European Parliament
2019-2024

Plenary sitting

B9-0460/2022

10.10.2022

MOTION FOR A RESOLUTION

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

on Commission Implementing Regulation (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusulfuron and tritosulfuron
(2022/2785(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Anja Hazekamp, Maria Arena, Tilly Metz

B9-0460/2022

European Parliament resolution on Commission Implementing Regulation (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusulfuron and tritosulfuron
(2022/2785(RSP))

The European Parliament,

– having regard to Commission Implementing Regulation (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusulfuron and tritosulfuron[1],

– having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[2], and in particular Article 17, first paragraph, and Article 21 thereof,

– having regard to Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution[3],

– 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

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1 OJ L 233, 8.9.2022, p. 43.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 67, 12.3.2015, p. 18.

principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[4],

– having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009[5],

– having regard to its resolutions of 10 October 2019, of 26 November 2020 and of 6 October 2021 objecting to the previous extensions of the approval period of the active substances chlorotoluron and difenoconazole[6],

– 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 the active substance 8-hydroxyquinoline was approved in accordance with Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 993/2011[7];

B. whereas the active substance chlorotoluron was included in Annex I to Council

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4 OJ L 55, 28.2.2011, p. 13.

5 OJ C 433, 23.12.2019, p. 183.

6 - European Parliament resolution of 10 October 2019 on the draft Commission implementing regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron (OJ C 202, 28.5.2021, p. 7);
- European Parliament resolution of 26 November 2020 on Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, picloram, prosulfocarb, sulphur, triflusulfuron and tritosulfuron (OJ C 425, 20.10.2021, p. 87);
- European Parliament resolution of 6 October 2021 on Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron (OJ C 132, 24.3.2022, p. 65).

7 Commission Implementing Regulation (EU) No 993/2011 of 6 October 2011 approving the active substance 8-hydroxyquinoline, 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 market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 263, 7.10.2011, p. 1).

Directive 91/414/EEC[8] on 1 March 2006 by Commission Directive 2005/53/EC[9] and has been deemed to be approved under Regulation (EC) No 1107/2009 and a procedure to renew the approval of chlorotoluron under Commission Implementing Regulation (EU) No 844/2012[10] has been ongoing since 2013;

C. whereas the active substance difenoconazole was included in Annex I to Directive 91/414/EEC on 1 January 2009 by Commission Directive 2008/69/EC[11] and has been deemed to be approved under Regulation (EC) No 1107/2009;

D. whereas the approval period for 8-hydroxyquinoline has already been extended by one year by Commission Implementing Regulation (EU) 2021/1449[12] and now again by Implementing Regulation (EU) 2022/1480 which extends the approval period until 31 December 2023;

E. whereas the approval period for chlorotoluron has already been extended by one year by Commission Implementing Regulation (EU) No 533/2013[13], and subsequently by one year every year since 2017 by Commission Implementing Regulations (EU)

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8 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

9 Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ L 241, 17.9.2005, p. 51).

10 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

11 Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (OJ L 172, 2.7.2008, p. 9).

12 Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron (OJ L 313, 6.9.2021, p. 20).

13 Commission Implementing Regulation (EU) No 533/2013 of 10 June 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methyl-cyclopropene, chlorothalonil, chlorotoluron, cypermethrin, daminozide, forchlorfenuron, indoxacarb, thiophanate-methyl and tribenuron (OJ L 159, 11.6.2013, p. 9).

2017/1511[14], (EU) 2018/1262[15], (EU) 2019/1589[16], (EU) 2020/1511[17], (EU) 2021/1449, and now again by Implementing Regulation (EU) 2022/1480 which extends the approval period until 31 October 2023, and which will make it the seventh extension of the original approval period;

F. whereas the approval period for difenoconazole has already been extended three times by one year by Implementing Regulations (EU) 2019/1589, (EU) 2020/1511 and (EU) 2021/1449, and now again by Implementing Regulation (EU) 2022/1480 which extends the approval period until 31 December 2023;

