



2021/2705(RSP)

27.5.2021

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3) of the Rules of Procedure

on Commission Implementing Regulation 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
(2021/2705(RSP))

Committee on the Environment, Public Health and Food Safety

Member responsible: Grace O'Sullivan

B9-0000/2021

European Parliament resolution on Commission Implementing Regulation 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 (2021/2705(RSP))

The European Parliament,

- having regard to 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 origin¹
- having regard to the opinion delivered on 20 April 2021 by the Standing Committee on Veterinary Medicinal Products in regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council², and in particular Articles 14 and 17 thereof,
- having regard to the Charter of Fundamental Rights of the European Union,
- having regard to Articles 13 and 191 of the Treaty of the Functioning of the European Union (TFEU),
- having regard to Articles 11 and 13 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers³,
- having regard to Rule 112(2) and (3) of its Rules of Procedure,
- having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC⁴ provides that no veterinary medicinal product should be allowed to be placed on the market in the Union unless it has been authorised, and its quality, safety and efficacy have been demonstrated and recognises that improved access to information gives the public the opportunity to express its observations and enables authorities to take due account of those observations.

¹ OJ L 131, 16.4.2021, p. 120.

² OJ L 152, 16.6.2009, p. 11.

³ OJ L 55, 28.2.2011, p. 13.

⁴ OJ L 4, 7.1.2019, p. 43.

- B. whereas Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC⁵ provides that information should be provided on how risk management decisions were reached and on the factors, other than the results of the risk assessment, as well as how those factors were weighed up against each other and that risk communication should contribute to a participatory and open dialogue between all interested parties in order to ensure that the prevalence of the public interest, and accuracy, comprehensiveness, transparency, consistency and accountability are taken into account in the risk analysis process,
- C. whereas the European Chemicals Agency (ECHA) assessment report of 18 February 2011 entitled ‘Imidacloprid, Product-type 18 (Insecticides, Acaricides and Products to control other Arthropods)’⁶ categorises significant toxicity data for aquatic and non-target species,
- D. whereas Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy⁷ provides that “The contamination of water and soil with pharmaceutical residues is an emerging environmental concern. In evaluating and controlling the risk to, or via, the aquatic environment from medicinal products, adequate attention should be paid to Union environmental objectives. In order to address that concern, the Commission should study the risks of environmental effects from medicinal products and provide an analysis of the relevance and effectiveness of the current legislative framework in protecting the aquatic environment and human health via the aquatic environment.”
- E. whereas Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market⁸ set out the minimum requirements including information on potentially harmful effects of the active substance, its metabolites and impurities on human and animal health or on groundwater, the environment and non-target species (flora and fauna);
- F. whereas Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market⁹ provides “any information on potentially unacceptable effects of the plant protection product on the environment, on plants plant products shall be included as well as known and expected cumulative and synergistic effects”,

⁵ OJ L 231, 6.9.2019, p. 1.

⁶ <https://echa.europa.eu/documents/10162/225b9c58-e24c-6491-cc8d-7d85564f3912>

⁷ OJ L 226, 24.8.2013, p. 1.

⁸ OJ L 93, 3.4.2013, p. 1.

⁹ OJ L 93, 3.4.2013, p. 85.

- G. whereas Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products¹⁰ notes that “the particulars and documents which must accompany an application for marketing authorization must demonstrate that potential hazards are outweighed by the benefits due to efficacy. Failing such demonstration, the application must be rejected”,
- H. whereas an application for the establishment of a maximum residue limit (MRL) for imidacloprid in *Salmonidae* was submitted to the European Medicines Agency (the ‘Agency’);
- I. whereas the Agency, based on the opinion of 9 September 2020 by the Committee for Medicinal Products for Veterinary Use¹¹, has recommended the establishment of an MRL for imidacloprid at 0,6mg/kg (600 µg/kg) in all fin fish as appropriate;
- J. whereas an MRL for aquatic use has not been established by the Codex Alimentarius¹²; whereas the Joint Food and Agriculture Organization and World Health Organization meeting on pesticide residues of 2008 recommended a maximum acceptable daily intake of 0,06 mg/kg from agricultural crop residues;¹³
- K. whereas the opinion of the Committee for Medicinal Products for Veterinary Use, underlying the Agency’s recommendation has only been made available in summary, and according to the Commission will only be made available in full after the adoption of the MRL;
- L. whereas an opinion with regard to the establishment of an MRL under Union law should be made publicly available and should be easily accessible;
- M. whereas ensuring that the risk assessment process is transparent promotes public understanding, contributes to giving the Agency greater legitimacy in the eyes of consumers and the general public, and provides greater accountability to Union citizens in a democratic system¹⁴;
- N. whereas imidacloprid is a neonicotinoid (NN) biocidal active substance that was commercialised for widespread use to treat crops and livestock due to its toxicity for a broad range of pests; whereas the mode of action of imidacloprid is that it acts as an antagonist of the nicotinic acetylcholine receptors (nAChR) in the central nervous system, thus disturbing synaptic signal transmissions and leading to a lethal hyperactivity of nerves and muscles of animals, vertebrates and invertebrates alike, irreversibly blocking nAChR and leading to paralysis and death¹⁵;

