Follow up to the European Parliament non-legislative resolution on the draft Commission implementing regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin

1. **Resolution tabled pursuant to Rule 112(2) and (3) of the European Parliament's Rules of procedure**

2. **Reference numbers:** 2019/2925(RSP) / B9-0230/2019 / P9_TA-PROV(2019)0099

3. **Date of adoption of the resolution:** 18 December 2019

4. **Competent Parliamentary Committee:** Committee on Environment, Public Health and Food Safety (ENVI)

5. **Brief analysis/assessment of the resolution and requests made in it:**

The resolution relates to the extension of the approval of a number of active substances, notably dimoxystrobin and mancozeb. It refers to the ongoing procedures for the renewal of the approvals and earlier extensions (**recitals B, C, E, F** and **G**) and recalls the objectives and certain provisions laid down in Regulation (EC) No 1107/2009 (**recitals H, I, J, K, L, N, P** and **T**). It refers to various hazard properties of the substances, such as endocrine disrupting potential of dimoxystrobin (**recital M**), toxicity to reproduction and aquatic toxicity for mancozeb (**recitals O** and **S**), and the inclusion of dimoxystrobin in the 'list of candidates for substitution' by the Commission Implementing Regulation (EU) 2015/408 (**recital M**). The resolution claims that applicants can take advantage of automaticity in the Commission's working methods which immediately extends the approval periods of active substances if the risk reassessment has not been finalised, by deliberately prolonging the reassessment process by providing incomplete data and asking for derogations and special conditions (**recital U**). It recalls the European Parliament's earlier resolution of 13 September 2018 on the matter of extension of approvals (**recital V**), and the position of the Dutch Parliament on the same matter (**recital W**).

The resolution states that the draft Commission regulation exceeds the implementing powers provided for in Regulation (EC) No 1107/2009 (**paragraph 1**) concerning the placing on the market of plant protection products.

The resolution claims that the draft Commission implementing regulation does not respect the precautionary principle; that the decision to extend the approval period for dimoxystrobin and mancozeb is not in line with the safety criteria laid down in Regulation (EC) No 1107/2009, and is based neither on evidence that these substances can safely be used, nor on a proven urgent need for the active substances in food production in the Union (**paragraphs 2** and **3**).

It calls on the Commission:

- to withdraw its draft implementing regulation and submit a new draft to the Standing Committee on Plants, Animals, Food and Feed that takes into account the scientific evidence on the harmful properties of all the substances concerned, especially those of dimoxystrobin and mancozeb (**paragraph 4**);

– to present proposals for non-renewal of dimoxystrobin and mancozeb in the next meeting of the Standing Committee on Plants, Animals, Food and Feed (**paragraph 5**);

– only to present draft implementing regulations to extend the approval periods of substances for which the current state of science is not expected to lead to a Commission proposal for non-renewal of the authorisation of the active substance concerned (**paragraph 6**);

– to withdraw the approvals for substances if proof or reasonable doubt exists that they will not meet the safety criteria laid down in Regulation (EC) No 1107/2009 (**paragraph 7**).

It further calls on the Member States to ensure the timely reassessment of authorisations for active substances for which they are rapporteur Member States and to solve current delays effectively (**paragraph 8**).

6. Responses to requests and overview of actions taken, or intended to be taken, by the Commission:

The Commission would first like to note in reaction to **paragraph 4** that following the favourable opinion of the Standing Committee on Plants, Animals, Food and Feed on 22 October 2019, the draft regulation was adopted and published on 29 November 2019 as Regulation (EU) 2019/2094.

Regarding **paragraph 1**, the Commission would like to point out that the draft regulation has been processed in line with the procedural steps set out in Regulation (EC) 1107/2009 as illustrated for the specific cases of dimoxystrobin and mancozeb below:

- An application for the renewal of approval of the active substance **dimoxystrobin** was submitted on 24 July 2013 and in accordance with the applicable legislation the technical dossier containing the necessary information on 31 July 2015.
- The Rapporteur Member State should have delivered its draft renewal assessment report one year later, i.e. by end of July 2016. However, the Rapporteur Member State only delivered the draft report on September 2017 i.e. more than 1 year late.
- The European Food Safety Authority (EFSA) put on hold the peer-review process to align it with the process for reviewing the classification of the substance by European Chemicals Agency (ECHA), as the Rapporteur Member State intended to submit a proposal to amend the existing classification under Regulation (EC) 1272/2008 (the Regulation on the classification, labelling and packaging of chemical substances). However, the Rapporteur Member State only did so in May 2019.
- Furthermore, in accordance with Article 13(3) of Commission Implementing Regulation (EU) No 844/2012, EFSA requested additional information from the applicant on 25 July 2019 to clarify whether the substance has endocrine disrupting properties according to the new scientific criteria adopted in Commission Regulation (EU) 2018/605. The applicant delivered the additional data within the deadline established by EFSA and is now under assessment by the Rapporteur Member State to be followed by a peer-review led by EFSA.
- An application for the renewal of approval of the active substance **mancozeb** was submitted on 30 June 2013 and in accordance with the applicable legislation the technical dossier containing the necessary information on 31 July 2015.

