REPORT

on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Pavel Poc
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EXPLANATORY STATEMENT - SUMMARY OF FACTS AND FINDINGS

General background and overview of evidence sources

In May 2017, the Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament requested to undertake an implementation report on Regulation (EC) 1107/2009 on the placing of plant protection products (PPPs) on the market, hereafter referred to as “the Regulation”. This report is part of the implementation scrutiny program of the ENVI committee.

The Ex-Post Evaluation Unit (EVAL) of the Directorate for Impact Assessment and European Added Value (within Directorate-General for Parliamentary Research Services of the European Parliament, DG EPRS) provided expertise on the implementation of the Regulation. In order to prepare the required research evidence, a study aimed at evaluating the implementation of the Regulation was commissioned. The results were consolidated into a European Implementation Assessment (EIA) and officially published in April 2018\(^1\).

The study was based on four interconnected research lines:

- ‘Evaluation of the implementation of Regulation (EC) 1107/2009 on the placing of plant protection products on the market and its impacts. Mapping the usage made by Member States of the derogations granted under Article 53 of the Regulation’;
- ‘Assessing criteria and capacity for reliable and harmonised ‘hazard identification’ of active substances’;
- ‘Assessing Member States’ capacity for reliable ‘authorisation of PPPs’, and its uniformity’;
- Mapping the practices of scientific (risk assessment) evaluation of active substances used in plant protection products’;

A comprehensive study on the impact of the Regulation had never been carried out before. The EIA gathered new data and findings and is the main source of information for this implementation report.

It should be noted that in November 2016 the Commission published a Roadmap on the REFIT2 evaluation of the EU legislation on PPPs and pesticides residues, whose results are expected in early 2019.

The main purpose of both evaluations is to assess the implementation of Regulation (EC) 1107/2009. Although the scope of the Commission’s evaluation is broader\(^3\), the standard set of criteria for evaluation are, however, identical.

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\(^2\) [https://ec.europa.eu/food/plant/pesticides/refit_en](https://ec.europa.eu/food/plant/pesticides/refit_en)

\(^3\) In particular, it covers Regulation (EC) 1107/2009 on placing of plant protection products on the market, which is in the focus of this implementation report, and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
Additionally, in February 2016 the European Ombudsman reached its conclusion in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of PPPs. The Commission, in its risk manager role, has the duty to ensure that the active substances it approves are not harmful for human health, animal health, or the environment. The Ombudsman found that the Commission may be too lenient in its practices and might not be taking sufficient account of the precautionary principle.

There are also relevant judgements of the European Court of Justice and other relevant preliminary rulings that have been taken into consideration by the Rapporteur.

The recent controversy related to the renewal of the approval of the active substance glyphosate further highlighted that trust in the authorisation of PPPs in the EU has been seriously undermined. In October 2017 the Commission declared the European Citizens’ Initiative (ECI) “Stop Glyphosate and protect people and the environment from toxic pesticides”1 admissible. Over 1 million citizens called on the Commission “to propose to Member States a ban on glyphosate, to reform the pesticide approval procedure, and to set EU-wide mandatory reduction targets for pesticide use”.

Against this background in February 2018 the European Parliament decided to set up a special committee on the Union’s authorisation procedure for pesticides (PEST) to analyse and assess, among other things, the authorisation procedure for pesticides in the Union, including the methodology used and its scientific quality, the procedure’s independence from industry, and the transparency of the decision-making process and its outcomes.

Furthermore in April 2018 as a follow-up to its reply to the ECI2 the European Commission officially proposed a targeted revision of the General Food Law and published proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain3, amending, among others, the Regulations whose implementation is discussed here.

This shows that evaluating a complex regulatory system to harmonise and monitor the placing of plant protection products on the EU internal market is high on the political agenda.

All the above mentioned facts have fed into the present report. The Rapporteur also takes into consideration other relevant studies and reports carried out by national authorities and stakeholders.

