European Parliament
2014-2019

TEXTS ADOPTED

P8_TA(2018)0356

Implementation of the Plant Protection Products Regulation

European Parliament resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI))

The European Parliament,

– 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[1],

– having regard to 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[2],

– having regard to 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[3],

– having regard to Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides[4],

– having regard to its resolution of 15 February 2017 on low-risk pesticides of biological origin[5],

– having regard to the decision of the European Ombudsman of 18 February 2016 in Case 12/2013/MDC on the practices of the Commission regarding the authorisation and placing on the market of plant protection products (pesticides)[6],

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1 OJ L 309, 24.11.2009, p. 1.
2 OJ L 70, 16.03.2005, p. 1.
3 OJ L 353, 31.12.2008, p. 1.
4 OJ L 309, 24.11.2009, p. 71.
5 Texts adopted, P8_TA(2017)0042.
6 https://www.ombudsman.europa.eu/en/decision/en/64069

– having regard to the European Implementation Assessment on Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and to its relevant annexes, as published by the European Parliamentary Research Service (DG EPRS)[1] in April 2018,

– having regard to the judgments of the Court of Justice of the European Union of 23 November 2016 in Cases C-673/13 P (*Commission v Stichting Greenpeace Nederland and PAN Europe*) and C-442/14 (*Bayer CropScience v Board for the authorisation of plant protection products and biocides*),

– having regard to the Commission proposal for a Regulation of the European Parliament and the Council of 11 April 2018 on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods][2],

– having regard to the mandate and the work of the European Parliament's Special Committee on the Union's authorisation procedure for pesticides (PEST),

– having regard to Rule 52 of its Rules of Procedure, as well as Article 1(1)(e) of, and Annex 3 to, the decision of the Conference of Presidents of 12 December 2002 on the procedure for granting authorisation to draw up own-initiative reports,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A8-0268/2018),

A. whereas the evaluation of the implementation of Regulation (EC) No 1107/2009 (hereinafter ‘the Regulation’) has revealed that the objectives of protecting human and animal health and the environment are not fully being achieved and that improvements could be made in order to achieve all the objectives of the Regulation;

B. whereas the evaluation of the implementation of the Regulation should be considered in conjunction with the EU’s overarching pesticide policy, including the rules laid down by Directive 2009/128/EC [the Sustainable Use Directive], Regulation (EU) No 528/2012 [the Biocides Regulation], Regulation (EC) No 396/2005 [the Maximum Residue Level Regulation], and Regulation (EC) No 178/2002 [the General Food Law];

C. whereas the implementation of the Regulation is not proving satisfactory and should be in line with related EU policies, including in the field of pesticides;

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1 http://www.europarl.europa.eu/RegData/etudes/STUD/2018/615668/EPRS_STU(2018)615668_EN.pdf

2 COM(2018)0179.

D. whereas the available evidence shows that the practical implementation of the three main instruments of the Regulation – approvals, authorisations and enforcement of regulatory decisions – leaves room for improvement and does not ensure the complete fulfilment of the objectives of the Regulation;

E. whereas certain provisions of the Regulation have not been applied at all by the Commission, in particular Article 25 on the approval of safeners and synergists and Article 27 on a negative list of unacceptable co-formulants;

F. whereas other key provisions, such as application of the cut-off criteria for active substances that are endocrine disrupters, have been significantly delayed as a result of unlawful behaviour by the Commission;

G. whereas concerns have been raised by stakeholders regarding the evaluation approach as established by law, in particular as regards who should produce the scientific studies and evidence for the active substance evaluations and the use of the hazard-based approach during those evaluations;

H. whereas the burden of proof should remain on the applicant, so as to ensure that public money is not spent on studies which can eventually benefit private interests; whereas, at the same time, transparency must be ensured at each step of the authorisation procedure, in full compliance with intellectual property rights, while it must also be ensured that good laboratory principles are consistently upheld throughout the Union;

I. whereas there are concerns associated with the practical implementation of the established evaluation approach; whereas in particular there are major concerns associated with the incomplete harmonisation of data requirements and methodologies used that may hinder the evaluation process;

J. whereas the performance of national competent authorities was found to be a major factor influencing the evaluation of active substances; whereas there are substantial differences among Member States as regards available expertise and staff; whereas the Regulation and the relevant supporting legal requirements are not being uniformly implemented across Member States, and this has significant implications for health and the environment;