G. whereas the Commission has failed to explain the reasons for the extensions other than saying: 'Due to the fact that the assessment of those active substances has been delayed for reasons beyond the control of the applicants, the approvals of those active substances are likely to expire before a decision has been taken on their renewal';

8-hydroxyquinoline

H. whereas in 2015 the Committee for Risk Assessment of the European Chemicals Agency (ECHA) issued an opinion that 8-hydroxyquinoline should be classified as reproductive toxicity category 1B[18];

I. whereas in 2016 the European Food Safety Authority (EFSA) in its peer-review of the pesticide risk assessment of 8-hydroxyquinoline identified several data gaps and two critical areas of concern: on the one hand, 8-hydroxyquinoline is to be classified as reproductive toxicity category 1B; on the other, the substance would not meet either of the interim provisions of these approval criteria (Point 3.6.5 concerning human health

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[14] Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, forchlorfenuron, fosthiazate, indoxacarb, iprodione, MCPA, MCPB, silthiofam, thiophanate-methyl and tribenuron (OJ L 224, 31.8.2017, p. 115).

[15] Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron (OJ L 238, 21.9.2018, p. 62).

[16] Commission Implementing Regulation (EU) 2019/1589 of 26 September 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron (OJ L 248, 27.9.2019, p. 24).

[17] Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, picloram, prosulfocarb, sulphur, triflusulfuron and tritosulfuron (OJ L 344, 19.10.2020, p. 18).

[18] Committee for Risk Assessment opinion of 5 June 2015 proposing harmonised classification and labelling at EU level of Quinolin-8-ol; 8-hydroxyquinoline, https://echa.europa.eu/documents/10162/fb6bbac1-35b5-bf75-8592-0ccd93ad2615

for the consideration of endocrine-disrupting properties) as together with the classification, adverse effects were observed on endocrine organs in the available studies[19];

J. whereas in 2017 8-hydroxyquinoline was placed on the 'list of candidates for substitution' by Commission Implementing Regulation (EU) 2017/2065[20] because it is considered to have endocrine-disrupting properties that may cause adverse effects in humans, and because it is classified, in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[21], as being toxic for reproduction category 1B;

Chlorotoluron

K. whereas, according to Regulation (EC) No 1272/2008, chlorotoluron has a harmonised classification of very toxic to aquatic life, very toxic to aquatic life with long lasting effects, suspected of causing cancer (Carc. 2), and suspected of damaging the unborn child (Repr. 2);

L. whereas chlorotoluron has been associated with endocrine-disrupting properties in scientific publications[22];

M. whereas in 2015 chlorotoluron was placed on the 'list of candidates for substitution' by Implementing Regulation (EU) 2015/408 because it is considered to have endocrine-disrupting properties that may cause adverse effects in humans, and because it meets the criteria for it to be considered a persistent and toxic substance;

N. whereas Parliament has already objected to the previous extensions of the approval period of chlorotoluron in its resolutions of 10 October 2019, of 26 November 2020 and of 6 October 2021;

O. whereas the Commission in its responses[23] to the previous objections to the extensions

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[19] EFSA, Peer review of the pesticide risk assessment of the active substance 8-hydroxyquinoline, EFSA Journal 2016;14(6):4493, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4493

[20] Commission Implementing Regulation (EU) 2017/2065 of 13 November 2017 confirming the conditions of approval of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation (EU) No 540/2011 and modifying Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substance 8-hydroxyquinoline in the list of candidates for substitution (OJ L 295, 14.11.2017, p. 40).

[21] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on 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).

[22] See inter alia: Hong, M., Ping, Z., Jian, X., 'Testicular toxicity and mechanisms of chlorotoluron compounds in the mouse', Toxicology Mechanisms and Methods 2007;17(8):483-8.