**The Regulation in the broader context of the EU pesticide policy**

In 2006, the European Commission adopted a thematic strategy on the sustainable use of pesticides in all Member States. As a follow-up, in 2006, the Commission published a proposal for a regulation repealing Directive 91/414/EEC. The final act (Regulation (EC) 1107/2009 which is in the focus here) was published in the Official Journal in 2009.

The Regulation laid down rules for the authorisation of PPPs in commercial form and for their

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placing on the market, use and control within the EU. It laid down both rules for the approval of active substances, safeners and synergists, which PPPs contain or consist of, and rules for adjuvants and co-formulants.

An important new element introduced by the Regulation were a number of strict cut-off criteria for the approval of active substances at EU level. The criteria were introduced with the intention to ban the most toxic substances from the market. The introduction of cut-off criteria means that the approval process is governed by a hazard-based approach, which was not the case under Council Directive 91/414/EC.

The hazard-based approach was underpinned by another principle of EU environmental legislation: the precautionary principle. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks posed by the PPPs to human or animal health or the environment.

**Regulatory procedures for approval of active substances and authorisations of PPPs**

In the European Union, PPPs are subject to a dual approval process: active substances are approved at EU level, commercial PPPs are subsequently authorised at Member State level.

Three main instruments are at the core of the Regulation:

a) approval of active substances performed by national competent authorities, EFSA and the Commission together with Member States’ experts (grouped in the Standing Committee on Plants, Animals, Food and Feed /PAFF Committee/);

b) authorisation of PPPs containing approved active substances;

c) enforcement of regulatory decisions taken in frame of approvals and authorisations.

The approval procedure consists of several stages:

1. Application for approval is submitted to an EU country called Rapporteur Member State (RMS);

2. RMS verifies if the application is admissible;

3. RMS prepares a draft assessment report;

4. EFSA issues its conclusions;

5. PAFF Committee votes on approval or non-approval;

6. Adoption by the Commission;

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1 Article 4 of Regulation (EC) 1107/2009 establishes that an active substance shall only be approved if it is not classified as a carcinogen, a mutagen, toxic for reproduction, persistent and bio-accumulative, toxic for the environment, or an endocrine disrupter for humans and non-target organisms. It means that if the hazard identification stage leads to a classification of the active substance that meets any of the cut-off criteria just mentioned, then it should be banned and therefore its use in PPPs prohibited in the European Union. (Bozzini 2018, Annex II to the EIA, p. 21)
7. Publication of a Regulation in the EU Official Journal.

A plant protection product usually contains more than one component. The active component against pests/plant diseases is called the “active substance”. PPPs contain at least one approved active substance, these may include micro-organisms, pheromones and botanical extracts.

The controls of the placing on the market of PPPs and their use are carried out by Member States.

**Main areas of concern**

The EIA published by EPRS identified a number of different concerns related to the implementation of the Regulation. In the draft report the Rapporteur focuses mainly on the aspects that have negative consequences for the achievement of health and environment objectives.

In particular, those include an increase in derogations granted under Article 53 without providing satisfactory justifications or the fact that a number of crucial aspects are not being sufficiently assessed (for example non-intentional mixtures and combination effects, environmental impact on biodiversity, pesticide degradation at low concentrations, developmental immunotoxicity and developmental neurotoxicity).

Although the Regulation brought about clear progress in terms of better protection of public health and the environment by introducing the hazard cut-off criteria, insufficient harmonization (e.g. ecotoxicology) hinders the evaluation of substances and hence the effective implementation in the relevant scientific areas.

The evaluation identified a number of concerns related to transparency. Particularly problematic is the unavailability of economically feasible and accessible alternatives, and the fact that good agricultural practice in the context of integrated pest management and increased use and availability of low-risk substances are not sufficiently promoted. It also appears that the objectives and instruments of the regulation do not seem to be in line with EU policies in the field of agriculture, food security, climate change and sustainable use of pesticides and maximum residue levels of pesticides in food and feed. Enforcement of the Regulation is problematic. There are indications of an increase of trade in illegal and counterfeit PPPs, which has been identified in recent years.

