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Special Committee on the Union's authorisation procedure for pesticides

2018/2153(INI)

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DRAFT REPORT

on the Union's authorisation procedure for pesticides
(2018/2153(INI))

Special Committee on the Union's authorisation procedure for pesticides

Rapporteurs: Norbert Lins, Bart Staes

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on the Union's authorisation procedure for pesticides
(2018/2153(INI))

The European Parliament,

– having regard to its decision of 6 February 2018 on setting up a Special Committee on the Union's authorisation procedure for pesticides, its responsibilities, numerical strength and term of office[1],

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

– 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[3],

– 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[4],

– having regard to Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products[5],

– having regard to Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances,

– having regard to Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products,

– having regard to Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate[6] and Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate[7],

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[1] Texts adopted, P8_TA(2018)0022.
[2] OJ L 309, 24.11.2009, p. 1.
[3] OJ L 70, 16.3.2005, p. 1.
[4] OJ L 353, 31.12.2008, p. 1.
[5] OJ L 155, 11.6.2011, p. 127.
[6] OJ L 173, 30.6.2016, p. 52.
[7] OJ L 208, 2.8.2016, p. 1.

– having regard to Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011[1],

– having regard to its resolutions of 13 April 2016[2] and of 24 October 2017[3] on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011,

– having regard to its resolution of 15 February 2017 on low-risk pesticides of biological origin[4],

– 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),

– having regard to Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[5],

– having regard to the study 'IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides', published on 20 March 2015,

– having regard to the opinion of the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) on the classification of glyphosate of 15 March 2017,

– having regard to the judgment of the Court of Justice of the European Union of 23 November 2016 in Case C-442/14 *Bayer CropScience SA-NV, Stichting De Bijenstichting* v *College voor de toelating van gewasbeschermingsmiddelen en biociden*,

– having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009[6],

– having regard to the Commission proposal for a regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in

[1] OJ L 333, 15.12.2017, p. 10.
[2] Texts adopted, P8_TA(2016)0119.
[3] Texts adopted, P8_TA(2017)0395.
[4] Texts adopted, P8_TA(2017)0042.
[5] OJ L 55, 28.2.2011, p. 13.
[6] Texts adopted, P8_TA(2018)0356.

the food chain (COM(2018)0179)[1],

– having regard to Scientific Opinion 5/2018 of the Scientific Advice Mechanism (SAM) on the EU authorisation processes of plant protection products, of June 2018[2],

– having regard to Rule 52 of its Rules of Procedure,

– having regard to the report of the Special Committee on the Union's authorisation procedure for pesticides (A8-0000/2018),

General considerations

A. whereas the EU authorisation procedure for plant protection products is one of the most stringent in the world; whereas in the light of the concerns raised about the assessment of glyphosate, the Special Committee on the Union's authorisation procedure for pesticides (PEST) aims to identify areas that can be further improved with regard to the Union authorisation procedure for plant protection products, by providing recommendations that it considers to be necessary in order to ensure the achievement of a high level of protection of both human and animal health and the environment;

B. whereas the decision-making process has been found to be lacking in transparency throughout the procedure, from lack of public access to the full studies and raw data through to the risk management stage;

C. whereas the methodologies used for the scientific assessment of active substances, in the form of guidance used by EFSA and Member States, do not always reflect the current state of scientific and technical knowledge as required by Article 4 of the Regulation; whereas some key tests are either not included in the risk assessment or recent scientific methods are missing (as in the cases of up-to-date ecotoxicological tests for soil organisms and assessment of environmental concentration and residues in dust, wind, air and water);

D. whereas the updated bee guidance used by EFSA in its recent review of three neonicotinoids has not yet been formally adopted; whereas the guidance on soil organisms currently used by EFSA dates from 2002;

E. whereas the widespread and prophylactic use of plant protection products is of concern;

F. whereas there is a lack of monitoring post-authorisation;

G. whereas the lack of data concerns active substances, safeners, synergists and co-

[1] Commission proposal for a Regulation of the European Parliament and of the Council 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] https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf

formulants, as well as formulations and mixtures of products; whereas, therefore, the full impact of pesticides on human and animal health as well as on the environment is not properly known;

H. whereas it has been found that national competent authorities involved in the approval and authorisation process are in some cases understaffed and underfunded; whereas this impacts on the quality of the assessments, both for active substances and plant protection products, and the time in which they can be delivered;

I. whereas EU Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin provides that 'known cumulative and synergistic effects' must be considered 'when the methods to assess such effects are available';

J. whereas such methodologies are now available and a pilot assessment, looking at the cumulative effects of exposure to pesticides in food on the human nervous and thyroid systems, is expected to be finalised by end of 2018 by EFSA;

K. whereas there is currently no legal obligation to test active substances for their developmental neurotoxicity (DNT), examples of which include causing autism, attention deficit hyperactivity disorder (ADHD) and dyslexia; whereas, in this context, EFSA is working on an ongoing project to develop non-animal alternatives for screening DNT effects;

Application for approval of active substances

L. whereas concern has been raised about the right of applicants to choose the Rapporteur Member State (RMS) upon first application for approval of an active substance;

M. whereas concern has furthermore been raised over the fact that the RMS given responsibility by the Commission for the renewal of an assessment report may be the same one which did the initial draft assessment report;

N. whereas for new active substances, only 11 out of 28 Member States have been chosen as Rapporteur Member States by applicants since the entry into force of the Regulation, which illustrates that there are significant differences concerning expertise and staffing;

O. whereas Article 8(1) of the Regulation requires the applicant to provide a summary dossier, which should include inter alia the summaries and results of tests and studies for each point of the data requirements, including an assessment of all information submitted;

P. whereas concern has been raised by stakeholders concerning the evaluation approach as established by law, and in particular over who should produce the scientific studies and evidence for the evaluation of active substances;