- The Rapporteur Member State should have delivered its draft renewal assessment report one year later, i.e. by end of July 2016. However, the Rapporteur Member State only delivered the draft report in September 2017, i.e. more than one year late.
- EFSA made available its conclusion on the peer review process for mancozeb on 17 June 2019, i.e. with about one year delay as EFSA awaited the opinion of the Risk Assessment Committee (RAC) of the ECHA on the classification of mancozeb, which was adopted in March 2019. The Commission is in the process of preparing a review report and a draft regulation as foreseen in Article 14(1) of Regulation (EU) No 844/2012 following initial discussions with the Member States in the Standing Committee. A vote will be scheduled as soon as possible, after which the Commission will be able to adopt the regulation.

Consequently, the decision-making process on the renewal of the approval of dimoxystrobin and mancozeb could not be concluded before the expiry of the earlier approval period, which was 31 January 2020. All of the delays incurred are beyond the control of the applicant.

Therefore, in accordance with the provisions of Article 17 of Regulation (EC) No 1107/2009, the Commission was obliged to extend the approval periods for dimoxystrobin and mancozeb. The same reasoning applies to the other substances concerned for which the decision-making process on the renewal of approval could also not be finalised before the respective expiry dates of their approval. In case the assessment procedure of a substance can be concluded before the end of the extended approval period, the decision on the renewal or non-renewal of this substance will be adopted at the earliest possible date, and in case of non-renewal of the approval, the extension granted will be rescinded.

The Commission regrets that Article 17 has to be applied regularly because of considerable delays in concluding the renewal processes for active substances. Deviations from the time limits for the renewal process set in Implementing Regulation (EU) No 844/2012 occur for various reasons, but primarily during the assessment by the Rapporteur Member State.

The Commission, therefore, considers that by adopting a regulation that fully complies with the procedural steps and legal requirements set out by the co-legislators in the Plant Protection Products legislation, the Commission does not exceed its implementing powers. Consequently, there are no reasons to withdraw the regulation.

At the meeting of the European Parliament's Committee on the Environment, Public Health and Food Safety on 2 December 2019, the Commission extensively explained the state of play of the authorisation procedure and why it had not exceeded its implementing powers.

With respect to the **other provisions of the resolution**, the Commission considers that they fall outside the remit of the right of scrutiny, which is limited to the question of whether the draft implementing act exceeds the implementing powers provided for in the basic act. The Commission is not required to justify the draft implementing act as regards these points. Nevertheless, the Commission has carefully considered the positions expressed by the European Parliament and would like to make the following comments:

In relation to **paragraphs 2** and **3**, **as well as recitals M** and **T,** the Commission points out that Article 17 of Regulation (EC) No 1107/2009 reflects the choice of the co-legislators that it has to be fully demonstrated that the criteria for approval of the active substance in accordance with Article 4 are expected to be fulfilled before a decision on the renewal of approval of an active substance is taken. Article 17 of that regulation does not distinguish between substances meeting the cut-off criteria, substances meeting the criteria to be identified as candidates for substitution, and substances that do not meet these criteria. As to the specific properties referred to in the resolution, the Commission would like to note that

dimoxystrobin was identified as an endocrine disruptor under the interim criteria specified in Regulation (EC) No 1107/2009 prior to the adoption of the scientific criteria in Regulation (EU) No 2018/605. The interim criteria are no longer valid and dimoxystrobin was not identified as a potential endocrine disruptor in the study underpinning the impact assessment conducted prior to the adoption of Commission Regulation (EU) 2018/605.

As regards **paragraphs 5, 6,** and **7**, the Commission would like to emphasise that at the current state of the procedure, there are no clear indications that the approval of dimoxystrobin could not be renewed. This is different from other cases, e.g. chlorpyrifos or chlorpyrifos-methyl, where during the peer-review of the draft assessment delivered by the Rapporteur Member State clear evidence emerged that the approval criteria are no longer met. The Commission has withdrawn the approval of these two substances rather than extended the current approvals to complete the full assessment. For mancozeb, the Commission will in the near future present a draft regulation to the Standing Committee on Plants, Animals, Food and Feed. A vote will be scheduled as soon as possible, after which the Commission will be able to adopt the regulation.

As regards **paragraph 8**, the Commission shares the European Parliament's view that the Member States should deliver their assessment reports on time.

In conclusion, the Commission considers that it is implementing the regulatory framework agreed by the co-legislators, which in fact obliges the Commission to adopt the Commission regulation upon meeting the conditions set out in Article 17 of Regulation (EC) No 1107/2009. Therefore, the Commission did not exceed its implementing powers.