K. whereas transparency at all stages of the approval procedure should be improved, and increased transparency may help to encourage public confidence in the system regulating plant protection products; whereas the transparency of the authorisation related to the activities of competent authorities is also unsatisfactory in many cases; whereas the Commission has proposed changes to the General Food Law with the aim of addressing concerns relating to the data and evidence supplied during the evaluation process and increasing transparency;

L. whereas authorisations of plant protection products, which take place exclusively at national level, often face delays in risk management decisions; whereas this leads in some cases to an increase in authorisations granted by Member States under derogation, making use of Article 53 of the Regulation; whereas there are cases where such derogations are used against the initial intention of the legislator;

M. whereas the Regulation introduces the provision that integrated pest management (IPM) should have become part of the statutory management requirements under the cross-compliance rules of the common agricultural policy; whereas this is yet to happen;

N. whereas the available evidence shows that this piece of EU-level regulation enhances and adds value to national efforts and actions;

O. whereas serious considerations of alternatives often emerge only after a change in the legal requirements; whereas, for example, in the case of the extended ban on neonicotinoids the most recent assessment (30 May 2018)[1] suggests that readily available non-chemical alternatives exist for 78 % of uses of neonicotinoids;

P. whereas no new active substances have been put forward for approval since 31 May 2016; whereas innovation and the development of new products, particularly low-risk products, are important;

Q. whereas the availability of counterfeit pesticides on the market is a matter of real concern; whereas counterfeit pesticides can be harmful to the environment and can also damage the effectiveness of the Regulation;

Main conclusions

1. Considers that the EU is the appropriate level at which regulatory action in the field of pesticides should continue to take place;

2. Points out that environmental measures aimed at preventing, limiting and containing the spread of pathogens and pests have to remain the focus of all current and further actions;

3. Considers that the adoption and implementation of the Regulation represent a significant step forward regarding the treatment of plant protection products (PPPs) in the EU as compared to the past;

4. Highlights that special attention should be paid to the role of small and medium-sized enterprises (SMEs) in the development of new products, as SMEs often lack the substantial resources that are needed for the process of development and approval of new substances;

5. Is concerned at the fact that the Regulation has not been effectively implemented and that, as a result, its objectives as regards agricultural production and innovation are not being achieved in practice; highlights the fact that, partly owing to the low degree of innovation, the number of pesticide active substances is decreasing;

6. Recalls that there is a substantial need for an integrative approach and that Regulation (EC) No 1185/2009 concerning statistics on pesticides[2] has to be part of the assessment, with its results being used to reduce quantities, thus minimising risks and their negative impact on health and the environment;

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1 ANSES - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (France) - Conclusions, 2018.

2 OJ L 324, 10.12.2009, p. 1.

7. Notes that the objectives and instruments of the Regulation and its implementation are not always sufficiently in line with EU policies in the fields of agriculture, health, animal welfare, food security, water quality, climate change, sustainable use of pesticides and maximum residue levels of pesticides in food and feed;

8. Is concerned that the implementation of the Regulation, in relation to the use of animals in testing for hazard identification and risk assessment, is not in line with the 3R requirements (the principles of replacement, reduction and refinement) of Directive 2010/63/EU on animal experiments, and that the two-year bioassay for carcinogenicity can lead to controversial results[1];

9. Recalls that the precautionary principle is a general EU principle laid down in Article 191 of the Treaty on the Functioning of the European Union, and that this principle aims to ensure a high level of protection for the environment through preventive decision-making;

10. Finds it unacceptable that the approval requirements for safeners and synergists have not yet been applied, contrary to Article 25 of the Regulation;

11. Finds it unacceptable that the negative list of co-formulants has still not been adopted, especially after the ban on POE-tallowamines in combination with glyphosate, which has highlighted the adverse effects that certain co-formulants can have;

12. Takes note of the Commission's ongoing REFIT Evaluation of Regulation (EC) No 1107/2009 and of its planned completion by November 2018; trusts that these findings will be an adequate basis for the co-legislators to discuss the future development of the Regulation;

13. Is concerned by the steadily increasing use and identified cases of misuse of emergency authorisations granted under Article 53 in some Member States; notes that some Member States use Article 53 significantly more than others; notes the technical assistance provided by the European Food Safety Authority (EFSA) in accordance with Article 53(2) of the Regulation, in examining the use of emergency authorisations; notes the results of the EFSA investigation into the emergency authorisations in 2017 of three neonicotinoids, which showed that while some emergency authorisations were necessary and within the parameters laid down in the legislation, others were not justified; considers it essential that Member States provide the necessary data to enable EFSA to carry out its mandate effectively;

