Follow up to the European Parliament non-legislative resolution on the draft Commission regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cycloxydim, flonicamid, haloxyfop, mandestrobin, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione in or on certain products

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

2. **Reference numbers:** 2020/2734 (RPS) / B9-0254/2020 / P9_TA-PROV(2020)0238

3. **Date of adoption of the resolution:** 17 September 2020

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 calls on the Commission to withdraw the draft Commission regulation and to submit a new one (**paragraph 12**), based on the following grounds:

- The draft Commission regulation is not compatible with the aim and content of Regulation (EC) No 396/2005 (**paragraph 2**);
- The Union and the Commission should respect the principle of environmental responsibility, and should not encourage the use in third countries of products that some Member States ban on their territory and of which the Union is trying to restrain the use (**paragraph 3**);
- Free trade rules should never lead to a lowering of the Union's protective standards (**paragraph 4**);
- The resolution acknowledges that the European Food Safety Authority (EFSA) is working on methods to assess cumulative risks, but also notes that the problem of the assessment of cumulative effects of pesticides and residues has been known for decades. It therefore requests EFSA and the Commission to address the problem as a matter of absolute urgency (**paragraph 5**).
- Specific concerns are reported in relation to the proposed increased maximum residue levels (MRLs) for the following substance/crops combinations:
    - **Flonicamid** in strawberries, blackberries, raspberries, other small fruits and berries, radishes, other root and tuber vegetables, lettuces and salad plants, and pulses (**paragraphs 6 and 7**). In the justification (**recitals C and D**), the objector refers to the opinion of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) on the classification of flonicamid, views of the Danish authorities on malformations caused by the substance and that the substance is under scrutiny in the United States for potentially posing a higher risk to pollinators than previously understood based on new studies submitted by the flonicamid manufacturer;
    - **Haloxyfop-P** in linseeds (**paragraphs 8 and 9)**. In the justification **(recitals F, G, H, I, and J)**, the objector refers to various toxicological effects of the

active substance, the fact that products containing it are not authorised in France, and restrictions of use imposed in the approval conditions because of adverse effects in the aquatic environment**;**

- **Mandestrobin** in grapes and strawberries. No particular justification is provided (**paragraphs 10 and 11**).

6. Response to the requests in the resolution and overview of the action taken, or intended to be taken, by the Commission:

The Commission considers that the draft regulation is fully in line with the provisions laid down in Regulation (EC) No 396/2005. It is based on applications for MRLs (either domestic uses or import tolerances) and a scientific opinion of the Evaluating Member State and EFSA confirming the safety of the MRLs for consumers, which was developed following the procedure outlined in Articles 6 to 11 of Regulation (EC) No 396/2005.

The Commission affirms that the draft Commission regulation is in line with the procedural steps set out in Council Decision 1999/468/EC on comitology and Regulation (EC) No 396/2005, and that it is therefore within the implementing powers conferred on the Commission in this latter regulation. Moreover, the Standing Committee on Plants, Animals, Food and Feed had given a favourable opinion on the draft act and the Council has decided not to oppose it.

In relation to **paragraph 3**, the Commission clarifies that two of the substances specifically mentioned in the resolution are approved for use in the EU (flonicamid and mandestrobin), whilst the MRLs for haloxyfop relate to the active substance haloxyfop-P[1], which is also approved in the EU and used in plant protection products in many Member States.

The Commission agrees with **paragraph 4** of the resolution that free trade rules should not lead to a lowering of the Union's protective standards and emphasises that EFSA has confirmed that the proposed MRLs (including for imports) are safe to consumers and that they fully comply with the Union's protective standards (maximum residue levels).

The Commission also agrees that working on methods to assess cumulative risks is a matter of high importance as mentioned in **paragraph 5,** and refers to the action plan on priorities for the development and the subsequent implementation of the methodology that it intends to deliver jointly with EFSA by end of 2020, as stated in the report to Council and Parliament on the REFIT evaluation of the pesticides legislation.