Q. whereas Article 8(5) of the Regulation requires the applicant to add scientific peer-reviewed open literature on the active substance and its relevant metabolites to the dossier;

R. whereas for new active substances, normally only data from regulatory studies generated by the applicant are available;

S. whereas scientific peer-reviewed open literature provides important complementary information to the studies based on Good Laboratory Practices (GLP) provided by applicants, and can include findings that alert evaluators to adverse effects that are not seen by standard testing;

T. whereas the principles of GLP have been developed by the OECD to ensure that a study was carried out as prescribed by a particular test method to prevent fraudulent practices; whereas the EU has adopted these principles through Directive 2004/10/EC, which requires Member States to ensure that laboratories carrying out safety studies on chemical products comply with the OECD Principles of GLP and with Directive 2004/9/EC, which lays down the obligation of Member States to designate the authorities responsible for GLP inspections in their territory; whereas OECD test guidelines have been adopted to ensure the methodological validity of a study;

Draft assessment by the Rapporteur Member State (RMS)

U. whereas pursuant to Article 11(2) of the Regulation 'the rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge';

V. whereas it has been found that different Member States, when acting as RMS, use different practices when it comes to referencing the applicant's summaries of peer-reviewed literature; whereas it is a fundamental rule that any scientific work should clearly indicate statements made by others by using quotation marks;

W. whereas Parliament acknowledges the debate over the literature review in the risk assessment report on glyphosate by the German Federal Institute for Risk Assessment (BfR); whereas there are concerns that important assessment elements in the draft risk assessment report on glyphosate were taken from the application, without being clearly indicated as references;

EFSA opinion on draft assessment reports and ECHA classification of active substances

X. whereas the decreasing trust in EFSA is a concern;

Y. whereas there is an imbalance of national expertise at EFSA as currently about two thirds of national experts working for EFSA come from only six Member States;

Z. whereas according to Article 4(1), second subparagraph of the Regulation, the assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied (= 'cut-off criteria'); whereas one of these cut-off criteria concerns the classification of a substance as a carcinogen (category 1A or 1B) in accordance with the provisions of Regulation (EC) No 1272/2008;

AA. whereas the International Agency for Research on Cancer (IARC) classified glyphosate as probably carcinogenic to humans (Group 2A) according to its nomenclature (equivalent to category 1B in Regulation (EC) No 1272/2008), while EFSA and ECHA

concluded that no classification as carcinogenic was warranted pursuant to the provisions of Regulation (EC) No 1272/2008;

AB. whereas while IARC based its conclusion solely on published literature, EFSA and ECHA used unpublished studies submitted by the applicant according to Article 8 of the Regulation as the core basis of their evaluation;

AC. whereas several other competent authorities around the world, including those of the US, Canada, New Zealand, Australia and Japan, have subsequently finalised new assessments of glyphosate and none of these organisations have confirmed the IARC assessment;

AD. whereas, as shown by a comparison carried out by EFSA in 2017 of 54 pesticides that had been assessed under both the EU and IARC systems, in 14 cases the EU classification was more conservative (and thus stricter) than IARC, in 11 cases (glyphosate and 10 other active substances) less strict, and in 29 cases equivalent;

AE. whereas concern has been and is still being raised over the opinions by EFSA and ECHA concerning their conclusions in favour of not classifying glyphosate as carcinogenic;

AF. whereas it was unfortunately not possible to resolve those concerns in the Special Committee;

Commission approval of active substances

AG. whereas the Regulation lays down a six-month deadline for the Commission, from the EFSA conclusions to the Commission's final approval;

AH. whereas the decision to renew the approval of glyphosate did not contain legally binding risk mitigation measures, even though a high long-term risk was found for almost all uses of glyphosate for non-target terrestrial vertebrates, including mammals and birds;

AI. whereas it is not clear under what conditions the Commission considers a risk to be unacceptable for the environment;

AJ. whereas the fact that the Commission, with the support of the Member States, approves active substances found by EFSA to pose high risks to the environment and biodiversity is a concern, given that according to Article 4(3)(e) of the Regulation a plant protection product shall have no unacceptable effects on the environment;

AK. whereas the European Ombudsman, in her decision in case 12/2013/MDC of 18 February 2016, stated that submission of confirmatory information should not concern data requirements which existed at the time of the submission of the application in relation to the assessment of risks to health and for which adequate guidance documents were available;

AL. whereas confirmatory data are generally not subject to the same scientific scrutiny or assessment as data submitted in the original application as they are not subjected systematically to an EFSA peer review; whereas the European Ombudsman, in her 2016

decision, invited the Commission to consider whether, from now on, all confirmatory information should be systematically subject to an EFSA peer review and whether the guidance documents should be amended accordingly;

AM. whereas despite the risks identified by EFSA in its conclusions on active substances, the Commission often leaves risk mitigation measures to the Member States, notwithstanding the possibility granted to it under the Regulation to impose them at EU level; whereas this approach was condemned by the European Ombudsman in her decision in case 12/2013/MDC;

AN. whereas there is a lack of availability of low-risk plant protection products; whereas only ten substances are approved as low-risk active substances out of a total of almost 500 available on the EU market;

Authorisation of plant protection products by Member States

AO. whereas plant protection products should be fully assessed prior to their authorisation; whereas understaffing and/or underfunding may result in over-reliance on the assessment conducted for the approval of the active substances in the context of decisions for plant protection products;

AP. whereas the procedure for authorisation of plant protection products, and in particular the data requirements for risk assessment, should take into account the actual use of plant protection products;

AQ. whereas Article 25 of the Regulation requires safeners and synergists to be subject to the same approval procedure as active substances, for inclusion on a positive list; whereas the Commission has not yet approved any safeners or synergists;

