**Follow-up to the European Parliament non-legislative resolution on the draft Commission regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyproconazole and spirodiclofen 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:** 2024/2759 (RPS) / B10-0021/2024 / P10\_TA(2024)0007

**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 and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels (MRLs) for two non-approved active substances cyproconazole and spirodiclofen in or on certain products. The resolution only focuses on cyproconazole.

The draft regulation intends to lower the MRLs of cyproconazole to the limit of determination (LOD) for 273 out of 315 existing MRLs. Cyproconazole is no longer approved as an active substance for use in the EU. The approval expired because no application for renewal was submitted, therefore all existing authorisations in the EU have been revoked.

20 MRLs based on Codex Alimentarius maximum residue limits (CXLs) are proposed to be maintained and 22 MRLs are proposed to be reduced to the CXL which is established at a lower level. All these MRLs have been examined in detail case by case and found safe for EU consumers by the European Food Safety Authority (EFSA).

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 R**), cyproconazole being classified in accordance with Regulation (EC) No 1272/2008 as ‘toxic for reproduction’ (category 1B), toxic if swallowed (acute tox. 3), toxic to the liver (STOT RE 2) as well as very toxic for aquatic life (aquatic acute 1) and very toxic for aquatic life with long-lasting effects (aquatic chronic 1) (**recital F**) and cyproconazole belonging to the triazole group of ergosterol-biosynthesis inhibitors, and thus potentially causing endocrine-disrupting effects (**recital G**). According to the resolution, all MRLs of cyproconazole, based on former EU uses and CXLs, should be lowered to the LOD to ensure a high level of human health protection (**recital M, P, O and V**).

The resolution claims that based on a number of publications, azole fungicides constitute a significant source of the increasing incidence of environmental resistance to *Aspergillus* spp and that EFSA’s scientific report is not yet published but is expected by end of December 2024 (**recital N**).

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 the 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 Q**).

The resolution stresses that cumulative and synergistic effects need to be taken into account when setting MRLs and that it is urgent to speed up the development of appropriate methods for this assessment (**recital W**).

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 cyproconazole to the LOD and to refuse any request for import tolerances (**paragraph 4**).

**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). While it is correct that cyproconazole is classified as toxic for reproduction, category 1B and therefore meets the so called "cut-off criteria" set by Regulation (EC) No 1107/2009, it is possible, for this specific effect – toxicity for reproduction – to establish a safe threshold of exposure for certain substances, below which no adverse health effects are expected to occur, allowing to establish safe MRLs. Cyproconazole is one of these substances and EFSA was able to establish toxicological reference values (acceptable daily intake (ADI) and acute reference dose (ARfD)) and to perform a risk assessment in which it concluded that the MRLs based on CXLs are safe for consumers. The objection by the Parliament is preventing the Commission from adopting the regulation.

Regarding **paragraphs 3 and 4**, 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 substance is classified as toxic for reproduction (category 1B), is not in compliance with Regulation (EC) No 396/2005. It is also not compatible with the World Trade Organization’s Sanitary and Phytosanitary (SPS) Agreement, given that, based on EFSA’s risk assessment, MRLs above the LOD can be established that are safe for consumers.

As regards the request in **paragraph 4** to refuse any requests for import tolerances, the Commission underlines that no MRLs based on import tolerance requests were proposed for cyproconazole. All proposed MRLs above the LOD were only based on CXLs. Furthermore, 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 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.