



ADAMA

CTGB
Board for the Authorisation of
Pesticides & Biocides
Bennekomseweg 41
6717 LL EDE

Oosterhout, 21 september 2016,

By REGISTERED LETTER

RE: Intention of withdrawal of glyphosate registrations containing the co-formulant POE-tallowamine (CAS No 61791-26-2) and proposed timelines

Dear Madam, Sir,

On 01/09/2016 the Board for the Authorization of Pesticides & Biocides has published several intentions to withdraw or change all POE-tallowamine containing glyphosate registrations as per 22/08/2016, according to the Commission Implementing Regulation (EU) 2016/1313. In these intentions, a sell-out period of 4 months (until 22/12/2016) and a use-out period of 6 months (until 22/02/2017) have been proposed for registration holders, distribution and end-users, respectively.

With this letter Nufarm Deutschland GmbH, Nufarm UK Ltd, Adama Registrations B.V., R. van Wesemael B.V. and UPL Europe Ltd. wish to present their view on the published intentions for withdrawal and the proposed periods of grace. The companies stated above agree with the CTGB that – following the Commission Implementing Regulation (EU) 2016/1313 – all POE-tallowamine containing glyphosate products should be banned from the Dutch market. As such, we do not argue against the withdrawal of these approvals.

However, we do not agree with the timelines proposed by the Board. The Board states in the provisional decisions that: “Bij de lengte van de vastgestelde termijn is hiermee voldoende rekening gehouden met de mate waarin de intrekking voor de markt of gebruiker voorzienbaar was en de mogelijkheid om de gevolgen van de intrekking op te vangen.” This *foreseeability* of a change in registrations is a crucial point in the decision-making for periods of grace by the Board. We are of the opinion that the Board did not take this into account when setting the proposed periods of grace. Please find here-under several arguments as to why our companies are of the opinion that this ban was not foreseeable, both on the EU-level and on the national level.

EU-level

1. The discussion on POE-tallowamine is already ongoing for quite some time, but only recently made its way into the renewal Regulation of Glyphosate. In Regulation (EU) 2016/1056 of 29 June 2016, it is still stated that a review should be initiated by the Commission:

Taking into account the extension of the approval period of glyphosate described in the preceding recitals, and in light of the concerns identified by the Authority as regards the use of the co-

formulant POE-tallowamine (CAS No 61791-26-2) in plant protection products containing glyphosate, the Commission will initiate a review of the approval of glyphosate according to Article 21 of Regulation (EC) No 1107/2009, as soon as possible.

So on 29 June, there was still no formal need to withdraw the POE-tallowamine containing formulations.

2. On 11 July a SCOPAFF-meeting was held. In this meeting, the glyphosate dossier was discussed by the member states. There is still no summary of this meeting available, but it can be assumed that the ban on POE-tallowamine was voted in that meeting (<https://www.euractiv.com/section/agriculture-food/news/eu-agrees-ban-on-glyphosate-co-formulant/>). Following this meeting The Commission Implementing Regulation (EU) 2016/1313 was published in the Official Journal of the European Union on 02/08/2016, with entry into force on 22/08/2016 (20 days after publication of the Regulation).
3. The Commission Implementing Regulation (EU) 2016/1313 states that:

Article 1

In the seventh column, 'specific provisions', of entry 25 on glyphosate in Part A of the Annex to Implementing Regulation (EU) No 540/2011, the text is replaced by the following:
'Only uses as herbicide may be authorised.

...

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

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

As this Regulation was published in the Official Journal of the European Union on 02/08/2016, it is correct that this Regulation should be implemented as per 22/08/2016. However, this Regulation does not state a starting, nor a completion date for the implementation of the ban of POE-tallowamine containing glyphosate formulations and consequently does not state a specific end-date for periods of grace. Different member-states thus acted differently on this POE-tallowamine issue and every member state fixed different periods of grace for POE-tallowamine containing formulations. For example, the United Kingdom and Spain interpreted the wording in the regulation as such that they need to assure that the POE-tallowamine containing products disappear from their markets between 22/08/2016 and the new Annex I end-date of glyphosate. These countries have thus not yet taken any action for the ban of POE-tallowamine. The same goes for Poland and Hungary who did not yet implement a ban on POE-tallowamine. Belgium have granted a 6 month sell-out period plus 12 month end-use period, in line with all other decisions. From this, it is clear that the wording in the Implementing Regulation is certainly vague about its timelines for final implementation and hence subject to interpretation by the individual member states.

From the points stated above, it is clear that the action from the Commission has taken everybody, approval holders and authorities, by surprise, as the implementation day of

the ban (22/08/2016) was only published 20 days before the Entry Into Force. In addition the timelines stated in this regulation are not clear at all and subject to interpretation.

National (NL) level

1. Since POE-tallowamine is under discussion in the background for a long time already, UPL Europe Ltd. anticipated on an eventual ban of this surfactant by applying for a composition change for their Glyphosate 360 SL registration Etna Next (at that time still Etna Pro), 10945 N, in January 2015. The approval was granted by the board meeting of 29/04/2016. Reason for this long evaluation before approval is that according to the CTGB, the replacement of the co-formulant could not be considered as a minor change and had thus to go through the zonal process.