AR. whereas Article 27 of the Regulation requires the Commission to include, in Annex III, a negative list of unacceptable co-formulants; whereas the Commission has not yet adopted the negative list of co-formulants, but has stated its intention to do so by the end of 2018; whereas certain Member States have developed their own negative lists of co-formulants, in the absence of such a list at Union level;

AS. whereas the absence of these EU lists makes the thorough risk assessment of plant protection products more difficult;

AT. whereas concern has been raised with regard to the zonal system, and in particular the delays in the procedure and the frequent full or partial re-evaluations of applications in the context of mutual recognition, arising from the differing national requirements of evaluation models of Member States in the same zone;

AU. whereas the Commission is working on an IT system, the Plant Protection Products Application Management System (PPPAMS), which will be accessible to the public and will facilitate the mutual recognition system;

AV. whereas concern has been raised that there is currently no overview of all plant protection products authorised in the EU, as Member States are not obliged to systematically inform the Commission about their decisions on authorisation;

AW. whereas Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products requires data on acute toxicity of the plant protection product but not on its long-term toxicity;

AX. whereas Member States are working on setting up a comparative assessment of plant protection products with substitution candidates; whereas the objective is to replace such products with lower-risk plant protection products;

AY. whereas the use and identified cases of emergency authorisations granted under Article 53(2) of the Regulation is steadily increasing; whereas some Member States use Article 53 significantly more than others; whereas the recent EFSA evaluation of the emergency authorisations of three neonicotinoids concluded that in some cases those authorisations were in line with the provisions set out in the legislation, while in other cases those conditions were not met;

AZ. whereas since the entry into force of the Regulation, the Commission has only once used the possibility to request an opinion from EFSA under Article 53(2);

General observations

1. Considers that, although the EU has one of the most stringent systems in the world, both the Regulation as such and its implementation need to be improved;

2. Welcomes the recommendation of the Scientific Advice Mechanism that the Commission facilitate a broader discussion throughout society in order to establish an EU-wide shared vision for food production, including the role of plant protection products therein; whereas such considerations should take into account, among other factors, affordability of food for consumers, income and long-term viability of agricultural production, as well as the risks and benefits to human and animal health and the environment associated with different scenarios for the use of plant protection products, including a zero use scenario;

3. Calls on the Member States to allocate sufficient resources to the assessment of active substances and plant protection products and to ensure independent, objective and transparent assessment;

4. Calls on the Commission and the Member States in their role as risk managers to duly apply the precautionary principle when deciding whether or not to authorise active substances / plant protection products, and under what conditions, and to communicate systematically on how this principle has been taken into account;

5. Considers that greater attention should be paid to the widespread and prophylactic use of plant protection products and the effects thereof on the environment in the EU system;

6. Calls for the creation of an effective post-market vigilance system to monitor the impacts of the use of plant protection products on human and animal health and on the environment as a whole;

7. Welcomes EFSA's ongoing project to model DNT effects, but considers this to be insufficient until there is a legal requirement for active substances and other pesticide components to be assessed for DNT effects as part of the authorisation process; calls on the Commission to propose amending the Regulation to ensure that active substances and other components in plant protection products be assessed for DNT effects;

8. Calls for Horizon Europe to provide sufficient funding to promote independent research on the adverse effects of plant protection products on human and animal health and the environment;

9. Calls on EFSA and the Commission to improve their risk communication in order to inform the public in an appropriate and easily understandable way;

Application for approval of active substances

10. Calls on the Commission to propose amending the Regulation so as to empower it to adopt a work programme with regard to the designation of the RMS for applications for approvals, on the basis of expertise, resources, relevance for the product, technical capacity and ability to achieve scientifically robust and reliable outcomes, together with a comprehensive peer review process and a stakeholder consultation, on lines similar to the system for re-approval of active substances;

11. Calls on the Commission to allocate the evaluation of applications for renewal to a Member State other than that which was in charge of the previous evaluation(s), provided the necessary level of expertise and resources can be ensured;

12. Calls on the Commission to ensure that only Member States that can guarantee a high quality of assessment become RMS;

13. Calls on EFSA to carry out an assessment of the national reference laboratories attached to the competent authorities of the RMS concerned in order to ensure the same level of expertise for the RMS draft assessment report (DAR);

14. Further calls on the Member States to responsibly carry out their auditing of GLP-certified laboratories, and calls on the Commission to create a verification system for Member State audits led by itself;

15. Takes note of the Commission's proposal on the transparency and sustainability of the EU risk assessment in the food chain;

16. Considers it important that applicants should be required to register all regulatory studies to be performed, in a public register and prior to starting the studies; stresses that the provisions regarding the public register also include registration by the certified laboratory of the dates when the study has started and concluded, and the publication of the control data, to be included in a register of historical controls; considers that only regulatory studies that have been registered may be submitted with an application;

17. Stresses the need to require applicants to provide all studies to the RMS, including the raw data, in a machine-readable format;

18. Calls for public access to be granted to the studies in a machine-readable format and in their entirety, directly following adoption of the DAR, in order to allow for independent scrutiny while ensuring that those who requested the studies can only use them for non-commercial purpose, so as to safeguard the relevant intellectual property rights;

19. Calls on the Commission to assess whether it would be appropriate to no longer require the applicant to provide scientific peer-reviewed open literature on the active substance and related formulations, instead assigning this task to the RMS;

20. Stresses that scientific peer-reviewed open literature, where available, should be given the same weight in the assessment as GLP-based studies;

21. Recommends a reassessment of the current rules for the literature review so as to ensure a balance between peer-reviewed and GLP-based studies;

Draft assessment by the RMS

22. Insists that the RMS should strictly apply Article 9 of the Regulation, so as to ensure that applications are complete before they are deemed admissible;

