**Follow up to the European Parliament resolution on Commission Implementing Regulation (EU) 2021/621 of 15 April 2021 amending Regulation (EU) No 37/2010
to classify the substance imidacloprid as regards its maximum residue
limit in foodstuffs of animal origin**

1. **Resolution tabled pursuant to Rule 112 (2) and (3) of the European Parliament's Rules of procedure**
2. **Reference numbers:** 2021/2705 (RSP) / B9-0313/2021 / P9\_TA(2021)0284
3. **Date of adoption of the resolution:** 10 June 2021
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 setting of a maximum residue limit (MRL) for the active substance imidacloprid, to be included in veterinary medicines for food-producing animals.

It refers to the procedure for establishing MRLs and the European Medicines Agency (EMA) opinion on MRL for imidacloprid (**recitals H, I, J** and **K**), noting that such an opinion should be made publicly available and should be easily accessible (**recital L**). It considers that ensuring that the risk assessment process is transparent promotes public understanding, contributes to giving EMA greater legitimacy in the eyes of consumers and the general public and provides greater accountability to Union citizens in a democratic system (**recital M**).

It further notes the European Chemicals Agency (ECHA) assessment report of 18 February 2011 (**recital C**) and the chemical characteristics of imidacloprid (**recital N**) and notes that Commission Implementing Regulation (EU) 2018/783 bans the use of imidacloprid on all crops grown outdoors, because of its adverse effects on pollinators (**recital O**).

It also considers possible negative impacts of imidacloprid on biodiversity, the potential for contamination of ground and surface water (**recital P**), as well as concerns about impacts on soil quality (**recital Q**).

It notes that the knowledge is lacking of the pollutant effects in the environment of many individual chemicals and chemical mixtures (**recital Z**) and regrets the lack of access to scientific studies submitted to EMA as well as the lack of information on the feasibility of controls on and risk management of waste water discharge into the aquatic environment (**recital AB**).

It notes the new provisions in recently adopted Regulation (EU) 2019/6, on veterinary medicinal products, that risk management decisions should take into account ‘other relevant factors, including societal, economical, ethical, environmental and welfare factors and the feasibility of controls’ **(recitals AA**). It further notes that this Regulation envisages the possible refusal of marketing authorisations for veterinary medicines if risks to public or animal health or to the environment are not sufficiently addressed (**recital AE**).

The resolution states that Implementing Regulation (EU) 2021/621 exceeds the implementing powers provided for in Regulation (EC) No 470/2008 (**paragraph 1**).

The resolution claims that Implementing Regulation (EU) 2021/621 violates the freedom of information and the fundamental principles of transparency, democratic scrutiny, and accountability, insofar as the underlying opinion by the Committee for Medicinal Products for Veterinary Use has only been made available in summary (**paragraph 2**).

It calls on the Commission:

* to repeal Implementing Regulation (EU) 2021/621 and to submit a new draft to the committee including imidacloprid in the list set out in Annex IV to Regulation (EC) No 396/2005 of pharmacologically active substances for which no maximum levels can be fixed for aquatic use **(paragraph 3**);
* to apply the precautionary principle when following an assessment of available information, so that the risk of harmful effects on the environment, biodiversity, animal welfare and human health is quantified **(paragraph 10**);
* to communicate systematically on how the precautionary principle and the principle of informed consent have been taken into account and how the conclusions of the opinion of the Committee for Medicinal Products for Veterinary Use were derived **(paragraph 11**);
* to uphold the democratic principle of informed consent and to undertake a fitness check of the risk assessment process to establish MRLs for veterinary medicinal products in foodstuffs of animal origin; considers it essential that it should be fully consistent as regards the aims referred to in the Commission communication of 11 December 2019 entitled ‘The European Green Deal’, the Commission communication of 20 May 2020 entitled ‘A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system’ and the EU biodiversity strategy for 2030 **(paragraph 12**);
* to ensure that time-cumulative, up-to-date, peer-reviewed, eco-toxicological tests for non-target species in the soil and aquatic environment are included in the risk assessment, and that it also covers environmental residues in the air, soil and water, including the long-term, cumulative toxic effects, and that it specifies the independent, peer-reviewed scientific studies and scientific opinions that were considered; stresses that this information should be publically accessible **(paragraph 13**);
* to submit a legislative proposal to ensure that there is consistency with and coherence as regards Regulations (EU) 2019/6 and (EU) 2019/1381 and all food-related legislation in the event that the risk assessment to establish MRLs is undertaken by agencies other than the European Food Safety Authority (EFSA); and calls on the Commission to ensure also that such assessment is transparent and serves to better protect biodiversity and aquatic ecosystems, insects, earthworms and soil microorganisms **(paragraph 14**).
1. **Response to the requests and overview of the action taken, or intended to be taken, by the Commission:**