[23] Commission follow up to the European Parliament non-legislative resolution on the draft Commission implementing regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron, SP(2019)669, https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2019/2826(RSP)&l=en;

of the approval period of chlorotoluron only refers to the 'study underpinning the impact assessment conducted prior to the adoption of Commission Regulation (EU) 2018/605'[24] in which 'chlorotoluron was not identified as a potential endocrine disruptor', but fails to acknowledge that that study did not lead to the removal of chlorotoluron from the list of candidates for substitution;

P. whereas after the adoption of Commission Delegated Regulation (EU) 2017/2100[25] and Regulation (EU) 2018/605, the Commission tasked EFSA and ECHA with developing harmonised guidance to ensure that the endocrine disruptor criteria adopted by the Union are applied consistently for the assessment of biocides and pesticides in the Union; whereas this guidance which incorporates new OECD tests was published in June 2018[26], but has not been used to assess the endocrine-disrupting properties of chlorotoluron;

Q. whereas therefore, chlorotoluron has not been properly assessed to allow for it to be no longer considered as an endocrine disrupter;

R. whereas the draft renewal assessment report in relation to chlorotoluron should have been delivered by 2016, but was only delivered three years later, in 2019, and, a further three years later, it has still apparently not been assessed by EFSA;

Difenoconazole

S. whereas difenoconazole used on its own, as well as in combination with different azoles, such as penconazole, is suspected of inducing triazole-resistance in the fungal

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Commission follow up to the European Parliament non-legislative resolution on Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, picloram, prosulfocarb, sulphur, triflusulfuron and tritosulfuron, SP(2021)129, https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2020/2853(RSP)&l=en; Commission follow up to the European Parliament non-legislative resolution on Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8- hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron, SP(2021)735, https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2021/2869(RSP)&l=en.

[24] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

[25] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

[26] EFSA and ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, EFSA Journal 2018, 16(6):5311, http://www.efsa.europa.eu/en/efsajournal/pub/5311.

strain *Aspergillus fumigatus*[27];

T. whereas triazole resistance in *Aspergillus fumigatus* is a growing public health concern[28]; whereas data from several studies[29] strongly suggest that agricultural azoles are responsible for medical treatment failure in azole-naïve patients in clinical settings;

U. whereas one in four patients admitted to intensive care due to COVID-19-related health problems have been found to be infected with *Aspergillus fumigatus*, of which 15 % of them are diagnosed with a resistant variant of *Aspergillus fumigatus*; whereas those patients become almost untreatable and their survival rate is estimated at just 20 %[30];

V. whereas extending the approval periods of substances which lead to resistance to fungal medicines is unacceptable from a health point of view;

General considerations concerning extensions of approval periods

W. whereas Regulation (EC) No 1107/2009 aims to ensure a high level of protection of both human and animal health and the environment, and at the same time to safeguard the competitiveness of Union agriculture; whereas particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children;

X. whereas the precautionary principle should apply, and whereas Regulation (EC) No 1107/2009 specifies that substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and that they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment;

Y. whereas Regulation (EC) No 1107/2009 indicates that in the interest of safety the approval period for active substances should be limited in time; whereas the approval period should be proportionate to the possible risks inherent in the use of such substances, but in this case it is clear that no such proportionality exists;

Z. whereas Article 17 of Regulation (EC) No 1107/2009 cannot be understood as allowing

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[27] Verweij, P.E., Lucas, J.A., Arendrup, M.C., Bowyer, P., Brinkmann, A.J.F., Denning, D.W., Dyer, P.S., Fisher, M.C., Geenen, P.L., Gisi, U., Hermann, D., Hoogendijk, A., Kiers, E., Lagrou, K., Melchers, W.J.G., Rhodes, J., Rietveld, A.G., Schoustra, S.E., Stenzel, K., Zwaan, B.J., and Fraaije, B.A., 'The one health problem of azole resistance in Aspergillus fumigatus: current insights and future research agenda', Fungal Biology Reviews, Volume 34, Issue 4, 2020, pp. 202-214, https://www.sciencedirect.com/science/article/pii/S1749461320300415

[28] Cao, D., Wang, F., Yu, S., Dong, S., Wu, R., Cui, N., Ren, J., Xu, T., Wang, S., Wang, M., Fang, H., and Yu, Y., 'Prevalence of Azole-Resistant Aspergillus fumigatus is Highly Associated with Azole Fungicide Residues in the Fields', Environmental Science & Technology, 2021, 55(5), 3041-3049, https://www.researchgate.net/publication/349087541_Prevalence_of_AzoleResistant_Aspergillus_fumigatus_is_Highly_Associated_with_Azole_Fungicide_Residues_in_the_Fields