**Recommendations by the rapporteur**

The Rapporteur is convinced that further efforts on both EU and national level are needed to ensure effective implementation of the Regulation. Even though the objectives of the Regulation related to health and the environment are reported as relevant to the real needs, the evaluation showed that these two objectives are not being achieved in practice. This comes as a result from problems with the practical implementation of the three main instruments of the Regulation identified by the EPRS evaluation - (a) approval of substances, (b) authorisation of PPPs containing approved substances, and (c) enforcement of regulatory decisions taken in the framework of approvals and authorisations.

In relation to negative impacts on public health and the environment, the Rapporteur
considers several aspects of the implementation particularly problematic. These include: misuse of the emergency authorisation procedure, evidenced by an increased number of derogations granted under Article 53, frequent use of the confirmatory data procedure, compatibility of the Regulation with the precautionary principle, incomplete harmonisation of data requirements and methodologies used in some scientific fields used for the evaluation of substances against the cut-off criteria.

The Rapporteur welcomes the recent proposal of the Commission on transparency and sustainability of the EU risk assessment model covering among others PPPs, whilst noting, however, that some of the crucial aspects of the regulatory decision making process are not sufficiently addressed by this proposal and in particular the risk management stage performed by the PAFF Committee in the context of approval of active substances. Increased transparency is also needed as regards aspects of the authorisation by the Member States’ competent authorities.

Additionally, effective implementation cannot be achieved without better harmonisation with EU policies and without increased incentives to promote alternative solutions.

The available evidence shows that enforcement of regulatory decisions under the Regulation is insufficient and that better controls at national level are needed.
MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION
on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009
(2017/2128(INI))

The European Parliament,
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/EEC¹,
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/EEC²,
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 1907/2006³,
of 21 October 2009 establishing a framework for Community action to achieve the
sustainable use of pesticides⁴,
– having regard to its resolution of 15 February 2017 on low-risk pesticides of biological
origin⁵,
– 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,
– having regard to the European Implementation Assessment on Regulation (EC) 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)⁷ 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

⁶ https://www.ombudsman.europa.eu/en/cases/decision.faces;jsessionid=414F07CA7B69C35675EE16710B5AB5AC

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

2. 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,

3. 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;

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

¹ ANSES - Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail (France) - Conclusions, 2018
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\(^1\) 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;

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. 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 in the event of any risk; reiterates that the precautionary principle is clearly not being applied in the general context of risk analysis of pesticides;

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

10. 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;

11. 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;

12. 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;

13. 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;

14. 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;

15. 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;

16. 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; welcomes, in this regard, the fact that the Commission, in its REFIT evaluation of the General Food Law, concluded that EFSA
has been highly transparent and has shared data within the boundaries of the strict confidentiality rules laid down by the co-legislators; 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;

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

18. 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;

19. 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;

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

21. 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;

22. 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 8 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;

23. Takes the view that Regulation 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;
24. 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;

25. 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;

26. 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;

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

28. 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;

29. Highlights that the available guidance documents are not always 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;

30. 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;

31. 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;

32. Expresses its concern regarding the small number of new substances that have been approved, while at the same time other substances have been taken off the market; stresses the importance of a suitable toolbox of PPPs for farmers in order to secure the EU’s food supply;

33. 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;

34. 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;

Recommendations

35. 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;

36. 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;

37. 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;

38. 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;

39. 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;

40. 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;

41. 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;
42. 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\(^2\); calls on the Commission to assess whether the cut-off criteria as laid down in the Regulation are fit for purpose in this regard;

43. 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;

44. 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;

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

46. 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;

47. 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;

48. 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 is not always used in a targeted and sustainable manner.