The Commission has carefully considered the positions expressed by the European Parliament and would like to make the following comments:

The Commission would first like to note in reaction to **paragraphs 1, 2** and **3** that the procedure for the establishment of MRLs is set out in Regulation (EC) 470/2009 on the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, in its Articles 8, 12, 14 and 17. This regulation establishes MRLs of pharmacologically active substances in foodstuffs of animal origin.

This Commission implementing regulation is fully in line with the implementing powers provided for in the basic act. 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 legislation on MRLs, the Commission does not exceed its implementing powers. Consequently, there are no reasons to repeal the regulation.

Regarding **paragraphs 10** and **13**, the Commission would like to point out that Commission Regulation (EU) 2018/782 on establishing principles for the risk assessment and risk management recommendations, adopted under Regulation 470/2009 lays down the methodology to be used in the scientific risk assessment and the establishment of risk management recommendations relevant to MRL applications.

When preparing an opinion on a MRL, the EMA assessment focusses on the consumer safety of the residues of a substance remaining post-treatment in foodstuffs of animal origin. To this end, EMA has thoroughly examined the possible risks that the residues of imidacloprid could pose to human health and concluded that the proposed MRL values would sufficiently safeguard public health. In its assessment, EMA took due account of the assessment of imidacloprid by the Joint World Health Organization/Food and Agriculture Organization Meeting on Pesticides (JMPR) as well as by EFSA and ECHA.

The Commission would like to recall that an established MRL is a precondition to apply for a marketing authorisation for a veterinary medicine intended for food-producing animals. The active substance cannot be used in food-producing animals until a marketing authorisation is granted for a veterinary medicine. During the assessment of an application for a marketing authorisation for any veterinary medicine under the centralised procedure, the EMA and the Commission examine the safety of the product for human health, animal health and the environment.

In relation to **paragraphs 11** and **14,** the Commission would like to emphasise that the Commission and EMA are fully committed to transparency of the work of EMA, including on the opinions on MRLs of active substances contained in veterinary medicinal products in foodstuffs. Immediately after the EMA opinion is adopted, a summary opinion is published on EMA`s website. Once the Commission publishes the MRL Regulation in the Official Journal of the European Union, the full EMA opinion and the European public MRL assessment report (EPMAR) are published on the EMA website.

During the preparation of its opinion as regards the establishment of MRLs, EMA thoroughly examines the possible risks that residues of the active substances could pose to human health and proposes MRL values that sufficiently safeguard public health.

As regards **paragraph 12**, the Commission would like to point out that Regulation (EU) 2019/6 (regulating veterinary medicinal products), which becomes applicable on 28 January 2022 and will replace the current framework (Directive 2001/82/EC), consolidates environmental protection requirements and puts specific emphasis on fighting antimicrobial resistance.

Regulation (EU) 2019/6 maintains the requirement for the environmental risk assessment, to continue to be part of the authorisation documentation. In addition, environmental incidents observed following the administration of a veterinary medicinal product are considered as adverse events, which are taken into account for the benefit-risk balance of veterinary medicinal products. Article 37(2)(j) also provides for a possibility to refuse a marketing authorisation for a veterinary medicinal product, where the active substance is considered persistent, bioaccumulative and toxic or very persistent, bioaccumulative and toxic and is intended for food-producing animals. In addition, Article 72 of that Regulation provides for a catching-up procedure in respect of veterinary medicinal products authorised before 1 October 2005 and identified as potentially harmful to the environment and which have not been subject to an environmental risk assessment.

The above provisions are in line with the aims of the ‘The European Green Deal’ and the ‘Farm to Fork Strategy’ for a fair, healthy and environmentally-friendly food system.

In conclusion, the Commission considers that it is implementing the regulatory framework agreed by the co-legislators, which obliges the Commission to adopt the Regulation upon meeting the conditions set out in Regulation (EC) No 470/2009. Therefore, the Commission did not exceed its implementing powers.