23. Stresses that the assessment should include a thorough evaluation of the raw data, as well as data related to final product formulations; calls on the RMS to clearly demonstrate in the DAR that all studies have been properly checked for their relevance, scientific quality and validity, and if necessary to include further studies that were considered as not relevant by the applicant;

24. Calls on the Commission to propose amending the Regulation to ensure that an active substance is assessed on the basis of the most frequent uses and the most frequently used formulations;

25. Calls for all assessments to be based on a systematic review of all available evidence and full transparency regarding the use of ‘weight of evidence’;

26. Recommends that the RMS should limit reproducing paragraphs to a minimum and only to justified cases; insists that, as long as the assessment is made by the applicant, should passages be taken from the application dossier a clear distinction should be made between the assessment of the authority and the assessment of the applicant;

EFSA opinion on draft assessment reports and ECHA classification of active substances

27. Calls on the Commission and the Member States to ensure that key tests (e.g. up-to-date ecotoxicological tests for soil organisms and assessment of environmental concentration and residues in dust, wind, air and water) and up-to-date scientific methods are included in the risk assessment;

28. Calls on the Commission to propose amending the Regulation in order to include in it a post-marketing monitoring system similar to pharmacovigilance, with a view to enabling proper assessment of the long-term effects on human and animal health and on the environment;

29. Calls on the Commission to develop a standardised EU-wide IT platform or database to

support the sharing of post-market monitoring data;

30. Calls on the Commission to set maximum residue levels for soils, using, inter alia, the data collected through post-market environmental monitoring;

31. Calls for the data collected through post-market environmental monitoring to be used to verify the accuracy of Predicted Environmental Concentrations (PECs) in fate models;

32. Calls on the Commission to propose amending Commission Regulation (EU) No 284/2013 to include data requirements regarding the long-term toxicity of the pesticide product and further routes of exposure, notably via wind and water erosion of soil, using up-to-date modelling;

33. Calls on EFSA to regularly update its guidance documents in line with the most recent developments in all relevant fields, with a view to assessing the short- and long-term effects of residue mixtures and formulations in soil and residue levels in wind and dust; stresses that the guidance documents should provide sufficiently clear orientations for risk managers;

34. Calls on the Commission and the Member States, in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), to adopt without delay any pending guidance, including the updated bee guidance used by EFSA in its recent review of three neonicotinoids;

35. Welcomes the pilot assessment on cumulative effects, and calls for its completion as planned by the end of 2018 and the rapid implementation thereafter of cumulative risk assessments as part of the authorisation process; calls for research in relation to other routes of exposure in addition to the nervous and thyroid systems to be prioritised and accelerated;

36. Calls on EFSA and ECHA to increase the user-friendliness of the information provided on their websites;

37. Calls on the Member States to ensure that they are properly represented in EFSA;

38. Recommends that scientific knowledge and capacity be secured by supporting, expanding and strengthening the expert network of EU agencies, Member State bodies, institutes and university research groups involved in risk assessments;

39. Further recommends cooperation in international science networks with international experts, to support the scientific discussion and input in order to strengthen the international cooperation of the peer-review system, which leads to more internationally recognised results of high quality;

40. Recommends to EFSA that it publish its opinions in peer-reviewed journals in order to intensify constructive discussion and incentivise and encourage more national experts to participate in its work;

41. Calls for EFSA to be allocated sufficient funds to enable it to carry out its tasks in an independent, objective and transparent manner, so as to ensure a high level of protection

of human and animal health and the environment;

42. Calls for adequate resources to be allocated to enable finalisation of landscape-scale post-market environmental monitoring and analysis, including monitoring of pesticide residues in soils and dust, the results of which should be shared with EFSA;

43. Calls on the Commission's Scientific Advice Mechanism to act on request as a mediator in scientific controversies concerning active substances;

44. Calls on the Scientific Advice Mechanism to initiate a systematic review of all available studies concerning the carcinogenicity of glyphosate and glyphosate-based formulations and to act as a mediator between the relevant actors, in order to prepare for any future decision on the renewal of approval of glyphosate;

Commission approval of active substances

45. Strongly regrets the numerous delays at Commission level following peer review by EFSA, and urges the Commission to meet its deadlines as laid down in the Regulation;

46. Expresses its concern at the lack of transparency in the PAFF Committee; 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 PAFF Committee's decisions;

47. Calls on the Commission to adopt clear criteria for what constitutes unacceptable effects on the environment;

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 essential for active substance approvals; regrets that the derogation by confirmatory data procedure has led to certain plant protection products that would have otherwise been banned to remain on the market for an extended period of time;

49. Calls on the Commission to amend the relevant guidance document so that confirmatory data would systematically be subject to a full EFSA peer review, as is the case with original data from the application;

50. Calls on the Commission to include legally binding risk mitigation measures in the approval of active substances in order to deal with known risks posed by plant protection products, rather than leaving the matter to the discretion of Member States alone;

51. Calls on the Commission to ensure full application of Article 25 of the Regulation so that safeners and synergists may only be used following their approval; stresses that the data requirements for approval of safeners and synergists should be the same as those required for active substances, and calls for the adoption of an implementing act pursuant to Article 25(3) of the Regulation;

52. Calls on the Commission to adopt the first negative list of co-formulants pursuant to Article 27 of the Regulation by the end of 2018, together with criteria and a procedure to identify further ones; calls, to this end, for the integration of data required under REACH, the CLP Regulation and the Biocides Regulation, and of data collected by Member States during the formulation of their own negative list of co-formulants;

53. Stresses that active substances of biological origin should be subject to the same rigorous evaluation as other active substances, in line with its resolution of 15 February 2017 on low-risk pesticides of biological origin;