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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.
has led to certain PPPs that would have otherwise been banned remaining on the market for an extended period of time;

49. 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);

50. 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) 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 Regulation¹;

51. 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;

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

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Food Safety

on implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI))

Rapporteur: Peter Jahr

SUGGESTIONS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

1. Stresses the importance of a regulatory framework that encourages competitiveness, stimulates and facilitates research and innovation in order to develop better and safer plant protection products (PPPs), while at the same time securing the availability of a broad range of plant protection products; believes that future reviews of the regulatory framework should encourage the authorisation of PPPs compatible with sustainable agriculture systems, which are environmentally sound, effective and affordable, and which also take due account of non-target impacts, notably on bees and other pollinators and other insects beneficial to farming, such as the natural predators of pests;

2. Notes that the EU approval process for PPPs is one of the most stringent in the world, currently taking over 11 years, requiring an average of over 200 scientific studies and costing in excess of EUR 220 million to bring a product to the EU market; underlines its belief that the Regulation’s set of targets can be achieved most effectively if farmers and producers, irrespective of the Member States they are operating in, have access to a broad range of active substances and PPPs that allows them to efficiently tackle pests; stresses that the availability of a broad range of PPPs is the basis for any meaningful reduction strategy as farmers would otherwise be dependent on less targeted and hence less efficient PPPs, which would lead to higher consumption; expresses, therefore, its concerns about the small number of new active substances that have been authorised since Regulation (EC) No 1107/2009 entered into force; points out that since the current rules were introduced, only eight new active substances have been authorised for use on the EU market; stresses that sustainable, low-risk PPPs (and the active substances in them) play a key role here; stresses the fact that, if farmers have no access to PPPs, they will be powerless to prevent the growth of certain natural pathogens present in crops,
thus jeopardising our food security;

3. Points out that this regulation is part of the wider EU PPPs regime, which also includes the Sustainable Use Directive (SUD), the regulation setting Maximum Residue Levels (MRL) and the Regulation on Classification, Labelling and Packaging of Substances and Mixtures1, and that all four parts must be considered together in order to identify whether they are fit for purpose, including with a view to reducing the total volume of PPPs used, notably through the Member States and the Commission ensuring the implementation of integrated pest management (IPM) and encouraging the use of low-risk pesticides as well as agronomic practices; recalls that there is a substantial need for an integrated approach and that Regulation (EC) No 1185/2009 on statistics on pesticides should be taken into account;

4. Notes that the proper and appropriate use of plant protection products must comply with the provisions of Directive 2009/128/EC and, in particular, with the general principles of IPM and its holistic approach; regrets that these principles are not being implemented to their full potential in the Member States and that IPM development is being hindered by the limited availability of low-risk, non-chemical pesticides, including low-risk plant protection alternatives; notes that resistance is a biological inevitability when dealing with fast-reproducing pests and diseases; emphasises the use of IPM as a way to prevent resistance and the need to avoid blanket treatment when often not a single pest is even detected;

5. Highlights the importance of continuous training and education for farmers in the proper and appropriate use of plant protection products; urges the Member States and competent authorities to make better use of all available measures to increase the safe use of plant protection products and reduce adverse environmental effects; stresses the need to distinguish between professional and private use of PPPs, given that they are not subject to the same obligations, and calls on the Commission and the Member States to clearly distinguish between these two kinds of use and to amend the rules accordingly; stresses that PPPs are not only used in agriculture, but also for weed and pest control in urban areas, including public parks and railways; emphasises that professional and non-professional users of PPPs should receive adequate training;

6. 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 in line with the principles of Directive 2009/128/EC; highlights the potential efficiency gains in plant protection that could be realised through the use of precision farming technologies, which would lead to a significant reduction in the quantities used and would also reduce the environmental impact; calls on the Commission to fully embrace this form of scientific and technological progress and ensure that farmers, consumers and the environment benefit from it;

7. Notes that, for some tools in the ‘toolkit’ such as biological controls using the natural predators of pests or their parasites or parasitoids to work, it is important that untargeted broad spectrum pesticides should be avoided until being used as a last resort;

8. Highlights the important role PPPs play in enabling crops to be grown and harvested
with reduced losses resulting from diseases and pest infestations, and increasing quality yields and rural incomes;

9. Notes that PPPs represent a significant expense for farmers as part of their crop production systems;

10. Underlines the need for knowledge sharing and skill 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 within rural development;

