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European Food Safety Authority

HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

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Subject: Your application for access to documents of 10 December 2015

Ref.: PAD 2015/143

Dear Mr Pigeon,

I refer to your e-mail submitted on 10 December 2015 by means of which you requested access to *"the 5 mouse studies' full version including raw data (...) that Mr Tarazona insisted had played such an important role in reaching a different conclusion than IARC in the interpretation of the animal evidence"* (hereinafter the *"Studies"*) in accordance with Regulation (EC) No 1049/2001[1] (hereinafter referred to as the *"PAD Regulation"*). Having carefully considered your request, we regret to inform you that EFSA is not in the position to release the requested Studies to you.

EFSA interpreted that your request refers to the five long term toxicity and carcinogenicity mice studies that are mentioned in the section "Carcinogenicity" in the background document to the EFSA Conclusion published on 12 October 2016[2], notably:

1) 18-Month Oral Oncogenicity Study in Mice
2) Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice
3) Glyphosate Technical: Dietary carcinogenicity study in the mouse
4) A chronic feeding study of glyphosate (Roundup technical) in mice
5) Glyphosate – 104 week combined chronic feeding/oncogenicity study in rats with 52 week interim kill (results after 104 weeks)

EFSA has consulted the five owners of the Studies submitted in the frame of the renewal of the authorisation for the active substance Glyphosate under Regulation (EC) No 1107/2009[3] and Commission Regulation (EU) No 1141/2010[4] as amended by Commission Implementing Regulation (EU) No 380/2013[5]. In particular, in accordance with Article 4(4) of the PAD Regulation, EFSA liaised with the owners with a view to assessing whether these partially or entirely fall within the

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1 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43-48, applicable to EFSA.

2 Available at http://www.efsa.europa.eu/sites/default/files/4302_glyphosate_complementary.pdf

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 Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances, OJ L 322, 8.12.2010, p. 10–19.

5 Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission, OJ L 116, 26.4.2013, p. 4.

exceptions to disclosure foreseen in the PAD Regulation. Four of the owners consulted replied to EFSA; one of the consultations is still pending.

The data owners provided justifications to support the refusal of the access request based on the following grounds:

- These Studies are covered by the exception foreseen by Article 4(2) first indent of the PAD Regulation, namely the protection of "*commercial interests including intellectual property rights*" and their full protection is also the direct consequence of the qualification as confidential of information contained in the Studies under the terms of Article 63 of Regulation (EC) No 1107/2009.
- As highlighted by the owners of the Studies, the Studies requested include protected know-how relating to the scientific and technical expertise in conducting these Studies, disclosure of which will undermine the competitive position of the companies.
- These unpublished Studies are owned by the companies and contain property data that if released will jeopardise the exercise of their intellectual property.
- These documents include business and data property of the owners and their disclosure will undermine their commercial interests.
- Finally disclosure of the Studies would provide access to commercial information, resulting from an investment of the owners both in terms of time and resources, which could be used by potential competitors in particular outside the EU.

Having considered the arguments put forward by the owners of the Studies and after having carefully carried out a concrete examination of the Studies falling in your request, EFSA concludes that the Studies are protected in application of Article 4(2), first indent, of the PAD Regulation, namely the protection of "*commercial interests and intellectual property rights*". Please note that these Studies are also to be protected in application of Article 63 of Regulation (EC) No 1107/2009, as they classify as confidential information.

Moreover, EFSA has specifically undertaken the balance of interests at stake in application of the PAD Regulation, and concluded that no overriding public interest on disclosure applies to this request.

Indeed the public interest of accessing background information relating to the renewal of approval of this active substance, in accordance with Article 38(1)(c) of EFSA's Founding Regulation[6], is granted by having published the relevant background documentations backing the EFSA's conclusions published at the following link http://www.efsa.europa.eu/en/press/news/151119a.
This includes as well the sanitised supplementary summary dossier for the AIR II renewal procedure where detailed descriptions of the toxicological studies are available (MII, section 3, pp 502f).
Therefore, given the fact that the accessibility of the Studies, in particular to competitors, would put at risk the commercial interests and intellectual property rights of the owners of the Studies, their disclosure would be disproportionate to the objective that is necessary to attain. In fact EFSA considers that the information granted to the public at large within this particular renewal process satisfies a good

[6] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24, as last amended.

level of transparency that is proportional to the protection of the commercial interests and intellectual property rights of the owners.

It follows that the Studies requested are not disclosed to you in application of the exceptions to disclosure provided for in the PAD Regulation, namely Article 4(2) first indent (protection of *"commercial interests including intellectual property rights"*) as combined with the provisions set out in Article 63 of Regulation (EC) No 1107/2009.

To exercise your right to appeal against this negative decision by a confirmatory application, you may write to EFSA at the address below. You have fifteen working days from receipt of this letter to appeal. Beyond this deadline, your initial request will be considered as fully satisfied. In case you submit a confirmatory application, EFSA will inform you of the outcome of this re-examination of your request within fifteen working days of receipt, either by granting you access to the documents or by confirming the refusal. In the latter case, you will also be informed of any further appeal routes available.

Further correspondence must be sent to:

EFSA
Dirk Detken, Head of the Legal and Regulatory Affairs Unit
Via Carlo Magno 1/A
I – 43126 Parma
e-mail: EFSA.public.access.to.documents@efsa.europa.eu

Yours sincerely,

Dirk Detken
Cc: J. Tarazona (EFSA)