At the time of submission it was not known when this formulation change would be approved, but there was also no haste to change the composition as there were no signs that the ban of POE-tallowamine was imminent. The fact that the Board did not fix a sell-out or use-out period for the existing stock of the old POE-tallowamine containing product after approval of the new product reassured UPL and by extension also the other registration holders that a POE-tallowamine ban was not imminent at that point.

2. After several requests for information about the glyphosate dossier submitted to the Board by Nufarm, the answer was the same at every occasion: "we don't know". The last answer as such from the Board is dated 18 July. Please note that at that point, the SCOPAFF-meeting in which the ban had been agreed, had taken place already. So although this was discussed by the Commission and the Member states, the Ctgb had not taken a position yet.
3. Following the publication of the Commission Implementing Regulation (EU) 2016/1313 in the Official Journal of the European Union on 02/08/2016, CTGB only informed the registration holders of POE-tallowamine containing glyphosate formulations by phone on 17/08/2016 of the implementation of the ban per 22/08/2016 in the Netherlands. During this phone conversation, it was stated that no periods of grace would be granted. As this communication was done by phone, it could not be regarded as official, but it caused panic in the market already, as could have been expected. As comparison, Belgium informed the registration holders on 04/08/2016 of the ban they would implement per 22/08/2016.
4. After this first phone-call several emails were sent to inform the registration holders of new decisions concerning periods of grace. Amongst these an email stating a **FINAL** decision on 25/08/2016 (3 days after the implementation date) with 4 months sell-out and 6 months use-out. This email was then followed by a publication in the "Staatscourant" on 30 August, stating a **PROVISIONAL** decision for the ban and making reference to the CTGB-website for further information and insight in the provisional decision documents. In this "Staatscourant", no information was given about eventual periods of grace. Only on 31/08/2016 the registration holders were informed by email about this provisional decision. The distribution and end-users for their part, had to wait until 01/09/2016 for the publication of the relevant information, with intended periods of grace on the CTGB website. Note that this was only published after UPL pointed the CTGB to the fact that the data referred to in the "staatscourant" was not available on the CTGB website.

All of the above illustrates that the communication between the Ctgb and the approval holders, but also from the Ctgb to the public, was poor. This very late and poor

communication and the fact that they did not implement any fixed periods of grace for the old composition of Etna Next shows clearly that the Board was taken by surprise as well and that they did not at all anticipate this ban. It is thus very logical that, if the national regulatory authority was taken by surprise by a decision from Europe, the registration holders, who should get the information from their national authorities, have also been taken by surprise. Apart from the fact that this very poor communication could be regarded as maladministration, the approval holders question the Board's statement about the *foreseeability*: if the Board didn't even know until the very last moment, how could approval holders know? And as stated in the beginning, this directly impacts the periods for sell-out and use-out.

Glyphosate is a very broadly used active substance used throughout most of the year from pre-emergence application to pre-harvest (desiccation) applications. Due to this fact, registration holders tend to produce this product in large volumes to be able to sell the product during the whole year when needed, distribution tends to always have enough product in stock and even the end-users usually have product in reserve. As substantiated above, neither the registration holders, nor distribution or end-users have seen this ban coming. The registration holders could thus not anticipate production in the context of this ban or alert distribution. Even if the date of 29 June would be taken into account as a first serious indication of imminent ban, the existing stocks of POE-tallowamine containing product still clearly predate this day. Nevertheless, the Board still decided to allocate short periods of grace. In addition and especially, in the allocated use-out period (6 months, *i.e.* from now until 22 February), the agricultural use of glyphosate will be very limited due to the fact that there is no need for a systemic herbicide as glyphosate in winter season. If the Board maintains the proposed use-out period the volume of glyphosate that will still be in stock at the end of these periods of grace will be barely lower than the situation as it is today for all elements of the chain, from registration holder to end-users. By setting the end-date at 22/02/2017, the Board thus indirectly stimulates illegal use by the end-user: they will have the choice to have the product they paid for destroyed or use it with very limited chance to be caught. In addition, the distribution will not sell anything anymore as the user will not be able to use-out the product he is still allowed to buy during the sell-out period. This will lead to major logistical and economic issues for registration holders and distribution. All undersigned companies are willing to submit the amount of product they currently still hold in stock to show the Board what implications this sudden ban would have on registration holder level. From these numbers, it can be expected that the amount of product currently standing at distribution and end-user level is also at the least "considerable".

Our companies, in communication with our customers, are of the opinion that by setting the final end date for the use-out period on 22 May 2017 (c.q. 3 months longer than what is now proposed by the board), it can be expected that the end-users will have had the time to use-out the existing stocks. In the light of these existing stocks, we would thus like to propose the following periods of grace:

- Sell-out period: 4 months, until 22/12/2016 (same as is now proposed by the Board),
- Use-out period: 9 months, until 22/05/2017.

With these proposed periods of grace, the Board stays well within the maximal timelines that were recently fixed in the publication in the "staatscourant", while they allow the market to sell out their current stocks and the end-user to use-out the product. By applying the proposed timelines, the amount of product that will potentially be sprayed illegally after the end-use date will be non-existent and the amount of unsold / unused

product that will have to be taken back by distribution and registration holders will be manageable.

We look forward to your answer and hope the Board can agree with us that, in the light of this very sudden, unforeseeable decision, realistic timelines for the use-out of the current stock will be allowed.

Yours sincerely,

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