¹⁰ *OJ L 311*, 28.11.2001, p. 1

¹¹ https://www.ema.europa.eu/en/documents/mrl-summary/imidacloprid-fin-fish-summary-opinion-cvmp-establishment-maximum-residue-limits_en.pdf

¹² http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=206

¹³ http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report08/Imidacloprid.pdf

¹⁴ See judgments of the Court of Justice in Case T-235/15, *Pari Pharma GmbH v European Medicines Agency*, ECLI:EU:T:2018:65; see also Case T-718/15, *PTC Therapeutics International Ltd v European Medicines Agency*, ECLI:EU:T:2018:66 and T-729/15, *MSD Animal Health Innovation GmbH and Intervet International BV v European Medicines Agency*, ECLI:EU:T:2018:67 .

¹⁵ Sánchez-Bayo, F., Tennekes, H.A., ‘Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence

- O. whereas Commission Implementing Regulation (EU) 2018/783¹⁶ bans the use of imidacloprid on all crops grown outdoors, because of its adverse effects on pollinators;
- P. whereas hazardous chemicals that are applied under veterinary prescription and used to treat infections of sea lice are ultimately released into the aquatic environment; their effects not only have the potential to negatively impact sensitive non-target organisms, the release of those compounds has been identified as a major environmental concern¹⁷ due to the high mobility of imidacloprid in soil and the resulting contamination of ground and surface water;¹⁸
- Q. whereas there is increasing evidence that the use of imidacloprid has a devastating impact on biodiversity in particular that of rivers and waterways¹⁹, not only affecting crustaceans²⁰, molluscs²¹ and non-target (insect) species but also soil organisms²², as well as bringing declines in bird populations²³; whereas there is increasing concern about the residence and accumulation of pesticide residues and their metabolites in soils and their potential to lead to soil acidification; notes with concern that imidacloprid use in Japan led to a dramatic collapse of fish stocks, which have not recovered²⁴;
- R. whereas the harmonised classification and labelling referred to in Regulation (EC) No 1272/2008 of the European Parliament and of the Council²⁵, categorised imidacloprid

and Implications for Environmental Risk Assessments’, International Journal of Environmental Research and Public Health. 2020,17(5),1629, [IJERPH | Free Full-Text | Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments \(mdpi.com\)](#)

¹⁶ Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (*OJ L 132, 30.5.2018, p. 31*).

¹⁷ Burridge, L., Weis, J.S., Cabello, F., Pizarro, J., Bostick, K., ‘Chemical use in salmon aquaculture: A review of current practices and possible environmental effects’, *Aquaculture*, 2010, volume 306, 1-4, pp. 7-23, <https://www.sciencedirect.com/science/article/pii/S0044848610003297>.

¹⁸ Sánchez-Bayo, F., Tennekes, H.A., ‘Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments’, International Journal of Environmental Research and Public Health. 2020,17(5),1629, [IJERPH | Free Full-Text | Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments \(mdpi.com\)](#)

¹⁹ Butcherine, P., Kelaher, B.P., Taylor, M.D., Barkla, B.J., Benkendorff, K., ‘Impact of imidacloprid on the nutritional quality of adult black tiger shrimp (*Penaeus monodon*)’, *Ecotoxicology and Environmental Safety*, 2020, volume 198,

<https://www.sciencedirect.com/science/article/abs/pii/S0147651320305212?via%3Dihub>²⁰ Butcherine, P., Kelaher, B.P., Taylor, M.D., Barkla, B.J., Benkendorff, K., ‘Impact of imidacloprid on the nutritional quality of adult black tiger shrimp (*Penaeus monodon*)’, *Ecotoxicology and Environmental Safety*, 2020, volume 198, <https://www.sciencedirect.com/science/article/abs/pii/S0147651320305212?via%3Dihub>

²⁰ Butcherine, P., Kelaher, B.P., Taylor, M.D., Barkla, B.J., Benkendorff, K., ‘Impact of imidacloprid on the nutritional quality of adult black tiger shrimp (*Penaeus monodon*)’, *Ecotoxicology and Environmental Safety*, 2020, volume 198, <https://www.sciencedirect.com/science/article/abs/pii/S0147651320305212?via%3Dihub>

