September 2016

Intention of withdrawal plant protection products containing glyphosate and the co-formulant POE-tallow amine (CAS No 61791-26-2) and the intended grace periods for sell-out and use-up

Dear Mr. 5.1.2.e Woo

On 01 September 2016 the Board for the Authorization of Pesticides & Biocides has published several intentions to withdraw or change all POE-tallow amine (CAS No 61791-26-2) containing glyphosate registrations as per 22 August 2016, according to the Commission Implementing Regulation (EU) 2016/1313. In these intentions, a sell-out period of 4 months (until 22 December 2016) and a use-out period of 6 months (until 22 February 2017) have been proposed for registration holders/distribution and end-users, respectively.

Monsanto Europe N.V. agrees that following the Commission Implementing Regulation (EU) 2016/1313, POE-tallow amine containing glyphosate products should be removed from the Dutch market, either by withdrawing their authorization or by replacing POE-tallow amine in the formulation.

Monsanto Europe N.V. also acknowledges that the ctgb grants grace periods for sell-out and use-up of existing stocks of POE-tallow amine containing glyphosate products. However, we disagree with the timelines proposed by the board for the reasons explained below.

On 30 June 2016, the proposal to change the conditions of approval for glyphosate was added to the agenda of the Standing Committee of 11-12 July 2016 via an addendum to the agenda¹. During the July Standing Committee meeting, Member states voted in favor of the proposal. The Commission Implementing Regulation (EU) 2016/1313 was published in the Official Journal of the European Union on 2 August 2016, with entry into force on 22 August 2016 (20 days after publication of the Regulation). Therefore, the ban and especially the timelines in which the ban was pushed through were not foreseeable for the registration holders, producers and even less for the end users.

The decision to ban POE-tallow amine in the EU was rather a political inspired decision than a scientific one. There is no new information or data that led to the decision to ban POE-tallow amine. In the context of the glyphosate renewal, the European Commission gave a mandate to the EFSA to assess the co-formulant POE-tallow amine based on the evaluation in Renewal Assessment Report (RAR). Therefore, within the context of this mandate, EFSA could only use the information provided in the RAR and consequently could not accept submission of additional information that could demonstrate

¹ http://ec.europa.eu/food/plant/docs/sc_phyto_20160711_pppl_agenda_add.pdf

the safety of this co-formulant. Consequently, EFSA confirmed the observation in the RAR that *'compared to glyphosate, a higher toxicity of the POE-tallow amine was observed on all endpoints investigated'*. This makes sense as glyphosate has such a benign toxicology profile. This statement however does not allow any conclusion on the overall toxicity of POE-tallow amine. Moreover, EFSA could not support the assessment of the RAR: there was not enough data to establish ADI, AOEL and ARfD. Also the genotoxicity, long-term toxicity and carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential could not be clarified due to lack of data. Further EFSA concluded that no synergistic effects between glyphosate and POE-tallow amine were observed.

To date, POE-tallow amine is not included in Annex III of Regulation (EU) 1107/2009, that lists co-formulants that are not accepted for inclusion in plant protection products.

POE-tallow amine containing glyphosate plant protection products have been approved for the Dutch market for around 40 years. POE-tallow amine containing plant protection products were evaluated and their risks were thoroughly assessed: all approved uses are safe for human and animal health and the environment.

Glyphosate is a broadly used herbicide that is applied throughout the growing cycle (February till November). Therefore, glyphosate plant protection products are produced in large amounts and stocked at producer, distributor and farmer level. As mentioned above the implementation time for the POE-tallow amine ban could not be anticipated. The proposed grace period for sell-out of 4 months plus an additional use-up of 2 months are much shorter than the grace periods provided in Regulation (EU) 1107/2009, which are 6 months for sell-out plus additional 12 months for use-up of existing stocks. Please also take into account that half of the grace period for use-up is in winter, a time when glyphosate is usually not applied.

Given that

- the decision to ban POE-tallow amine and its implementation at EU level and in the Netherlands could not have been anticipated by registration holders, manufacturers, distributors and end-users;
- no new data led to the decision to ban POE-tallow amine in the EU and consequently in the Netherlands;
- POE-tallow amine is not included on Annex III of Regulation (EU) 1107/2009;
- POE-tallow amine containing glyphosate products have been approved in the Netherlands for about 40 years;
- all plant protection products including those containing POE-tallow amine were evaluated and their risks were thoroughly assessed; the approved uses were found to be safe for human and animal health and the environment;
- the proposed grace period is significantly shorter than provided in Regulation (EU) 1107/2009 and the shorter grace period is not convincingly justified;
- the proposed grace period does not overlap very well with the application time of the product

we kindly ask you to grant the maximum grace period as provided in Regulation (EU) 1107/2009 for sell-out of six months and an additional 12 months for use-up of existing stocks starting with the entry into force date of the final decision (i.e. 11 November 2016).

Please feel free to contact us for further discussion.

We look forward to receiving the confirmation on the extended grace periods.

Yours sincerely,

5.1.2.e Woo

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