Authorisation of plant protection products by Member States

54. Calls on the Commission to undertake an in-depth assessment of the zonal system, with a view to assessing how best to ensure the proper harmonised scientific assessment of plant protection products while safeguarding the responsibilities of Member States for the authorisation thereof;

55. Calls on EFSA to establish harmonised guidelines for plant protection products and on the Commission subsequently to adopt them;

56. Calls on the Member States to ensure that all plant protection products undergo proper assessments, including exposure scenarios, on the basis of data obtained for the plant protection product itself, and considers that extrapolation of data on plant protection products should only be done from data obtained on active substances, where this is scientifically justified and confirmed as reliable by post-market monitoring;

57. Stresses the need to require applicants to provide all studies to the Member State examining the application for authorisation, including the raw data, in a machine-readable format;

58. Calls for public access to be granted to the above studies, in a machine-readable format and in their entirety, as soon as the Member State examining the application has submitted its assessment report to the other Member States in the same zone, thus allowing for independent scrutiny while ensuring that those who requested the studies can only use them for non-commercial purposes and in order to safeguard relevant intellectual property rights;

59. Stresses that the authorisation of plant protection products should continue to take place at national level, in order to take account of country-specific situations;

60. Calls on the Member States to minimise their national data requirements, in the interests of greater predictability and efficiency;

61. Calls on the Member States to do their utmost to meet the deadlines and provisions relating to mutual recognition;

62. Urges the Member States to increase efficiency through greater zonal and inter-zonal coordination, in order to better share the workload and make the best use of each Member State’s resources, and limit derogations under Article 53 of the Regulation;

63. Calls on the Member States to strictly apply Article 53 of the Regulation, to only accept and examine completed applications for derogations, and to only submit completed notifications of derogations to the Commission and other Member States;

64. Calls on the Commission to fully use its control rights under Article 53(2) and (3), in order to limit the derogations and extensions granted under Article 53 to actual emergency situations;

65. Calls on the Member States to ensure that public consultation of stakeholders is undertaken prior to the granting of any emergency authorisation under Article 53;

66. Calls on all Member States to publish the completed application forms they receive requesting an emergency authorisation under Article 53, whether the authorisation is granted or refused;

67. Calls on the Member States to inform each other and the Commission concerning the authorisation and withdrawal of plant protection products, as well as mitigation measures, in order to ensure an EU-wide overview of plant protection products on the market and the risk management pertaining to them;

68. Calls on the Commission and the Member States to improve their data exchange on lower-risk plant protection products, in order to facilitate the comparative assessment of plant protection products;

69. Calls on the Commission and the Member States to promote low-risk pesticides, as an important measure for reducing the adverse impacts of pest management; acknowledges the need for more research in and development of these products;

70. Calls for a harmonised definition of ‘minor use’ in order to promote a level playing field, and recommends creating a single EU list of major crops;

71. Calls on the Member States to scale up their efforts to ensure that farmers are adequately trained in the proper use of plant protection products and the application of Integrated Pest Management (IPM);

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

EXPLANATORY STATEMENT

1. The Special Committee and its mandate

Nine years after the adoption of the Plant Protection Products Regulation (Regulation (EC) No 1107/2009) and following the controversy about the renewal of glyphosate, an active substance used in plant protection products, the European Parliament, on 6 February 2018, adopted a decision on setting up a Special committee on the Union's authorisation procedure for pesticides, its responsibilities, numerical strength and term of office (the so-called 'PEST Committee').

The PEST Committee's mandate, as laid down in Parliament's decision of 6 February 2018, requires the special committee to look into the Union's authorisation procedure for pesticides as a whole. In particular, the PEST Committee shall:

- analyse and assess 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;

- analyse and assess, using an evidence-based approach, the potential failures in the scientific evaluation of the approval, or renewal of approval, of active substances such as glyphosate by the relevant EU agencies, as well as compliance by the EU agencies with the relevant Union rules, guidelines and codes of conduct in force;

- analyse and assess, in particular, whether the Commission has acted in accordance with the provisions of Regulation (EC) No 1107/2009 when taking decisions with regard to the conditions of approval of glyphosate and the renewal of approval of glyphosate;

- analyse and assess possible conflicts of interest at all levels of the approval procedure, including at the level of the national bodies of the rapporteur Member State in charge of the assessment report drawn up in accordance with Regulation (EC) No 1107/2009;

- analyse and assess whether the EU agencies responsible for the evaluation and classification of active substances are adequately staffed and financed so as to enable them to fulfil their obligations; to analyse and assess the possibility of commissioning and/or conducting independent research and testing, and the financing thereof;

- make any recommendations that it considers necessary with regard to the Union authorisation procedure for pesticides in order to achieve a high level of protection of both human and animal health and the environment; to undertake visits and hold hearings to this end with the EU institutions and relevant agencies, as well as with international and national institutions, non-governmental organisations and private bodies;

The committee, consisting of 30 members, is required to present a final report to Parliament containing factual findings and recommendations as to measures and initiatives to be taken within nine months of starting its work (i.e. by 12 December 2018).

2. Working methods

The PEST Committee was constituted on 12 March 2018. It appointed Eric Andrieu (S&D, FR) as the Chair and three Vice-Chairs (1st Vice-Chair: Bolesław Piecha (ECR, PL), 2nd Vice-Chair: Frédérique Ries (ALDE, BE) and 3rd Vice-Chair: Ms Kateřina Konecna (GUE/NGL, CZ)). The committee also appointed Norbert Lins (EPP, DE) and Bart Staes (Greens/EFA, BE) as co-rapporteurs.

The work plan established by the committee in order to gather the necessary evidence to draw up a report and come up with recommendations included two exchanges of views, six public hearings, three fact-finding missions and a videoconference. In addition, the Committee commissioned a briefing and a study.

