Follow up to the European Parliament non-legislative resolution on Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole

(Active substances, including flumioxazine)

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

2. **Reference numbers:** 2019/2825 (RSP) / B9-0103/2019 / P9_TA-PROV(2019)0026

3. **Date of adoption of the resolution:** 10 October 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 approval of the active substance flumioxazine. It refers to various hazard properties, *e.g.* toxic for reproduction category 1B and very toxic to aquatic life (**recitals H** and **K**). It further notes that the European Food Safety Authority (EFSA) concluded already in 2014 and subsequently in 2017 and 2018 that there were critical areas of concern (**recital L**)**,** its inclusion in the 'list of candidates for substitution' by Commission Implementing Regulation (EU) 2015/408 (**recital M)** and that flumioxazine has a high risk of bioconcentration, is highly toxic to algae and aquatic plants as well as moderately toxic to other species (**recital P**). It claims that applicants can take advantage of automaticity in the European Commission's working methods which immediately extend the approval periods of active substances if the risk reassessment has not been finalised, by prolonging the reassessment process on purpose by providing incomplete data and asking for derogations and special conditions (**recital S**). It recalls the European Parliament's earlier resolution of 13 September 2018 on the matter of extension of approvals (**recital P**), and the position of the Dutch Parliament on the same matter (**recital T**).

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 and that the decision to extend the approval period for flumioxazine is not in line with the safety criteria laid down in Regulation (EC) No 1107/2009, and is based neither on evidence that this substance can safely be used, nor on a proven urgent need for the active substance flumioxazine in food production in the Union (**paragraphs 2** and **3**).

It calls on the Commission:

– to withdraw its draft implementing regulation and to submit a new draft to the Committee that takes into account the scientific evidence on the harmful properties of all the substances concerned, especially of flumioxazine (**paragraph 4**);

– 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 5**);

– 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 6**).

It further calls on 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 7**).

6. Responses to the 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 15 April 2019, the draft Regulation was adopted on 7 May 2019 and published on 8 May 2019 as Regulation (EU) 2019/707.

Regarding **paragraph 1** of the resolution, 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) No 1107/2009 as illustrated for the specific case of flumioxazin below:

- An application for the renewal of approval of the active substance flumioxazin was submitted on 29 February 2012.
- The Rapporteur Member State delivered the draft report on 4 March 2013.
- EFSA launched the public consultation on the draft report on 18 March 2013. The Authority sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[1] on 5 June 2014.
- According to the provisions of Article 17 of Regulation (EU) No 1141/2010, the Commission referred a draft review report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 3 December 2014 proposing not to renew the approval of flumioxazin as, given the harmonised classification as toxic to reproduction category 1B, flumioxazin met the so called cut-off criteria according to Annex II of Regulation (EC) No 1107/2009.
- However, Regulation (EC) No 1107/2009 foresees two derogation possibilities from the cut-off criteria (i.e. negligible exposure or essential use to control a serious danger to plant health which cannot be contained by other available means) and, given that the applicant had submitted relevant information, it was then required to assess whether at least one of these was met before adopting the decision.

[1] EFSA Journal 2014;12(6):3736. Conclusion on the peer review of the pesticide risk assessment of the active substance flumioxazin. doi:10.2903/j.efsa.2014.3736. Available online : www.efsa.europa.eu/efsajournal.

- As flumioxazin was one of the first cases for which the derogations were invoked, in particular the first herbicide, both assessments required the development of the relevant assessment methodologies, which did not yet exist at the time.
- The draft technical guidance[2] to assess negligible exposure was developed by the Commission and Member States in 2015 whereas the methodology[3] to assess the essential use of herbicide active substances was developed by EFSA in 2016 and the applicant was then given six weeks to submit updated information in line with the new methodology. This led EFSA to finalise on 15 December 2016 a Scientific Report Evaluation of data concerning the essential use[4] of flumioxazin and on 31 August 2018 a conclusion on the peer review of the pesticide risk assessment in light of negligible exposure[5]
- In parallel, on 1 February 2018, the Rapporteur Member State in light of new scientific data submitted a proposal for harmonised classification and labelling of flumioxazine to the European Chemicals Agency (ECHA) under Regulation (EC) No 1272/2008. On 15 March 2019, the Risk Assessment Committee (RAC) of ECHA adopted an opinion modifying the classification of flumioxazin from toxic for reproduction category 1B to toxic for reproduction category 2[6]. The substance, therefore, appears to no longer meet the cut-off criteria according to Annex II of Regulation (EC) No 1107/2009. In line with Article 14 (1a) of Regulation (EU) No 844/2012, the Commission will mandate EFSA to assess the endocrine disrupting potential of flumioxazin according to the new criteria from Regulation (EU) No 2018/605 (the mandate is currently under preparation).

Consequently, the decision-making process on the renewal of the approval of flumioxazin could not possibly be concluded before the expiry of the earlier expiry date of its approval, which was 30 June 2019. 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 period for flumioxazin. 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. The Commission, therefore, considers that by adopting a regulation that fully complies with the procedural steps 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.

---

2 https://ec.europa.eu/food/sites/food/files/safety/docs/adv-grp_wg_20150625_tech-guidance.pdf

3 EFSA (European Food Safety Authority) , Dehnen-Schmutz K., Bastiaans L., Chauvel B., Gardi C., Heppner C., Koufakis I., 2016. Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA supporting publication 2016:EN-1060. 18 pp.
EFSA (European Food Safety Authority), 2017. Scientific report on the evaluation of data concerning the necessity of flumioxazin as a herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA Journal 2017;15(1):4688, 33 pp.

5 EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment for the active substance flumioxazin in light of negligible exposure data submitted. EFSA Journal 2018;16(9):5415, 16 pp.

6 CLH-O-0000001412-86-276/F.

At the meeting of the Committee on the Environment, Public Health and Food Safety of the Parliament on 25 September 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 Parliament and would like to make the following comments:

In relation to **paragraphs 2** and **3**, 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 regards, **paragraphs 5** and **6**, the Commission would like to note that in case a substance meets the cut-off criteria, it is obliged to verify whether one of the two derogation possibilities is met, which in the case of flumioxazine required the development of new methodologies as explained above and was subject to subsequent developments in relation to substance classification and meeting of the cut-off criterion in the first place. At the current state of the procedure, there is no great certainty that the approval of flumioxazine 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 proposed to withdraw the approval of these two substances rather than to extend the current approvals to complete the full assessment.

As regards **paragraph 7**, the Commission shares the Parliament's view that 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 obliged 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.