14. Stresses the importance of policymaking that is informed by regulatory science, producing verifiable and repeatable evidence using internationally agreed scientific principles as regards aspects such as guidelines, good laboratory practices and peer-reviewed research;

15. Is concerned that the incomplete harmonisation of data and testing requirements in some scientific fields leads to inefficient working methods, lack of trust among national authorities, and delays in the authorisation process, which may result in negative effects on human and animal health, the environment and agricultural production;

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[1] Source: Based on information and findings of the European Implementation Assessment, EPRS Study April 2018, p. 36 & II-33.

16. Regrets the limited public availability of information on the evaluation and authorisation procedure, as well as the limited access to information; regrets that the level of transparency of the rapporteur Member States is low (when acting in the framework of the approval procedure), and suggests that the accessibility and user-friendliness of information at the EFSA stage could be improved, and that transparency at the risk management stage seems to be lacking and is also considered problematic by stakeholders; welcomes the efforts of the European Chemicals Agency (ECHA) to increase transparency and user-friendliness through its website, and considers that this model could be employed in the future to improve transparency;

17. Highlights that the credibility of the PPP authorisation system strongly depends on public trust in European agencies, which provide the scientific opinions that are the basis for approval and risk management; underlines that transparency in the scientific assessment process is important to maintain public trust; calls, therefore, for the relevant agencies to be adequately funded and have the necessary staff to ensure an independent, transparent and timely authorisation process; further welcomes EFSA's continuous efforts to improve its system in order to ensure independence and the management of potential conflicts of interest, which was praised by the Court of Auditors as the most advanced system of the audited agencies in 2012, and which was recently updated in June 2017; calls on the Commission to propose improvements to further enhance the transparency of the regulatory process, including on access to the data in safety studies submitted by producers as part of their applications for market authorisation of PPPs in the EU; recognises the need to review the procedure in order to improve evaluations, increase the independence of the authorities tasked with carrying out studies, avoid conflicts of interest and make the procedure more transparent;

18. Calls on the Commission to establish a European usage catalogue in order to better harmonise the regulation;

19. Is concerned that, in some cases, the PPPs available on the market and their application by users do not necessarily comply with the relevant authorisation conditions as regards their composition and usage; emphasises that non-professional use should be limited where possible to reduce misuse;

20. Underlines the importance of training for professional users to ensure the proper and appropriate use of PPPs; considers it fitting to distinguish between professional and amateur users; notes that PPPs are used in the context of private gardens, railways and public parks;

21. States that the Member States' right to refuse authorised PPPs remains unaffected;

22. Emphasises that the Regulation should better reflect the need to promote agricultural practices based on IPM, including by stimulating the development of low-risk substances; highlights that the lack of availability of low-risk PPPs hinders the development of IPM; notes with concern that only ten substances are approved as low-risk PPPs, out of a total of almost 500 available on the EU market;

23. Emphasises that the authorisation and promotion of low-risk pesticides that are non-chemical is an important measure to support low pesticide-input pest management; acknowledges the need for more research into these products, as their composition and functioning are radically different from those of conventional products; underlines that

this also includes the need for more expertise within EFSA and the national competent authorities to evaluate these biological active substances; stresses that PPPs of biological origin should be subject to the same rigorous evaluations as other substances; in line with its resolution of 15 February 2017 on low-risk pesticides of biological origin, calls on the Commission to submit a specific legislative proposal amending Regulation (EC) No 1107/2009, outside of the general revision in connection with the REFIT initiative, with a view to establishing a fast-track evaluation, authorisation and registration process for low-risk pesticides;

24. Takes the view that Regulation (EC) No 1107/2009 should also be amended to take more account of substances not regarded as PPPs and which, when used for plant protection, are governed by the Regulation; notes that such substances offer interesting alternatives in terms of integrated production methods and some bio-control products;

25. Emphasises that special attention and support should be given to PPPs for minor uses, as there is currently little economic incentive for companies to develop such products; welcomes the setting-up of the Minor Uses Coordination Facility as a forum for improving coordination between Member States, grower organisations and industry in developing solutions for minor uses;