At the exchanges of views and public hearings, the committee heard 34 experts (see full list in the Annex). While the first four public hearings were dedicated to the successive steps of the Union's authorisation procedure for plant protection products (i.e. application for approval of an active substance and Draft Assessment Report; EFSA opinion on the Draft Assessment Report and ECHA classification of active substances; Commission approval of active substances; and, authorisation of plant protection products by Member States), the last two public hearings focused on authorisation regimes in other OECD countries, environmental impacts of plant protection products and stakeholders' recommendations on the current EU regulation. Verbatim transcripts of all hearings have been drawn up. In order to allow Members to prepare for the hearings, written questions were sent to the invited experts ahead of each hearing and had to be answered in writing before the meeting. If needed, follow-up questions were asked after the hearing. The verbatim reports and written answers by experts are available on the PEST website.

Three fact-finding missions were organised to:

- the European Food Safety Authority (EFSA), Parma (7-8 May 2018),
- the European Union Minor Uses Coordination Facility (MUCF), Paris, and a Fruit Experimentation Station ('La Morinière'), Saint-Epain (5-6 July 2018), and
- the International Agency for Research on Cancer (IARC), Lyon, and a farm ('Le domaine d'Epoisses'), Dijon (18-20 September 2018).

The mission reports can be found on the PEST website.

A video conference will be held on 24 September 2018 with one of the Co-Lead Councils for the Plaintiffs in case Roundup Products MDL No. 2741.

The in-depth analysis commissioned by the committee focused on the guidelines for submission and evaluation of applications for the approval of active substances, while the briefing was dedicated to the impact of Regulation (EC) 1107/2009 on innovation and the development of alternatives and new plant protection products.

It should be noted that the European Implementation Assessment, carried out by DG EPRS (in the context of the ENVI implementation report on Regulation (EC) No 1107/2009) and published in April 2018[1], has also been taken into account when drafting this report.

[1] http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_STU(2018)615668

3. Structure of the report

In line with the hearings, this report is structured according to the different steps of the EU's authorisation procedure for plant protection products (with subchapters on 'Application for approval of active substances'; 'EFSA opinion on draft assessment report and ECHA classification of active substances'; 'Commission approval of active substances'; and, 'Authorisation of plant protection products by Member States'). The report also includes some general observations. While the Recitals contain factual findings, based on the evidence gathered by the committee in the course of its mandate, the paragraphs include the resulting recommendations and calls for action.

With a view to the ongoing evaluation of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin under the European Commission's Regulatory Fitness and Performance programme (REFIT), which is due to be finalised in the first half of 2019, the recommendations elaborated by the PEST Committee will come in handy and just in time to feed into this evaluation.

Accordingly, PEST's recommendations are expected to trigger a variety of actions aimed at tackling the shortcomings in the Union's authorisation procedure for plant protection products identified in this report, including an improvement of the current EU legal framework as such (Regulation (EC) No 1107/2009, in particular, but also related implementing regulations and guidance documents) and of its implementation.

The envisaged amendment of Regulation (EC) No 178/2002 on general food law (also amending several other sectoral pieces of legislation, including Regulation (EC) No 1107/2009) in order to improve transparency and sustainability of the EU risk assessment in the food chain, which was presented in April 2018 (COM(2018)0179)) and is currently still under negotiation, will possibly also bring about improvements regarding the transparency of scientific assessments as well as the quality and independence of the scientific studies assessed by EFSA.

4. Overview of the EU's authorisation system for plant protection products

While a comprehensive EU approach to plant protection regulation was first adopted in the early 1990s (Council Directive 91/414/EEC), the sale, use and control of plant protection products[1] is currently regulated by Regulation (EC) No 1107/2009 (the 'PPP Regulation').

The PPP Regulation lays down a two-step procedure, with active substances[2] approved at EU level and plant protection products authorised at national level. It is characterised by a strict separation of risk assessment and risk management. Other than its predecessor, the PPP

[1] Plant protection products ('PPPs', also referred to as 'pesticides') are products consisting of, or containing active substances, safeners or synergists, and intended for one of the following uses: 1) to protect plants or plant products against pests/diseases, 2) to influence the life processes of plants (such as substances influencing their growth, excluding nutrients) and 3) to preserve plant products.

[2] Active substances are components of plant protection products that actually control harmful organisms (the so-called pests, such as insects, fungi and weeds) or plant diseases.

Regulation is, in particular, also underpinned by the principle of hazard identification ('hazard-based approach')[1] and the principle of precaution[2].

The procedure for the **approval of an active substance** starts with an application submitted by a PPP producer or a chemicals company to competent authorities in any of the 28 Member States, which becomes the Rapporteur Member State (RMS) for that specific substance. For new active substances, the applicant is free to choose the RMS (which is different from the renewal of approval of active substances where a RMS and a co-RMS are appointed by the European Commission in the basis of specific criteria).

When a competent national authority (RMS) receives a dossier from an applicant, it starts the evaluation of the application, assessing its admissibility (i.e. its completeness according to guidelines on data requirements, formats, etc. and, in particular, whether the applicant provided all required tests and study reports), and the associated hazards. Once the dossier is admitted, the RMS carries out an initial scientific evaluation and prepares a Draft Assessment Report (DAR)[3].

In the following, the DAR is submitted to EFSA which carries out a peer review. The peer review process starts with the launch of a public consultation (involving the general public, Member States and the applicant). The collected comments are then assessed, with the assessment report confirmed, or, if need be, improved. At the end of the process, EFSA adopts a 'conclusion' on whether the active substance can be expected to meet the approval criteria (as laid down in Article 4 of the PPP Regulation).