As regards flonicamid (**paragraphs 6 and 7**), and in relation to **recitals C and D,** the Commission notes that based on the opinion of RAC referred to by the Parliament, flonicamid is not classified as toxic for reproduction. The Commission further notes that, as it is usual practice for all active substances, also for flonicamid the risk to bees has been comprehensively addressed under Regulation (EC) No 1107/2009. Active substances can only be approved if they have no unacceptable adverse effects on bees and all other safety requirements are met. The active substance was approved in the EU in 2010 based on EFSA conclusions, which specified that the substance was of low toxicity to bees.

Plant Protection Products containing flonicamid are currently authorised in 25 Member States. Member States can only authorise products that have no unacceptable effects on bees. The MRLs proposed in the draft regulation are linked to new product authorisations for root crops, leaf

[1] In order to enforce the correct use of haloxyfop-P, EFSA and the EU reference laboratories for pesticide residues recommended setting a residue definition covering all relevant metabolites in the framework of the Article 12 review under Regulation (EC) No 396/2005. Although haloxyfop cannot be used on any crop in the EU, residues of the substance will be found following the lawful use of haloxyfop-P

vegetables, berries and pulses, for which Member States have conducted such an assessment and have concluded that they are safe for bees.

The scrutiny of flonicamid in the US, **recital D,** refers to a letter of the Attorney General of California who requested the US Environmental Protection Agency (EPA) to conduct a full risk assessment before new uses in the US are authorised and does not contain any new information on the possible risk to bees. In the meantime, the US EPA has carried out such a comprehensive assessment and published in April 2020 an interim decision, including a Pollinator Advisory Statement[2]. In that context, the US EPA proposed risk mitigation measures and label changes with a view of protecting pollinators, similar to what is currently done in the EU. The interim decision is currently under public consultation until 2 November 2020 and will become a final one after consideration of the comments received.

The approval of flonicamid expires on 31 August 2023, and the interested companies have meanwhile submitted an application to renew the approval. Flonicamid will then be re-evaluated by a Member State and EFSA in the context of the renewal of approval procedure. Any new scientific information that may have become available by then will be included in the assessment.

As regards haloxyfop-P (**paragraphs 8 and 9**), the draft regulation intends to establish an import tolerance for haloxyfop in linseeds at 0.05 mg/kg, which is based on an authorised use of the active substance in Australia and which is safe for consumers. Haloxyfop-P is also approved as an active substance in the EU until 31 December 2020 and products containing it are currently authorised in 10 Member States for the use in plant protection products. Since EFSA identified some risks for groundwater and aquatic organisms, use restrictions were established in the EU which address and mitigate the risks and which need to be implemented by Member States when granting authorisations.

As regards mandestrobin (**paragraphs 10 and 11**), the Commission notes that Regulation (EC) No 396/2005 foresees that MRL applications in relation to EU uses and uses in third countries are treated equally in terms of consumer safety and data requirements. The active substance is approved in the EU until 9 December 2025 and products containing it are authorised in 6 Member States. According to the Good Agricultural Practices (GAPs) in Canada, MRLs of 3 mg/kg and 5 mg/kg are needed for strawberries and grapes, respectively, to combat the Botrytis grey mould, which would impact the yield and quality of the final products. Although no harmonised Codex Alimentarius maximum residue limits (CXLs) are established for this substance, these values were established by using international methodologies, which have been agreed by the EU and have been used in the past years.

Since EFSA confirmed that the MRLs are safe and fully supported by data, the values should be implemented in the annexes to Regulation (EC) No 396/2005 to achieve one of its basic objectives, which is facilitating trade (as referred to in Article 3(2)(g) of the regulation). In the specific case of mandestrobin, not setting the proposed MRLs would pose unnecessary trade barriers for the importation of the relevant crops, which are safe to EU consumers. In fact, the substance has a low toxicity profile and it was not necessary to establish an acute reference dose.

The Commission regrets that the European Parliament has rejected this measure, which is based on the scientific assessment of the European Food Safety Authority. Such decisions undermine the EU's well-established science-based approach to food safety.

Following the objection of the European Parliament, which prevents the Commission from adopting the draft regulation, the Commission is reflecting on the options for further action.

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[2] US EPA - Flonicamid Proposed Interim Registration Review Decision Case Number 7436 http://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0777-0032