[29] Berger, S., El Chazli, Y., Babu, A.F., Coste, A.T., 'Azole Resistance in Aspergillus fumigatus: A Consequence of Antifungal Use in Agriculture?', Frontiers in Microbiology 2017; 8: 1024, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5461301/

[30] https://huisarts.bsl.nl/levensbedreigende-schimmel-ontdekt-bij-kwart-coronapatienten-op-ic/

for an extension of an active substance's approval for an unlimited period of time, but should rather be understood as providing for a limited and exceptional extension of a few months, or a year at most, in order to avoid any interruption in the marketing and sale of phytosanitary products, –with due regard to the requirement to attain a high level of protection of human health and of the environment, which is both the primary objective of Regulation (EC) No 1107/2009 and a fundamental principle enshrined in Union primary law, namely Articles 35 and 37 of the Charter of fundamental Rights of the European Union and Articles 168 and 191 of the Treaty on the Functioning of the European Union;

AA. whereas the current interpretation of Article 17 of Regulation (EC) No 1107/2009 by the Commission goes against the general objectives of that Regulation and the intent of the co-legislators;

AB. whereas the Commission and Member States have the possibility and responsibility to act according to the precautionary principle when the possibility of harmful effects on health have been identified but scientific uncertainty persists, by adopting provisional risk management measures that are necessary to ensure a high level of protection of human health;

AC. whereas, more specifically, Article 21 of Regulation (EC) No 1107/2009 provides that the Commission may review the approval of an active substance at any time, especially where, in the light of new scientific and technical knowledge, it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4 of that Regulation, and whereas this review may lead to the withdrawal or amendment of the approval of the substance;

AD. whereas the identification of the three active substances as candidates for substitution did not contribute to any risk mitigation due to a poor implementation by Member States of the mandatory substitution scheme as set out in Article 50 of Regulation (EC) No 1107/2009;

AE. whereas the Commission in its Farm to Fork and Biodiversity Strategies has pledged to reduce the overall use and risk of chemical pesticides by 50 % and the use of more hazardous pesticides by 50 % by 2030;

AF. whereas the more hazardous pesticides are defined as pesticides containing active substances that meet the cut-off criteria as set out in points 3.6.2. to 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 or are identified as candidates for substitution in accordance with the criteria in point 4 of that Annex, which includes the active substances 8-hydroxyquinoline, chlorotoluron and difenoconazole as well as etofenprox, flufenacet, lenacil, nicosulfuron, nicosulfuron and tri-allate in relation to which the approval periods are all being extended by one year by Implementing Regulation (EU) 2022/1480, without a proper reassessment of the risks thereof;

AG. whereas the continuous extensions of the approval periods of these most hazardous chemical pesticides without a proper, complete and timely reassessment of their hazardous properties is counterproductive to achieving the aims of the European Green Deal;

AH. whereas, according to Article 4(7) of and point 3.6.4 of Annex II to Regulation (EC) No 1107/2009, an active substance cannot be approved when it is toxic for reproduction category 1B, except in cases where, on the basis of documented evidence included in the application, an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, in which cases risk mitigation measures have to be taken to ensure that exposure of humans and the environment to the active substance is minimised, or where the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the default value set in accordance with Article 18(1), point (b), of Regulation (EC) No 396/2005 of the European Parliament and of the Council[31];

AI. whereas, according to Article 4(7) of and point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, an active substance cannot be approved when it is considered to have endocrine-disrupting properties that may cause adverse effect in humans, except in cases where, on the basis of documented evidence included in the application, an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, in which cases risk mitigation measures have to be taken to ensure that exposure of humans and the environment to the active substance is minimised, or where the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the default value set in accordance with Article 18(1), point (b), of Regulation (EC) No 396/2005;

