Ref. Ares(2015)1279016 - 24/03/2015

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Acting Director-General

Brussels,
SANTE/E1/MK/as sanco.ddg2.e.1(2015) 1194142

Dear Dr Url,

Subject: **Request for scientific assistance on the arguments provided by Monsanto with regard to EFSA's opinion on Monsanto's Insect Resistance Management Strategy.**

On 20 November 2014 my services received a letter from Monsanto Europe S.A./N.V in which they argue that EFSA's recommendations regarding changes to Monsanto's Insect Resistance Management Strategy for the post-market environmental monitoring of maize MON810 are disproportionate. The EFSA GMO Unit was in copy of this letter.

Monsanto claims that familiarity and experience gained with maize MON810 support their current IRM strategy. In addition, they present arguments to support that the likelihood for resistance development in Mediterranean Corn Borer and European Corn Borer is extremely low. Finally, they argue that the monitoring of geographical zones (i.e. the hotspot areas) as proposed by EFSA cannot be put into practice.

Since EFSA has recently decided that Monsanto's arguments would not be addressed as part of the EFSA opinion on the 2013 monitoring report for maize MON810, I would like to request that EFSA assesses the elements provided in the letter, and indicates if the result of this assessment continues to support EFSA's views on the issues raised.

I would appreciate an answer by the end of June 2015.

Yours sincerely,

Ladislav Miko

Dr. Bernhard Url
Executive Director
European Food Safety Authority
Via Carlo Magno 1A
I-43126 Parma

Enclosures: 1. Letter from Monsanto on EFSA's opinion on Monsanto's IRM Strategy, reference Ares (2014) 3895300.

2. Annex, reference Ares (2014) 3895300

E-mail copy: Ms E. Waigmann, Mr P. Bergman, Ms S. Mestdagh, Mr Y. Devos (EFSA); Ms D. André, Ms S. Pelsser, Ms M. Kammenou (SANTE).

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Head of Unit Biotechnology and Plant Health
Ms Dorothée André
Directorate General Health and Food Safety
Unit E1 - Biotechnology and Plant Health
Rue Belliard 232 03/100
B-1049 Brussels

Brussels, 20 November 2014

Dear Ms André,

Subject: ***EFSA's opinions on Monsanto's IRM strategy for post-market environmental monitoring of MON 810***

To date, EFSA published four favourable scientific opinions on Monsanto's post-market environmental monitoring (PMEM) reports for MON 810 maize cultivation in the EU (EFSA, 2011, 2012a, 2013, 2014) representing four consecutive growing seasons, *i.e.*, from 2009 to 2012, respectively. In all these opinions EFSA agrees with Monsanto's conclusion that no adverse effects have been identified neither on the environment nor on human and animal health due to maize MON 810 cultivation. This observation is in line with the common scientific knowledge of this product as well as the experience of seed companies, farmers, operators and consumers worldwide. Therefore, EFSA's statement about several 'shortcomings in the overall methodology for post-market environmental monitoring of maize MON 810' is surprising, as it implies that the monitoring for potential adverse effects has to be intensified regardless of the initial favorable risk assessment and the supporting data and experience that became available afterwards.

In the current letter, we like to provide our view on EFSA's scientific opinions in terms of case-specific monitoring, *i.e.*, insect resistance management (IRM). Several of the recommendations proposed by EFSA are not in line with current scientific knowledge, experience and practices and would become non-proportional as related to the demonstrated safety if they would become mandatory conditions to the authorization to cultivate MON 810 in the EU. Such conditions imposed to MON 810 could seriously impact workability and hamper industry operations, potentially impacting product viability and resulting in the reduction of available options for farmers to control insect pests.

These issues were discussed before in focused tripartite meetings (EFSA, European Commission, EuropaBio) in the context of a harmonized proposal from EuropaBio on post-market environmental monitoring of GM crop cultivation and *Bt* maize in particular. During the meetings held on 8 January 2013 and 26 September 2013, EFSA was represented and discussed the harmonized IRM plans for single Cry1-protein expressing GM maize products with EuropaBio. However, no direct scientific feedback was

received from EFSA during these meetings. It is unfortunate that this detailed feedback is only indirectly communicated by means of the scientific opinions without a facilitated dialogue.

Therefore, we once more list our detailed opinion in the Annex to this letter, and we seek a reaction from both the risk assessor and the risk manager to our positions. We are open to explain our reasoning in more detail with EFSA's Standing working group on annual PMEM reports and the European Commission in person, in case this could help clarifying our arguments.

As a final note, we formally remind the European Commission that the 2012 cultivation season was the last year during which MON 810 was protected with a patent in the EU. As a result, as from the 2013 growing season Monsanto has neither legal nor practical means to ensure that the monitoring being conducted will represent all MON 810 plantings in the EU. We have presented several options to you in terms of monitoring coordination (*e.g.*, in our letter of 18 March 2013) to which we hope to receive feedback at your earliest convenience.

Yours sincerely,

[redacted]

cc of letter: S. Brown, S. Pelsser, E. Poudelet (European Commission)

E. Waigmann, S. Mestdagh (EFSA)

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