European Crop Protection

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DG IPOL Report on Impact of 1107/2009

Dear Ms Malmros

I am writing with regard to the exchange that took place in in the PEST Committee on 27 September 2018 on the report produced by DG IPOL on "The impact of Regulation (EC) No 1107/2009 on innovation and development of alternatives and new plant protection products."

From following the discussion, it seems that questions were raised around the accuracy of some of the numbers used by the author. The author referenced ECPA's written responses to the PEST Committee as a source.

In order to support the work of the Committee I thought it would be useful to explain the methodology that lay behind these numbers, and to clarify that the numbers are factually correct, and to explain why they are different from the numbers that have been provided by the Commission.

Two elements in the report were questioned:

1. Number of active substances

The IPOL report (p4) refers to our written response to the PEST Committee, which said:

> *"Due to the strict nature of EU legislation the number of substances on the market has decreased. In 2000 there was over 900 substances authorised, by 2008 that number was down to 425. The number in 2018 stands at 352, including 75 for bio control"*.

This number differs from those provided by the Commission because they do not represent the same analysis of the number of substances on the market and were not designed to be directly compared. Our Association represents manufacturers of synthetic chemical substances (even if our member companies are also active in the biologicals sector) and our numbers represent the number of synthetic chemical active substances approved and commercialised on the EU market.

To understand the answer, it is also useful to refer back to the question we were asked at the time. This answer was given in response to question 15 of the written questions we received before the PEST Committee which asked, "What aspects of the approval process could be reformed?" The answer was given through the prism of the approval process as it relates to our industry sector alone, rather than all sectors our member companies are engaged in, and the figures were extracted from the same database used by the Commission to provide its figures.

2. Number of applications for approval

The IPOL report (p4) states that:

> *"Since 2011, there have been applications for approval of 22 new ASs, of which 12 have been approved, two not approved and eight are pending a decision on approval. During the same period, there have been 148 applications for the renewal of ASs, of which 32 have been approved, eight not approved, 20 voluntarily withdrawn and 88 are still pending a decision on renewal of approval".*

This number was questioned by the Commission representative during the Committee exchange on the report. The author referenced our reply to question 17 of the written responses we submitted to PEST. This response, like with the number of active substances, only related to the numbers for our industry sector, not the total number of applications. The Commission was referring to all applications. Our full answer submitted to PEST, and the question itself, made it clear that we only referred to ECPA member companies:

> *"17. How many dossiers have been submitted by the ECPA's member companies since 2011 under Reg. 1107/2009 and how many have been approved for use, withdrawn or rejected?"*

ECPA answered:

> *"According to data compiled from the European Commission database, the EFSA register of questions as well as a screening of publications in the Official Journal of the European Union, we collected the following estimation. Since June 2011 under Regulation (EC) 1107/2009 ECPA member companies have submitted 22 applications for approval of a new active substance. Of these 12 have been approved, 2 not approved and 8 are pending a decision on approval."*

I hope this helps to clarify any questions which existed over the accuracy of the numbers, and I would be happy to provide any further explanation which would prove useful to the work of the Committee.

Yours sincerely

Jean-Philippe Azoulay
Director General