AJ. whereas it is unacceptable for substances which are likely to meet the cut-off criteria for active substances to continue to be allowed for use in the Union, thereby putting public and environmental health at risk;

AK. whereas applicants can take advantage of the automatic system built into Commission working methods which immediately extends the approval periods of active substances if the risk reassessment has not been finalised, by prolonging the reassessment process on purpose by providing incomplete data and asking for more derogations and special conditions, which leads to unacceptable risks for the environment and human health since during this time exposure to the hazardous substance continues;

AL. whereas, in its resolution of 13 September 2018, Parliament called on the Commission and Member States ‘to ensure that the procedural extension of the approval period for the duration of the procedure, pursuant to Article 17 of the Regulation, will not be used for active substances that are mutagenic, carcinogenic, toxic for reproduction and

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[31] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

therefore in category 1A or 1B, or active substances that have endocrine disrupting characteristics and are damaging to humans or animals, as is currently the case for substances such as flumioxazine, thiacloprid, chlorotoluron and dimoxystrobin';

AM. whereas following the previous extensions in 2021 of several active substances, including 8-hydroxyquinoline, chlorotoluron and difenoconazole, under Implementing Regulation (EU) 2021/1449, only one of the 39 substances covered by that Implementing Regulation has been renewed, while under Regulation (EC) No 1107/2009, the approval periods of as many as 46 substances are extended, many of them for a third, fourth, fifth, sixth or even seventh time;

AN. whereas the Commission approach to extend the approval periods of 46 active substances though the same implementing act limits the possibilities for opposition from Member States in committee to some of these active substances of particular concerns, including 8-hydroxyquinoline, chlorotoluron and difenoconazole;

AO. whereas the non-governmental organisations Pesticide Action Network Europe and Pollinis have submitted internal review requests to oppose the legality of repeated extensions of the approval periods of the active substances dimoxystrobin and boscalid respectively, whereas in the case of dimoxystrobin an action for annulment has been brought[32];

1. Considers that Implementing Regulation (EU) 2022/1480 exceeds the implementing powers provided for in Regulation (EC) No 1107/2009;

2. Considers that Implementing Regulation (EU) 2022/1480 is not consistent with Union law in that it does not respect the precautionary principle;

3. Strongly denounces the serious delays in the reauthorisation process and in the identification of endocrine-disrupting substances;

4. Considers that the decision to extend the approval periods for 8-hydroxyquinoline, chlorotoluron and difenoconazole is not in line with the safety criteria laid down in Annex II to Regulation (EC) No 1107/2009, and is based neither on evidence that those substances can be used safely, nor on a proven urgent need for those substances in food production in the Union;

5. Calls on the Commission to repeal Implementing Regulation (EU) 2022/1480 and to submit a new draft to the committee, which takes into account the scientific evidence on the harmful properties of all the substances concerned, especially of 8-hydroxyquinoline, chlorotoluron and difenoconazole;

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[32] Case T-412/22, *PAN Europe* v *Commission*, https://curia.europa.eu/juris/fiche.jsf?id=T%3B412%3B22%3BRD%3B1%3BP%3B1%3BT2022%2F0412%2FP&nat=or&mat=or&pcs=Oor&jur=C%2CT%2CF&num=T412%252F22&for=&jge=&dates=&language=en&pro=&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&oqp=&td=%3BALL&avg=&lgrec=en&lg=&cid=13059188

6. Calls on the Commission only to present draft implementing regulations to extend the approval periods of substances for which the current state of science is not expected to lead to a Commission proposal for non-renewal of the approval of the active substance concerned;

7. Calls on the Commission to withdraw the approvals for substances if proof or reasonable doubt exists that they will not meet the safety criteria laid down in Regulation (EC) No 1107/2009;

8. Calls on the Commission to duly justify its decisions to extend the approval periods of active substances in the future and to stop proceeding with such extension proposals ‘by package’, in order to increase Member States scrutiny of such decisions;

9. Calls on the Member States to ensure the proper and timely reassessment of the approvals for the active substances for which they are the reporting Member States, and to ensure that current delays are solved effectively and as soon as possible;

10. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.