26. Highlights that many authorised PPPs have not been evaluated against EU standards for more than 15 years, as a consequence of delays in the authorisation procedures;

27. Stresses the importance of creating an innovation-friendly regulatory framework which will allow the replacement of older chemistry by new and better crop protection products; underlines the importance of the availability of a broad spectrum of PPPs with different modes of action so as to avoid the development of resistances and maintain the effectiveness of crop protection product application;

28. Is concerned that the harmonisation of guidelines is not yet consolidated;

29. Stresses that missing or incomplete guidelines are serious shortcomings that have negative consequences for the implementation of the Regulation and hence for the achievement of its objectives;

30. Highlights that the available guidance documents are not legally binding, which creates regulatory uncertainty for the applicants and brings into question the results of the evaluations carried out in the framework of the approval procedures;

31. Welcomes the concept of the zonal system and its aim to facilitate the efficient authorisation of plant protection products; considers the mutual recognition procedure as vital for sharing the workload and encouraging compliance with deadlines; regrets the implementation problems associated with the mutual recognition principle; calls on the Commission to work with Member States to improve the functioning of the zonal system; underlines that the full implementation of the existing legislation should have the aim of avoiding duplication of work and making new substances available to farmers without unnecessary delays;

32. Underlines the need for knowledge-sharing and skills acquisition in relation to alternatives to chemical pesticides and IPM, including finding the optimum crop rotation for farmers' market and climatic situations; notes further that this has already been provided for in the

horizontal regulation of the CAP, notably also in the Farm Advisory Services financed under rural development;

33. Expresses its concern regarding the small number of new substances that have been approved; stresses the importance of a suitable toolbox of PPPs for farmers in order to secure the EU's food supply;

34. Expresses its concern that in recent debates, the EU's current science-based evaluation system for PPPs has been increasingly called in question; stresses the importance of maintaining and further strengthening a system which is scientifically robust, objective, and based on peer-reviewed evidence, derived from an open, independent and multidisciplinary scientific approach in authorising any active substance, in line with the EU's risk analysis principles and the precautionary principle as established in the General Food Law; insists that the procedure for the re-approval of active substances must take into account the practical use of PPPs, as well as scientific and technological progress in this area; points out that the complexities in the current evaluation and authorisation system lead to deadlines being missed and could mean that the entire system cannot work properly; stresses, therefore, the need to review and simplify the system;

35. Highlights the imbalance in the number of applications between some Member States of the same zone which are of similar size and have similar agricultural conditions;

36. Considers that produce imported from outside the EU which has been cultivated using PPPs should be subject to the same strict criteria as that produced within the EU; is concerned that PPPs not registered in the EU may be used in the production of imported produce;

Recommendations

37. Calls on the Commission and the Member States to ensure effective implementation of the Regulation as regards their specific roles in the approval and authorisation procedures;

38. Calls on the Member States to improve the serious and chronic understaffing of the national competent authorities, which leads to delays at the stage of hazard identification and initial risk assessment performed by Member States;

39. Calls on the Commission and the 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 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[1];

40. The use of active substances that are mutagenic, carcinogenic, toxic for reproduction and therefore in category 1A or 1B, or active substances that have endocrine disrupting characteristics and are damaging to humans or animals, that already have had one or more

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[1] Source: https://www.foodwatch.org/fileadmin/foodwatch.nl/Onze_campagnes/Schadelijke_stoffen/Documents/Rapport_foodwatch_Ten_minste_onhoudbaar_tot.pdf

procedural extensions of the approval period, pursuant to Article. 17, must be prohibited immediately;

41. Calls on the Commission and the Member States to acknowledge that the protection of human and animal health and the environment are key objectives of the legislation, while improving agricultural production and safeguarding the competitiveness of the agricultural sector;

42. Calls on the industry to provide all data and scientific studies in a uniform electronic and machine-readable format to the rapporteur Member States and the EU agencies; calls on the Commission to develop a harmonised model for data inputs so as to facilitate easier data exchange between Member States at all stages of the process; acknowledges that this data must be handled within the parameters of the EU data protection and intellectual property laws;

43. Calls on the Member States to strictly apply Article 9 of the Regulation on the admissibility of applications and to only accept complete applications for the assessment of the active substance;

