**Follow-up to the European Parliament non-legislative resolution on the draft Commission regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benomyl, carbendazim and thiophanate‐methyl in or on certain products**

**1.** **Resolution tabled pursuant to Rules 115(2) and (3) and (4)(c) of the European Parliament’s Rules of procedure**

**2.** **Reference numbers:** 2024/2758 (RPS) / B10-0020/2024 / P10\_TA(2024)0006

**3.** **Date of adoption of the resolution:** 18 September 2024

**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 draft Commission regulation intends to amend Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels (MRLs) for three non-approved active substances benomyl, carbendazim and thiophanate-methyl in or on certain products. The resolution only focuses on carbendazim and thiophanate-methyl.

The approval for carbendazim expired in 2014 while for thiophanate-methyl its approval was not renewed by Regulation (EU) 2020/1498.

The draft regulation proposes to set at the limit of determination (LOD) 623 out of the 630 existing MRLs for both carbendazim and thiophanate-methyl, while maintaining only 7 MRLs above the LOD.

The lowering of existing MRLs to the LOD is notably necessary for those MRLs for which the European Food Safety Authority (EFSA) identified potential risk for consumers, namely for the MRLs for carbendazim in grapefruits, oranges, papayas, and mangoes, and for the MRLs for thiophanate-methyl in grapefruits, oranges, mandarins, papayas, and mangoes.

On the other hand, EFSA found three existing MRLs for carbendazim (lemons, limes and mandarins) and one MRL for thiophanate-methyl (limes) safe for consumers and therefore the draft regulation intends to maintain these at current levels.

Finally, the draft regulation intends to lower one current MRL for carbendazim (in okra) and two MRLs for thiophanate-methyl (lemons and okras) based on good agricultural practices authorised in third countries, which EFSA also found safe for consumers.

The resolution objects to maintaining MRLs for imported products above the LOD due to the competitive disadvantages for EU farmers (**recitals A, B, C and Z**), carbendazim being classified in accordance with Regulation (EC) No 1272/2008 as ‘mutagen (category 1B)’ and ‘toxic for reproduction (category 1B)’ (**recitals E, R and S**), thiophanate-methyl being classified in accordance with the same regulation as ‘mutagen (category 2)’ and ‘reproductive toxicant (category 2)’ (**recitals K, R and S**) and having endocrine related effects (**recitals K, L and X1**) and both substances being classified in accordance with the same regulation as ‘very toxic for aquatic life and very toxic for aquatic life with long-lasting effects’ (**recital F**). In addition, the resolution refers to the Commission’s Farm to Fork Strategy, where the Commission has stated that “*the EU will consider, in compliance with WTO (World Trade Organization) rules and following a risk assessment, to review import tolerances for substances meeting the "cut-off criteria and presenting a high level of risk for human health*” (**recital V**).

The resolution states that the draft Commission regulation is not compatible with the aim and content of Regulations (EC) No 396/2005, (EC) No 178/2002 and (EC) No 1107/2009 (**paragraph 2**), and calls on the Commission to withdraw the draft regulation (**paragraph 3**), to submit a new draft lowering all MRLs for carbendazim and thiophanate-methyl to the relevant LOD and to refuse any request for import tolerances (**paragraph 4**). The resolution makes reference to the recent proposal of the Commission to precautionarily lower all the MRLs for thiacloprid pending the conclusion of an additional risk assessment (**recital O**).

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

With respect to **paragraph 2** of the resolution, the Commission considers that the draft regulation is fully in line with the provisions and objectives of Regulation (EC) No 396/2005 (the MRL Regulation), Regulation (EC) No 1107/2009 (the PPP Regulation) and Regulation (EC) No 178/2002 (the General Food Law). The objection by the Parliament is preventing the Commission from adopting the regulation.

Regarding **paragraph 3**, the Commission considers that in proposing the draft regulation it was correctly implementing the regulatory framework agreed by the co-legislators in line with its aim and content and observes that the Parliament’s objection prevents the Commission from proceeding with its adoption.

The request from the European Parliament to lower all MRLs to the LOD, because the active substances are classified as toxic for reproduction (category 1B), is not in compliance with Regulation (EC) No 396/2005 nor with the World Trade Organization’s Sanitary and Phytosanitary (SPS) Agreement.

While it is correct that carbendazim and thiophanate-methyl meet the so called "cut-off criteria" set by Regulation (EC) No 1107/2009, it is possible to establish a safe threshold of exposure below which no adverse health effects are expected to occur, allowing to establish safe MRLs. This is the case for carbendazim and thiophanate-methyl, for which, contrary to what is referred to in the resolution, EFSA established an acceptable daily intake (ADI) of 0.02 mg/kg bodyweight per day and an acute reference dose (ARfD) of 0.02 mg/kg body weight per day.

Concerning the reference made to the draft regulation on MRLs for thiacloprid, it must be emphasised that the decision to lower all the MRLs for thiacloprid to the LOD was not based on the fact that thiacloprid is classified as toxic for reproduction category 1B, but on the uncertainty regarding its potential endocrine-disrupting effects, which are not necessarily covered by its current toxicological reference values. The situation for carbendazim and thiophanate-methyl is fundamentally different.

As regards the request in **paragraph 4** to refuse any requests for import tolerances, Regulation (EC) No 396/2005 stipulates that MRL applications in relation to uses in the Union and in third countries are treated equally in terms of consumer safety and data requirements. Refusing import tolerances that are submitted in accordance with the procedure outlined in Articles 6 to 11 of Regulation (EC) No 396/2005 and for which EFSA confirms that they are safe for consumers would contravene the provisions of that Regulation (EC) No 396/2005 and go against the EU’s international obligations under the WTO’s SPS Agreement.

The Commission takes note of the Parliament’s position. It regrets that the Parliament’s objection prevents the Commission from adopting the draft regulation. The Commission is currently reflecting on what next steps to pursue.