Based on EFSA's conclusion, the European Commission, in charge of risk management, makes a proposal on whether or not to approve the active substance (draft implementing regulation). A regulatory committee, composed of representatives of all EU Member States (the Standing Committee for Plants, Animals, Food and Feed), then votes on the draft implementing regulation. The draft regulation must define whether the active substance under evaluation can be expected to meet the approval criteria and specify the conditions of use for the approval of the active substance (e.g. if Member States must pay attention to specific risk mitigation measures in the subsequent authorisation of PPPs). After the Standing Committee has delivered

[1] As regards the hazard-based approach vs. the risk-based approach, the difference between hazard and risk is substantial: hazard is defined as the intrinsic potential of a substance to cause harm, while risk is the likelihood of harm in specific circumstances.

[2] The principle of precaution prescribes that when there are uncertainties in scientific evidence over the risks associated with an activity, product or a process so that it is not possible to determine the extent to which their utilisation is safe for health and environment, then regulatory action should be taken, and it should aim at the reduction of potential harm. The precautionary principle is specifically referred to in Article 1(4) of the PPP Regulation.

[3] It should be noted that the DAR is of particular importance as an active substance that is classified as carcinogenic, mutagenic, toxic or PBT, among others, (and thus falls under the so-called "cut-off criteria" laid down in the PPP Regulation) by the RMS will be directly banned in the EU, without having to assess whether risks associated with its use can be managed.

an opinion[1], the Commission adopts and publishes a regulation approving or refusing the approval of the active substance[2].

Once active substances have been approved at EU level, an application for **authorisation of specific plant protection products** which include them as ingredients has to be submitted to a Member State.

In order to receive an authorisation, a plant protection product must satisfy a number of criteria, including that its active substances are approved. Three zones with comparable agricultural, plant health and environmental conditions have been set out in the EU to handle authorisations of PPPs (zone A/North, zone B/Centre and zone C/South). Applications for authorisation are submitted to a Member State, acting as zonal rapporteur, who evaluates the application for the relevant zone. National authorisation decisions are made primarily on the basis of the conclusions of this evaluation (mutual recognition).

In some instances, however, a Member State can decide not to grant or recognise an authorisation (e.g. if it considers that the product in question poses an unacceptable risk to human or animal health or the environment). Under certain conditions, Member States are also allowed to grant temporary authorisations (derogations) of plant protection products containing either non-approved active substances or approved substances with significantly restricted use (emergency authorisations under Article 53 of the PPP Regulation).

The assessment of the application is issued by the Member State within one year, followed by a decision on whether to grant or decline the authorisation.

[1] In case no qualified majority is reached in the Standing Committee, either in favour or against the Commission's proposal ("no-opinion"), the proposal is submitted to the Appeal Committee. If the Appeal Committee also delivers a no-opinion, the Commission may then decide.

[2] The approval of an active substance is generally granted for a maximum period of 10 years. Approvals can be renewed upon application by the manufacturer and subject to a similar procedure to that for initial approval. Renewals may be granted for a maximum of 15 years.

ANNEX I - List of experts heard

Date	Event	Topic	Experts
Thu, 12 April 2018, 14h00 - 17h30	1st PEST meeting (Exchange of views)	General overview of authorisation procedure of pesticides	European Commission: - Sabine Jülicher, Director (Directorate E, DG SANTE) - Klaus Berend (Head of Unit/Pesticides and biocides, DG SANTE) EFSA: - Berhard URL (Executive Director/EFSA) - Jose Tarazona (Head of Unit/Pesticides)
Thu, 26 April 2018, 14h00 - 17h30	2nd PEST meeting (Exchange of views)	EU authorisation procedure of pesticides	French Agency for food, environmental and occupational health and safety (ANSES): - Françoise Weber Swedish Chemicals Agency (KEMI): - Katarina Lundberg UK Health and Safety Executive (HSE): - Elizabeth Clayton

Mon, 7 May - Tue, 8 May 2018	Mission to EFSA, Parma		
Tue, 15 May 2018, 15h00 - 18h30	3rd PEST meeting (Hearing)	Application for approval of active substances and draft assessment reports	European Crop Protection Association (ECPA): - Jean-Philippe Azoulay (Director General) Bundesinstitut für Risikobewertung (BfR, (German Federal Institute for Risk Assessment): - Andreas Hensel (President) Global 2000: - Helmut Burtscher Julius Kühn-Institut (JKI, German Federal Research Centre for Cultivated Plants): - Georg Backhaus (President)

Thu, 7 June 2018, 14h00 - 17h30	4th PEST meeting (Hearing)	EFSA opinion on draft assessment reports and ECHA classification of active substances	EFSA: - Bernhard Url (Executive Director) - Jose Tarazona (Head of Unit/Pesticides) ECHA: - Björn Hansen (Executive Director) - Jack de Bruijn (Director responsible for risk management) - Mr. Ari Karjalainen (Senior expert) Scientific Advice Mechanism High Level Group: - Paul Nurse (Member of the Group of Chief Scientific Advisors) Private consultant: - Christopher J. Portier

Tue, 19 June 2018, 15h00 - 18h30	5th PEST meeting (Hearing)	First part: Presentation of the 'General Food Law' proposal of April 2018 Second part: Panel on the approval of active substances	European Commission, DG SANTE: - Vytenis Andriukaitis, Commissioner - Sabine Jülicher (Director 'food and feed safety, innovation', DG SANTE) Cabinet of the European Ombudsman: - Fintan Butler (Senior Advisor) OECD: - Bob Diderich (Head of Environment, Health and Safety Division) Agriculture University Wageningen: - Violette Geissen (Department of Soil Physics and Land Management)

