



TEXTS ADOPTED

P8_TA(2019)0023

Union's authorisation procedure for pesticides

European Parliament resolution of 16 January 2019 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 office¹,
- having regard to Article 191 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to the 7th General Union Environment Action Programme to 2020²,
- having regard to the United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the Aarhus Convention),
- 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/EEC³ ('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/EEC⁴,
- 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

¹ OJ C 463, 21.12.2018, p. 73.

² As set up by Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' (OJ L 354, 28.12.2013, p. 171).

³ OJ L 309, 24.11.2009, p. 1.

⁴ OJ L 70, 16.3.2005, p. 1.

amending Regulation (EC) No 1907/2006¹,

- having regard to Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC²,
- 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 powers³,
- 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 products⁴,
- having regard to Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances⁵,
- having regard to Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products⁶,
- 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 glyphosate⁷ 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 glyphosate⁸,
- 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 540/2011⁹,
- having regard to its resolutions of 13 April 2016¹⁰ and of 24 October 2017¹¹ 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

¹ OJ L 353, 31.12.2008, p. 1.

² OJ L 156, 25.6.2003, p. 17.

³ OJ L 55, 28.2.2011, p. 13.

⁴ OJ L 155, 11.6.2011, p. 127.

⁵ OJ L 93, 3.4.2013, p. 1.

⁶ OJ L 93, 3.4.2013, p. 85.

⁷ OJ L 173, 30.6.2016, p. 52.

⁸ OJ L 208, 2.8.2016, p. 1.

⁹ OJ L 333, 15.12.2017, p. 10.

¹⁰ OJ C 58, 15.2.2018, p. 102.

¹¹ OJ C 346, 27.9.2018, p. 117.

- 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 origin¹,
 - having regard to its resolution of 7 June 2016 on enhancing innovation and economic development in future European farm management²,
 - having regard to its resolution of 7 June 2016 on technological solutions for sustainable agriculture in the EU³,
 - having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009⁴,
 - having regard to the European Implementation Assessment on Regulation (EC) No 1107/2009 and to its relevant annexes, as published by the European Parliamentary Research Service (EPRS) in April 2018,
 - 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*⁵,
 - having regard to the decision of the European Ombudsman of 18 February 2016 in Case 12/2013/MDC on the practices of the Commission regarding the authorisation and placing on the market of plant protection products (pesticides),
 - 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 European Food Safety Authority (EFSA) ‘Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate’⁶, published on 12 November 2015, and its ‘Peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate’⁷, published on 7 September 2017,
 - 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 Scientific Opinion 5/2018 of the Scientific Advice Mechanism (SAM)

¹ OJ C 252, 18.7.2018, p. 184.

² OJ C 86, 6.3.2018, p. 62.

³ OJ C 86, 6.3.2018, p. 51.

⁴ Texts adopted, P8_TA(2018)0356.

⁵ Judgment of the Court (Fifth Chamber) of 23 November 2016, *Bayer CropScience SA-NV, Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden*, C-442/14, ECLI:EU:C:2016:890.

⁶ EFSA Journal 2015;13(11):4302.

⁷ EFSA Journal 2017;15(9):4979.

on the EU authorisation processes of plant protection products, of June 2018¹,

- having regard to the report from the Commission to the European Parliament and the Council on the implementation of Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides (COM(2017)0109),
- having regard to the implementation plan on increasing low-risk plant protection product availability and accelerating integrated pest management implementation in Member States, drawn up by the Expert Group on Sustainable Plant Protection and endorsed by the Council on 28 June 2016,
- having regard to the report of the UN Human Rights Council Special Rapporteur on the Right to Food, of 24 January 2017, on global pesticide use in agriculture and its impact on human rights,
- having regard to Article 13 of the TFEU, which states that when formulating and implementing the Union’s policies, in particular concerning its internal market, full regard should be paid to the welfare requirements of animals, since animals are sentient beings,
- having regard to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes²,
- having regard to the Special Eurobarometer 442 survey of March 2016, which states that 89 % of EU citizens agree that the Union should do more to promote greater awareness of the importance of animal welfare internationally and 90 % of EU citizens agree that it is important to establish high animal welfare standards,
- having regard to the fact that Parliament receives numerous petitions from concerned citizens exercising their rights under Articles 24 and 227 of the TFEU and Article 44 of the Charter of Fundamental Rights of the European Union, calling for an end to animal testing in Europe and worldwide and for the establishment of international animal welfare standards,
- 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 the food chain (COM(2018)0179)³,

¹ https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf

² OJ L 276, 20.10.2010, p. 33.

³ 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].