²¹ Ewere, E.E., Reichelt-Brushett, A., Benkendorff, K., ‘The neonicotinoid insecticide imidacloprid, but not salinity, impacts the immune system of Sydney rock oyster, *Saccostrea glomerata*’, *Science of the Total Environment*, 2020, volume 742, [The neonicotinoid insecticide imidacloprid, but not salinity, impacts the immune system of Sydney rock oyster, Saccostrea glomerata - ScienceDirect](#)

²² de Lima e Silva, C., Brennan, N., Brouwer, J.M., Commandeur, D., Verweij, R.A., van Gestel, C.A.M., ‘Comparative toxicity of imidacloprid and thiacloprid to different species of soil invertebrates’ *Ecotoxicology*, 2017, 26, pp. 555–564, <https://doi.org/10.1007/s10646-017-1790-7>

²³ <https://www.eea.europa.eu/publications/soer-2020>

²⁴ <https://www.nationalgeographic.com/animals/article/neonicotinoid-insecticides-cause-fish-declines-japan>

²⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on

as ‘harmful if swallowed’, ‘dangerous for the environment’ and ‘very toxic to aquatic life with long lasting effects’²⁶;

- S. whereas a study on imidacloprid exposure in the common carp fish (*Cyprinus carpio L.*) found degeneration in the brain, gills and eyes²⁷ in addition to histopathological changes (lesions), activation of biomarkers and alternation of gene expression levels; that study concluded that inflammation and oxidative stress are induced by imidacloprid exposure;
- T. whereas bioaccumulation of NN metabolite may occur in humans through the repeated intake of contaminated food, given that bioaccumulation of imidacloprid by low dose exposure was observed in an animal study²⁸;
- U. whereas various scientific studies have, in animal tests, concluded that imidacloprid acts as a reproductive toxicant and endocrine disruptor that may adversely affect the heart, kidney, thyroid and brain and can cause neurological symptoms including respiratory failure and death²⁹;
- V. whereas experimental evidence demonstrates that the toxicity of imidacloprid increases with exposure time as much as with dosage, described as ‘time-cumulative toxicity’, the toxicity of imidacloprid should therefore not only be understood in terms of acute lethality but should also be considered within a chronic framework³⁰;
- W. whereas Regulation (EU) No 283/2013 requires studies on long-term toxicity to be carried out;
- X. whereas Regulation (EC) No 396/2005 provides that ‘known cumulative and synergistic effects’ must be considered ‘when the methods to assess such effects are available’;
- Y. whereas Regulation (EU) No 284/2013 currently requires toxicological studies on operator, bystander, resident and worker exposure, several long-term and chronic toxicity studies for animals, and studies on fate and behaviour in soil, water and air;
- Z. whereas knowledge is lacking of the pollutant effects in the environment of many

classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (*OJ L 353, 31.12.2008, p. 1*).

²⁶ ECHA assessment report, ‘Imidacloprid, Product-type 18 (Insecticides, Acaracides and Products to control other Arthropods)’, <https://echa.europa.eu/documents/10162/225b9c58-e24c-6491-cc8d-7d85564f3912>

²⁷ Tyor, A.K., Harkrishan, Bhardwaj, J.K., Saraf, P., ‘Effect of Imidacloprid on Histopathological Alterations of Brain, Gills and Eyes in hatchling carp (*Cyprinus carpio L.*)’, *Toxicology International*, 2020, 27, pp. 70-78

²⁸ Kavvalakis, M.P., Tzatzarakis, M.N., Theodoropoulou, E.P., Barbounis, E.G., Tsakalof, A.K., Tsatsakis, A.M., ‘Development and application of LC-APCI-MS method for biomonitoring of animal and human exposure to imidacloprid’, *Chemosphere* 2013, volume 93, 10, pp. 2612-2620, [Development and application of LC-APCI-MS method for biomonitoring of animal and human exposure to imidacloprid - ScienceDirect](https://doi.org/10.1016/j.chemosphere.2013.07.041)

²⁹ Katić, A., Karačonji, I.B., ‘Imidacloprid as reproductive toxicant and endocrine disruptor: Investigations in laboratory animals’, *Archives of Industrial Hygiene and Toxicology*, 2018, 69(2), https://www.researchgate.net/publication/326247351_Imidacloprid_as_reproductive_toxicant_and_endocrine_disruptor_investigations_in_laboratory_animals

³⁰ Sánchez-Bayo, F., Tennekes, H.A., ‘Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments’, *International Journal of Environmental Research and Public Health*, 2020, 17(5), 1629. [IJERPH | Free Full-Text | Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments \(mdpi.com\)](https://doi.org/10.3390/ijerph17051629)

individual chemicals and chemical mixtures; not all chemicals have been assessed, and ecotoxicity assessments focus on very few species and ecosystems;