11. Stresses the contribution that the authorisation of low-risk PPPs makes to a sustainable EU farming sector, the importance of ensuring their availability and the important role low-risk PPPs can play in a comprehensive strategy of integrated pest management; draws attention to the importance of contributing to a better functioning agricultural ecosystem and a sustainable farming sector, while pointing out that the lack of availability of PPPs could jeopardise the diversification of agriculture and cause harmful organisms to become resistant to PPPs; believes, in this respect, that an assessment of their effectiveness and risks, and of their capacity to meet the environmental, health and economic needs of agriculture, must be guaranteed in order to increase acceptance and facilitate a broad uptake in farmers’ crop protection strategies; calls for the development of low-risk PPPs to be encouraged; observes that natural substances and products that are known to involve less risk should not need lengthy approval procedures; asks, therefore, for the introduction of an accelerated procedure (i.e. fast track procedure) for the evaluation, authorisation and registration of biological low-risk plant protection products;

12. Expresses concerns about the small number of new substances that have been approved, while at the same time other substances have been taken off the market; stresses the importance of a suitable toolbox of PPPs for farmers to secure the EU’s food supply;

13. Welcomes the fact that an implementation report for Regulation (EC) No 1107/2009 is being undertaken in order to scrutinise its performance with the aim of ensuring food safety and environmental protection and a high level of protection of human, plant and animal health; stresses the need, at the same time, to safeguard the competitiveness of the EU’s agriculture sector by ensuring a level playing field through access to a broad range of reasonably priced active substances and PPPs for all farmers and producers, irrespective of which Member State they are operating in; recalls recital eight of Regulation (EC) No 1107/2009, which clearly highlights that particular attention should be paid to the protection of vulnerable groups of the population, and that the precautionary principle should be applied; expresses, in this context, its concern that some Member States are not sufficiently equipped to deal with illegal and counterfeit plant protection products;

14. 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 Regulation (EC) No 1107/2009;
15. Stresses the fact that between 1993 and 2009, the number of authorised active pesticidal substances fell by 70%, while the number of pest outbreaks in the EU increased;

16. Recognises that PPPs have played a significant role in improving the agricultural sector’s ability to satisfy global nutritional needs, which has contributed to reducing the global share of undernourished people in the population from 18.6% in 1990-1992 to around 10.9% in 2014-2016, according to the FAO; takes the view, therefore, that the current system should be improved by intensifying efforts to eliminate adverse effects rather than by it being dismissed without having alternatives to hand that are equally capable of maintaining and further increasing the supply of food;

17. Expresses its concern that in recent debates, the European Union’s current science-based evaluation system for PPPs has been increasingly called into 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 (Regulation (EC) No 178/2002); 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;

18. Welcomes the Commission’s interpretation of the precautionary principle, as expressed in the REFIT evaluation of the General Food Law, 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; calls on the Commission to assess whether the cut-off criteria as laid down in Regulation (EC) No 1107/2009 are fit for purpose in this regard;

19. Notes that the Rapporteur Member State has to prepare and submit to the Commission, with a copy to the Authority, a report referred to as a ‘draft assessment report’, assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4; highlights that the Rapporteur Member State must make an independent, objective and transparent assessment in the light of current scientific and technical knowledge;

20. Expresses its concern that Regulation (EC) No 834/2007 provides no equally scientifically robust and thorough regime for the assessment of the effects on human and animal health and the environment in relation to the authorisation of substances for plant protection in organic production; notes that the principle of separating risk assessment and risk management is not applied in the aforementioned Regulation;

