# **European Glyphosate Task Force**

Monsanto Europe SA, Avenue de Tervuren 270-272, B-1150 Brussels,Belgium

Commissioner Adriukaitis, Berl 08/369, Rue de la Loi, 200, B-1049 Brussels Belgium

Email: vytenis.andriukaitis@ec.europa.eu

4 April 2016

Dear Commissioner,

### Glyphosate Task Force proposal for public access to studies

The Glyphosate Task Force (GTF) comprises 24 member companies working together for the sole purpose of the Renewal of Approval for Glyphosate in the European Union. The GTF members jointly submitted an application on March 24<sup>th</sup>, 2011 (updated May 9<sup>th</sup>, 2011) followed by a supplementary dossier on May 25<sup>th</sup>, 2012, to meet the requirements of the under the strict terms and conditions set forth by Commission Regulation (EU) No 1141/2010 of 7 December 2010 ("Regulation 1141/2010"), and also having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 ("Regulation 1107/2009") and Commission Implementing Regulation (EU) 2015/1885 of 20 October 2015 ("Regulation 2015/1885").

The GTF has provided what it considers to be a robust and thorough set of data including studies conducted by its members and peer reviewed scientific literature, which clearly demonstrates that glyphosate poses no unreasonable risks to humans or the environment when used according to the instructions. The submission includes multiple studies according to internationally agreed study methods (e.g. OECD), on the active substance from different manufacturing sources, conducted at different laboratories over a period of time.

The joint dossier submission included 14 carcinogenicity studies, which are owned by seven GTF members. They contain intellectual property and confidential information which are entitled under the current legislation to protection from public disclosure in order to protect the significant investment made by these members in the production of this data. An overview of these studies was published by Greim *et al* in 2015<sup>1</sup>, with an on-line link to data from those studies. In addition, robust summaries of the studies have been published in the redacted summary dossier as well as in the Renewal Assessment Report for the Renewal of Approval of Glyphosate in the EU<sup>2</sup>. Both have been reviewed by the European and Member State competent authorities and are available on EFSA's website.

The GTF notes the public debate about Glyphosate, particularly in the area of carcinogenicity concerning the conclusions of the BfR and EFSA, and IARC on this topic. We are seriously concerned that the anxiety that is being generated in the public mind by the questioning of the scientific findings of studies,

submitted in confidence and reviewed by the required institutions in the proper manner, is undermining the whole basis for the evaluation of plant protection products as set out in the legislation.

However, we have every confidence that the expert scientific assessment made on the basis of the current legislation demonstrates that the use of glyphosate poses no unacceptable risks. In order to help to address the public concern regarding the safety of glyphosate products without, in any way, setting a precedent for other studies and substances, the members of the GTF would like to indicate their willingness to voluntarily provide access to copies of all 14 carcinogenicity studies referred to above on an exceptional basis. This is subject to the removal of the confidential information and personal data identified in accordance with Article 63 of Regulation 1107/2009. The GTF proposes to provide this opportunity to interested members of the public to review the study reports in a physical reading room environment which is supervised so as to ensure that the rights of the study owners remain respected (unfair commercial use including misuse of copyright) and misinterpretation, under established rules such as those outlined in the Annex to this letter.

We are willing to work closely with the respective authorities such as EFSA or BVL to set up such physical reading rooms at their locations.

We believe that our voluntary proposal will enable those who question the renewal recommendations for glyphosate to better review and understand the evidence supporting the conclusion that Glyphosate is not carcinogenic.

Yours sincerely

Dr R.P. Garnett

Chair of the Board of the Glyphosate Task Force

On behalf of the Glyphosate Task Force

Note: at 12.30 on 30 March 2016, the supplemental data had 4 views, no shares and no downloads.

<sup>&</sup>lt;sup>1</sup> http://www.tandfonline.com/doi/full/10.3109/10408444.2014.1003423

<sup>&</sup>lt;sup>2</sup> The GTF submitted 14 studies, and in the redacted summary dossier there are summaries of all studies; in the RAR, the BfR summarized 12 studies and refers to 2001 Monograph for the other two.

## Annex: Proposal for data room rules

#### Location

 To be determined. Preference would be at EFSA or BVL locations. If required, industry may be able to offer facilities at one or more independent locations within EU.

#### · Period of Access

- Facility to be made available for a limited time
- Requestor can attend as often as he/she wishes during this period with an agreed notice time to allow the facilities to be prepared

### · Documents provided:

- Hard copies of the 14 carcinogenicity studies plus electronic copies
- All confidential data + private data shall be deleted or redacted (Regulation 1107/2009, Article 63)

#### Forms of access:

- The requester can read the documentation concerned and take hand written notes
- No possibility to remove the documents or parts of the documents from the reading room in any form
  - · computer reading facilities without network or internet access
  - ALL means of making and downloading electronic copies must be disabled, including, for example, screen prints, USB ports, CD drives and Bluetooth.
  - No making or transmitting of copies including, for example, photocopying, photography, use of mobile devices
- An officer must be present in the reading room at all times that access is being provided.

#### Requestor:

- Requestor(s) should register upfront and consent to this information being released upon request to the GTF Members.
- Maximum 3 requestors can be present in the reading room at the same time

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