- AA. whereas Regulation (EU) 2019/6 recognises that a risk management decision should take into account: ‘other relevant factors, including societal, economical, ethical, environmental and welfare factors and the feasibility of controls’;
- AB. whereas contrary to the case of studies submitted to the European Food Safety Authority (EFSA), studies submitted to the Agency do not need to be published; regrets the lack of access to scientific studies in full, scientific opinions and raw data, as well as the lack of information on the feasibility of controls on and risk management of waste water discharge into the aquatic environment;
- AC. whereas Regulation 470/2009 states that maximum residue limits must be established in accordance with generally accepted principles of safety assessment, taking into account any other scientific assessment of the safety of the substance concerned, which may have been undertaken by international organisations, in particular the Codex Alimentarius or, where such substances are used for other purposes, by scientific committees established in the Community;
- AD. whereas the Codex Alimentarius does not recommend imidacloprid for use in the aquatic environment, and ECHA suggests why this might be the case: ‘According to the **harmonised classification and labelling (ATP01)** approved by the European Union, this substance is very toxic to aquatic life with long lasting effects and is harmful if swallowed’³¹;
- AE. whereas Article 37 of Regulation (EU) 2019/6 provides that marketing authorisation is to be refused if risks to public or animal health or to the environment are not sufficiently addressed; considers this a justification for not establishing the MRL;
- AF. whereas the four major salmon-producing nations: Norway, Chile, the United Kingdom and Canada are not Member States and the Commission would therefore not be able to conduct appropriate audits of competent authorities in those countries, or to assess the adequacy of controls;
1. Considers that Implementing Regulation (EU) 2021/621 exceeds the implementing powers provided for in Regulation (EC) No 470/2009;
 2. Considers that Implementing Regulation (EU) 2021/621 is not consistent with Union law, in that it violates the freedom of information and the fundamental principles of transparency, democratic scrutiny, and accountability, in so far as the underlying opinion by the Committee for Medicinal Products for Veterinary Use has only been made available in summary;
 3. 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;

³¹ <https://echa.europa.eu/substance-information/-/substanceinfo/100.102.643>

4. Considers that all veterinary medicines, pesticides and pharmacological and chemical residues should go through standard tests and peer-reviewed evaluations because of their risk of causing further and permanent damage;
5. Considers that the Agency should make publicly available the full opinion of the Committee for Medicinal Products for Veterinary Use consisting of the scientific risk assessment and risk management recommendations and the scientific evidence on which they are based; considers the risk assessment of imidacloprid is deficient as regards the consideration of acute endpoint values and that it ignore delayed, cumulative and chronic effects; recalls that research in aquatic invertebrates revealed a delayed effect on mortality, especially among aquatic insect species that could not be detected in standard acute tests demonstrating that risk assessments for neonicotinoids have been inadequate in relation to protection of the environment³²;
6. Considers it essential to evaluate pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin in conjunction with the rules laid down by Regulation (EC) No 178/2002 of the European Parliament and of the Council³³ and Regulations (EC) No 396/2005, (EC) No 1367/2006, (EU) 2019/6 and (EU) 2019/1381.;
7. Considers that Directive 2001/82/EC is in urgent need of revision vis-à-vis protecting biodiversity, the aquatic and terrestrial environment and taking account of animal welfare and non-target organisms and microorganisms;
8. Considers that Regulation (EEC) No 470/2009 does not provide adequate consideration of the need to involve the European Parliament and citizens so that they may fully exercise their democratic right of scrutiny;
9. Reiterates the need to reinforce scientific cooperation, coordination and coherence between the Union agencies with competence in this field, namely the Agency, EFSA and ECHA together with national and international agencies, by developing a common framework for risk assessment for biocidal and phyto-pharmaceutical products used in food chains, so as to avoid inconsistencies and limit the potential for environmental damage and ecocide;
10. Calls on the Commission, in its role as risk manager, to duly 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;
11. Urges the Commission to communicate systematically on how the precautionary principle and the principle of informed consent have been taken into account and how the

³² Sánchez-Bayo F., Tennekes, H.A., ‘Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments’, *International Journal of Environmental Research and Public Health*. 2020,17(5),1629, [IJERPH | Free Full-Text | Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments \(mdpi.com\)](#)

³³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (*OJ L 31, 1.2.2002, p. 1*).

conclusions of the opinion of the Committee for Medicinal Products for Veterinary Use were derived;

12. Calls on the Commission 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;
13. Calls on the Commission to ensure that time-cumulative, up-to-date, peer-reviewed, ecotoxicological 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;
14. Calls on the Commission to submit and the Member States to support 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 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;
15. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.