21. Expresses its concern about systematic delays in the authorisation processes and the

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3 For example, Judgment of the General Court of 9 September 2011, France v Commission, T-257/07, ECLI:EU:T:2011:444.
increasing use of derogations as laid down in Article 53 of Regulation (EC) No 1107/2009; stresses that these delays seriously hinder the market introduction of efficient and safer innovative products, and that they also lead to an increasing use of emergency authorisations, which entail a higher environmental burden; underlines the necessity for Member States to comply with the legal deadlines, to ensure predictability for applicants and facilitate the market introduction of innovative PPPs that are in line with more stringent requirements; considers, moreover, that any derogation should be duly justified and reassessed on a regular basis; recalls recital 10 of Regulation (EC) No 1107/2009, which clearly highlights 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 they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment; highlights that a Commission audit carried out in 2016 and 2017 in seven Member States showed that the majority of the audited Member States did not have the correct systems in place to ensure the processing of applications within the legal deadlines, which should not exceed 120 days;

22. Deplores the unilateral decisions by Member States, which can lead to the abolition or a restriction in the use of products approved by other Member States, and the lack of harmonisation in the time taken to process requests for authorisation, which gives rise to distortions of competition in the internal market and forces farmers into technical dead ends, which are both harmful to the environment and counter-productive in terms of the competitiveness of farms;

23. 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 approvals 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; welcomes, in this regard, the fact that the Commission, in its REFIT evaluation of the General Food Law, concluded that the European Food Safety Authority (EFSA) has been highly transparent and has shared data within the boundaries of the strict confidentiality rules laid down by the co-legislators; further welcomes EFSA’s continuous efforts to improve its system 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 to improve evaluations, increase the independence of the authorities tasked with carrying out studies, avoid conflicts of interest and make the procedure more transparent;

24. Highlights the imbalance in the number of applications between some Member States of

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1 SWD(2018)0038.
2 https://www.eca.europa.eu/Lists/News/NEWS1210_11/NEWS1210_11_EN.PDF
the same zone, and of similar size and agricultural conditions;

25. Stresses the need to encourage work sharing and information exchange between Member States by fostering the availability and use of harmonised methodology and models to conduct evaluations, while reducing the existence of unnecessary additional national requirements, in order to ensure the optimal operation of the internal market; points to the existence of specific requirements in each Member State and the lack of harmonisation between the methodologies used for the evaluations as the main causes of the lack of trust between Member States and the reason why they carry out re-assessments based on their own national models; underlines the role of the Member States in the effective implementation of Regulation (EC) No 1107/2009; highlights the benefits of efficient authorisation, including more timely access to PPPs including low-risk alternatives; considers it vital to improve harmonisation of the legislation on placing PPPs on the market in the EU in order to prevent distortions of competition; underlines that the full implementation of existing legislation should have the aim of avoiding duplication of work and making new substances available to farmers without unnecessary delays;

26. Welcomes the idea and targets of the zonal authorisation system, but recognises that these targets could potentially be achieved more efficiently by a single authorisation system at Union level; asks the Commission to evaluate whether the authorisation process could be achieved in a more time- and cost-efficient manner either by improving the current system (e.g. by strengthening the harmonisation of methodology, models and application requirements, and/or by introducing a mandatory authorisation for the entire zone following a positive evaluation by the zRMS), or by setting up a single Union approval system;

27. Welcomes the idea and targets of the zonal authorisation system and recalls that this system should, in principle, lead to an authorisation of PPPs that is more time- and cost-efficient for all parties concerned; points out that the aim of the zonal evaluation of PPP applications, which allows applicants to propose one zonal Rapporteur Member State (zRMS) to carry out the assessment, should lead to the concerned Member States (cMS) taking a decision in cooperation with each other within the maximum time limit of 120 days after the zRMS has issued the registration report; expresses its concern that, in practice, these benefits have hardly materialised at all, leading to systematic delays in the authorisation process and an increased use of emergency authorisations; urges, therefore, the Member States to fully use the opportunity of work sharing provided by the zonal authorisation system, and encourages the Commission and competent authorities to support the Member States in so doing;

28. Stresses that the aim, in terms of the single market, of the procedure of mutual recognition by Member States in a particular geographical region was to simplify procedures and increase trust among the Member States; regards the application of the mutual recognition procedure as an important tool to increase work sharing and ensure compliance with deadlines while guaranteeing optimum protection for users, allowing applicants to apply for authorisation in another Member State which makes the same use of the product in question for the same agricultural practices, based on the assessment carried out for the authorisation in the original Member State, which, for its part, must be responsible at all times for the assessment issued to Member States.
applying mutual recognition;