Thu, 28 June 2018, 14h00 - 17h30	6th PEST meeting (Hearing)	Authorisation of plant protection products by Member States	Belgian Ministry of Health, Food Chain Safety and Environment: - Maarten Trybou (Head of Pesticides Unit) Spanish Ministry of Agriculture and Fisheries, Food and Environment: - José María Cobos Suarez (Deputy Director General of Plant and Forestry Health and Hygiene) Romanian Phytosanitary Authority: - Paulina Gabor (Director General) King's College London: - Robin Mesnage (researcher) COPA-COGECA - Pekka Pesonen (Secretary General)
Thu, 5 July - Fri, 6 July 2018	Mission to European Union Minor Uses Coordination Facility (MUCF), Paris, and the La Morinière Fruit Experimentation Station, Saint-Epain		

Thu, 30 August 2018, 14h00 - 17h30	7th PEST meeting (Hearing)	Comparative Analysis of Authorisation Procedures in OECD Countries	<u>Australian Pesticides and Veterinary Medicines Authority:</u> - Chris Parker (Chief Executive Officer) <u>Canadian Pest Management Regulatory Agency:</u> - Richard Aucoin (Executive Director) <u>US Environmental Protection Agency:</u> - Richard Keigwin (Director of the Office of Pesticide Programs)

Thu, 6 Sept 2018, 14h00 - 17h30	8th PEST meeting (Hearing)	First part: Environmental Impacts of Pesticides, including Mitigation Measures at Member State Level Second part: Stakeholders' Recommendations on the Current EU Regulation of the Approval of PPP	*First part:* University of Bergen & Utrecht University: - Jeroen P. van der Sluijs Belgian Bee Keeping Center for Research and Information (CARI): - Noa Simon-Delso (Scientific expert) European Observatory on Sustainable Agriculture (OPERA) at Catholic University of Sacred Heart, Piacenza (Italy): - Ettore Capri (Professor) *Second part:* Greenpeace Europe: - Franziska Achterberg (Food expert) Corporate Europe Observatory: - Martin Pigeon (Researcher and Campaigner) Crop Health and Protection: - John Chinn (Chair)

Tue, 18 Sept - Thu, 20 Sept 2018	Mission to International Agency for Research on Cancer (IARC), Lyon, and to a farm (‘Le domaine d’Epoisses’), Dijon		
Mon, 24 Sept 2018, 19h00 - 21h00	Coordinators meeting (open to all Members)	Videoconference with US lawyer about the ‘Roundup case’	Aimee Wagstaff (national Co-Lead Counsel for the Plaintiffs in case Roundup Products MDL No. 2741)

ANNEX II - List of stakeholders met by the Co-Rapporteurs

1) <u>Stakeholders met by MEP Norbert Lins:</u>

	Type	Organisation	Who	When
1	Industry	BASF	Dr. Thomas Christen	21.03.2018
2	Ministry	Federal Ministry of Food and Agriculture Germany	Clemens Neumann	27.03.2018
3	Industry	European Crop Protection Association (ECPA)	Graeme Taylor	27.03.2018
4	Industry	AG Glyphosat	Dr. Thorsten Küchler	10.04.2018
5	Industry	Industrieverband Agrar (IVA) (German Agrochemical Industrial Association)	Dr. Dietrich Pradt & Dr. Volker Kaus	17.04.2018
6	Industry	Verband der Chemischen Industrie (VCI) (German Association of the Chemical Industry)	Dr. Utz Tillmann	25.04.2018
7	NGO	Deutsche Umwelthilfe	Sascha Müller-Kraenner	25.04.2018
8	Industry	PROFEL	Bettina Breuer und Aline Rutsaert	25.04.2018
9	NGO	Greenpeace EU	Franziska Achterberg	02.05.2018
10	NGO	PAN	Dr. Angeliki Lysimachou	02.05.2018
11	NGO	WeMove.EU	David Schwartz	02.05.2018
12	NGO	Global 2000	Helmut Burtscher-Schaden	14.05.2018 (together with Bart Staes)
13	Agency	BfR	Prof. Dr. Andreas Hensel, Dr. Roland Solecki	14.05.2018

2) <u>Stakeholders met by MEP Bart Staes:</u>

	Type	Organisation	Who	When
1	Academia	Faculty of Bioscience Engineering, Department of Plants and Crops, Ghent University	Prof. Dr. Ir. Pieter Spanoghe	January 2018
2	Industry	European Crop Protection Association (ECPA)	Graeme Taylor	11.04.2018
3	NGO	People for the Ethical Treatment of Animals Foundation (PETA UK)	Emily McIvor	24.4.2018
4	Ministry	Belgian Ministry of Health, Food Chain Safety and Environment	Maarten Trybou	4.5.2018
5	NGO	GLOBAL 2000	Dr.Helmut Burtscher-Schaden	14.5.2018 (together with Norbert Lins)
6	NGO	AVAAZ	Pascal Vollenweider	26.6.2018
7	Attorney	Baum, Hedlund, Aristei & Goldman	Attorney Robert F. Kennedy Jr., Attorney Michael L. Baum	5.9. 2018
8	NGO	Pesticide Action Network (PAN) Europe	Dr. Martin Dermine	5.9.2018
9	NGO	Belgian Bee Keeping Center for Research and Information (CARI), Utrecht University, Bee Life	Dr. Noa Simon Delso	5.9.2018
10	Academia	University of Natural Resources and Life Sciences (BOKU), Vienna	Prof. Johann Zaller	5.9.2018
11	Academia	Brunel University London	Prof. Andreas Kortenkamp	5.9.2018
12	NGO	Pesticide Action Network (PAN) Europe	Dr. Angeliki Lyssimachou	5.9.2018
13	Research Centre	UFZ - Helmholtz Centre for Environmental Research, Leipzig, Germany	Prof. Matthias Liess	5.9.2018