44. Calls on the Commission and the Member States to ensure full and uniform application of the hazard cut-off criteria, following the existing harmonised guidance, and to make sure that substances are assessed for their risk only if there is evidence that they do not present hazardous (cut-off) properties, as required by the Regulation;

45. Calls on the Commission to finally implement the provisions on co-formulants, safeners and synergists, to establish a list of unacceptable co-formulants and rules so that safeners and synergists are tested at EU level, and to ensure that only those chemicals which comply with the EU approval criteria can be marketed;

46. Welcomes the Commission's interpretation of the precautionary principle, as expressed in the REFIT evaluation of the General Food Law[1], namely that it is not an alternative to a risk management approach, but, rather, a particular form of risk management; recalls that this view is also supported by EU court rulings[2];

47. Calls on the Commission and the Member States, when acting as risk managers in the approval and authorisation procedures, to duly apply the precautionary principle and to pay particular attention to the protection of vulnerable groups as defined in Article 3(14) of the Regulation;

48. Calls on the Commission, the agencies and the competent authorities to review and improve their communication on risk assessment procedures and risk management decisions, in order to improve public trust in the authorisation system;

49. Calls on the Member States to better implement the authorisation procedures at national level, in order to limit the derogations and extensions granted under Article 53 of the Regulation to actual emergency situations; calls on the Commission to fully use its control rights under Article 53(2) and (3); further calls on the Member States to fully comply with the obligation to inform other Member States and the Commission set out in Article 53(1),

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1 SWD(2018)0038.

2 For example, Judgment of the General Court of 9 September 2011, *France v Commission*, T-257/07, ECLI:EU:T:2011:444.

in particular regarding any measures taken to ensure the safety of users, vulnerable groups and consumers;

50. Calls on the Commission to finalise methods to determine when certain derogations should be applied, in particular as regards ‘negligible exposure’ or ‘serious danger to plant health’, without changing the letter or the spirit of the law; warns the Commission that any reinterpretation of the term 'negligible exposure' as 'negligible risk' would be against the letter and the spirit of the law;

51. Calls for more investment from the Commission and the Member States to incentivise research initiatives concerning active substances, including biological low-risk substances, and PPPs within Horizon Europe and the Multiannual Financial Framework 2021-2027; underlines the importance of a regulatory framework for PPPs at EU level that protects the environment and human health and also stimulates research and innovation in order to develop effective and safe PPPs while ensuring sustainable agricultural practice and IPM; highlights that a wide variety of safe and effective tools are needed to protect plant health; highlights the potential that precision farming techniques and technological innovation can have in helping European farmers optimise pest control in a more targeted and sustainable manner;

52. Calls on the Commission to strictly limit the use of the confirmatory data procedure to its purpose as laid down in Article 6(f) of the Regulation, namely where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge; stresses that complete dossiers are important for active substance approvals; regrets that the derogation-by-confirmatory-data procedure has led to certain PPPs that would have otherwise been banned remaining on the market for an extended period of time;

53. Calls on the Commission and the Member States to increase the overall transparency of the procedures, including by providing detailed minutes on the comitology discussions and the respective positions, in particular by explaining and justifying the decisions of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee);

54. Calls on the Commission and the Member States to ensure better coherence of the Regulation and its implementation with related EU legislation and policies, in particular with the Sustainable Use of Pesticides Directive, and to provide for incentives, including making available sufficient resources, that promote and stimulate in the short term the development and use of safe and non-toxic alternatives to PPPs; notes the failure of the regulatory framework to consider inevitable non-target impacts, notably on bees and other pollinators and other insects that are beneficial to farming as if they were predators of pests; notes the recent scientific study highlighting the ‘insect Armageddon’ whereby 75 % of winged insects have become regionally extinct across Germany, even in nature reserves where no pesticides were used for agriculture; calls on the Commission and the Member States to ensure the coherence of the CAP with the PPP legislation, in particular by maintaining the obligations under Regulation (EC) No 1107/2009 and Directive 2009/128/EC on the list of statutory management requirements (SMR 12 and SMR 13), as proposed by the Commission in the proposal for the CAP Strategic Plans Regulation[1];

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[1] Proposal for the CAP Strategic Plans Regulation - COM(2018)0392.

55. Call on the Member States to ensure effective enforcement of the Regulation, especially as regards controls on the PPPs marketed in the EU and regardless of whether they have been produced in the EU or imported from third countries;

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56. Instructs its President to forward this resolution to the Council and the Commission.