29. Is of the opinion that, given the discrepancies in practice among the Member States and the list of products which have been effectively authorised, these objectives have not been achieved; draws attention to the fact that, if the significant discrepancies between the Member States with regard to authorised PPPs and the mistrust between them persist, the principle of mutual recognition cannot be applied effectively; calls, therefore, on the Commission to improve the functioning of the mutual recognition system, proceeding in two stages:

a) reviewing the mutual recognition procedure with the aim of increasing its effectiveness and improving its implementation, the meeting of deadlines and increasing mutual trust between the Member States;

b) carrying out an impact assessment in order to gauge the feasibility of setting up an authorisation procedure for PPPs, possibly at European level and coordinated by the Commission, taking into account specific geographical characteristics, with the aim of harmonising the rules among the Member States, dramatically reducing costs and time limits and resolving problems of unfair competition by strengthening the internal market for PPPs, and bearing in mind the fact that this kind of procedure will not be possible without sufficient budgetary resources and expertise from the Member States;

30. Expects the impact assessment to confirm whether or not establishing a single authority at EU level, responsible for all aspects of the evaluation and authorisation of active substances, would avoid duplication of work, significantly reduce costs and administrative burdens, and ensure a uniformly high level of protection of the environment and human health as well as providing a ‘one-stop shop’ for the evaluation and registration of active substances;

31. Takes the view that an authorisation procedure for PPPs, which is harmonised at European level, might provide common solutions for small farms, which are currently in technical dead ends because of the cost of obtaining authorisation and the lack of investment and research on the part of private and public stakeholders;

32. Notes that the lack of coordination between the Member States is leading to duplication of work, resulting in inefficient expenditure and administrative burdens;

33. Notes with concern that farmers have fewer tools available to them due to the low number of new active substances that have been approved since the implementation of Regulation (EC) 1107/2009; reminds the Commission and the Member States of the importance of financing research and innovation, notably through public-private partnerships, aimed at finding viable, safe and effective solutions for plant protection in environmental, health and economic terms, and stresses the need to guide farmers in the implementation of these alternative solutions to enable them to reduce their use of PPPs and ensure that sustainable agriculture meets the demands of a growing global population, as well as addressing environmental and health concerns; highlights that research and technology have an important role to play in increasing the number of tools available to meet the current and future challenges faced by agriculture, such as counteracting resistance;
34. Welcomes the effort made by the Commission in creating the coordination tool for the approval of plant protection products for minor uses, but stresses the need to make active substances for these purposes more widely available, and recalls that in many Member States, minor uses represent a large majority of crops;

35. 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; such substances offer interesting alternatives in terms of integrated production methods and some bio-control products;

36. Welcomes the setting up of the Minor Uses Coordination Facility as a forum for improving coordination between the Member States, grower organisations and industry in developing solutions for minor uses; stresses the need for long-lasting and sustained financing of this facility;

37. Calls on the Member States to undertake an exchange of information and good practices resulting from research into combating organisms, which are harmful to crops, thereby paving the way for alternative solutions, which are practicable in environmental, health and economic terms;

38. Highlights that special attention should be given to the role of small and medium-sized enterprises (SMEs) in the development of new products, as SMEs often lack the vast resources that are necessary in the process of development and approval of new substances;

39. Calls on the Commission to strengthen the coordination of data generation, particularly residues data, across the Member States;

40. Considers that products imported from outside the EU, which have been grown using PPPs, should be subject to the same strict criteria as products produced inside the EU; is concerned that PPPs not registered in the EU may be used in the production of imported produce;

41. Calls on the Commission to propose a pan-European system of authorisation for minor uses and speciality crops and a common list of major/minor crops to be applied at EU level;

42. Takes the view that low-risk pesticides can play an important role in IPM and calls for an accelerated authorisation process for these substances in order to facilitate their inclusion in crop protection strategies.
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