- having regard to the Commission’s ongoing REFIT evaluation of Regulation (EC) No 1107/2009,
- 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 (A8-0475/2018),

General considerations

- A. whereas the purpose of Regulation (EC) No 1107/2009 (‘the Regulation’) is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production;
- B. 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 by several stakeholders 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;
- C. whereas the precautionary principle is an overarching principle for Union policy, as laid down in Article 191 of the TFEU; whereas the Regulation, as provided for in Article 1(4) thereof, is underpinned by the precautionary principle; whereas the risk management decision, as provided for in Article 13(2), must comply with the conditions of the precautionary principle as laid down in Article 7(1) of Regulation (EC) No 178/2002; whereas Article 7(2) of Regulation (EC) No 178/2002 provides that measures adopted on the basis of the precautionary principle must be proportionate;
- D. whereas concerns have been raised by several stakeholders about the assessment of glyphosate, in particular as to whether an independent, objective and transparent assessment has taken place, whether the classification criteria of Regulation (EC) No 1272/2008 have been properly applied, whether relevant guidance documents have been properly used and whether the approval criteria and the precautionary principle have been properly applied;
- E. whereas under Article 4(3) of the Regulation, a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, must, inter alia, have no immediate or delayed harmful effects on human health, including that of vulnerable groups, and must have no unacceptable effects on the environment;
- F. whereas the evaluation of the implementation of the Regulation has revealed that the objectives of protecting human and animal health and the environment are not being fully achieved and that improvements could be made in order to achieve all the objectives of the Regulation;
- G. whereas it is of the utmost importance to fully implement the Regulation in all Member

States;

- H. whereas the work of the national competent authorities involved in the approval and authorisation processes is often delayed; whereas it has been found that national competent authorities involved in the approval and authorisation process are in some cases understaffed and underfunded; whereas in addition to delays to assessment work, the lack of resources risks impacting the quality of the assessments, for both active substances and plant protection products;
- I. whereas the independence of the risk assessment forms the basis for trust in the Regulation and in EU food law;
- J. 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;
- K. whereas the right of access to documents held by EU institutions, including EU agencies, is an important right, exceptions to which are to be interpreted narrowly; points to the case law of the Court of Justice of the European Union, according to which transparency and access to documents contribute to greater legitimacy of EU agencies in the eyes of citizens and to ensuring EU agencies are more accountable to citizens in a democratic system¹;
- L. whereas Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances should be regularly updated to take into account current scientific and technical knowledge; whereas the Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances² remains the most comprehensive source of guidance documents and test guidelines, although several of the documents listed may have been superseded and should be updated; 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);
- M. 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;
- N. whereas guidance translates the requirements of legislation into practical steps, explaining what must be done, while test guidelines specify the test protocols that must be followed for data generation, explaining how tests must be done;
- O. whereas the widespread use, and prophylactic use when inappropriate, of plant

¹ See Case T-235/15, *Pari Pharma GmbH v European Medicines Agency*; see also Case T-729/15, *MSD Animal Health Innovation GmbH and Intervet International BV v European Medicines Agency*, and Case T-718/15, *PTC Therapeutics International Ltd v European Medicines Agency*.

² OJ C 95, 3.4.2013, p. 1.

- protection products is of concern;
- P. whereas the use of plant protection products for desiccation (i.e. the treatment of the actual crop plant prior to harvest in order to accelerate its ripening and facilitate its harvesting) is inappropriate;
- Q. whereas the use of plant protection products in areas used by the general public or by vulnerable groups is inappropriate;
- R. whereas according to the data compiled by the UN Food and Agriculture Organisation (FAO), the EU used 368 588 tonnes of pesticides in 2016, accounting for 11,8 % of global consumption;
- S. whereas according to the FAO the use of pesticides in the EU has been on an upward trend since 2009; whereas the trend is, however, very different across Member States, ranging from a sharp increase in some of them to a steep fall in others; whereas the total volume of pesticide active substances sold in 16 EU Member States increased by 1,6 % from 2011 to 2016;
- T. whereas until 2018, 493 active and basic substances have been approved;
- U. whereas the Commission report on the implementation of Regulation (EC) No 1185/2009 highlights the deficiencies of statistics on pesticide use and the lack of knowledge about the use of specific active substances;
- V. whereas according to the 2016 European Union report on pesticide residues in food¹, published by EFSA in 2018, 96,2 % of the samples were within the limits permitted by EU legislation;
- W. whereas there is a lack of public knowledge about hazard and risk and acceptable and unacceptable hazards and risks, and about the level of compliance with maximum residue level (MRL) values across Europe;
- X. whereas authorisation decisions on newly developed active substances and plant protection products are invariably made under uncertainty regarding real-life impacts; whereas there is a lack of monitoring post-authorisation; whereas data are missing on exact quantities of each plant protection product applied, on the implementation and effectiveness of mitigation measures, and on the potential harmful effects on human and animal health and the environment;
- Y. whereas the lack of data concerns the real-life impacts of active substances, safeners, synergists and co-formulants and their metabolites, 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;
- Z. whereas the pilot project 'Environmental monitoring of pesticide use through honey bees' has not been implemented yet, despite its inclusion in the Union budget for the financial years 2017 and 2018;
- AA. whereas one of the aims of the 7th General Union Environment Action Programme to

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/5348>

2020 is for chemicals to be produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment, and whereas there is still uncertainty about the full impacts on human health and the environment of the combined effects of different chemicals;

- AB. whereas Article 4(3) of the Regulation provides that plant protection products ‘shall have no immediate or delayed harmful effect on human health... taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available’; whereas Regulation (EC) No 396/2005 provides that ‘known cumulative and synergistic effects’ must be considered ‘when the methods to assess such effects are available’;
- AC. 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 EFSA by the end of 2019;
- AD. 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 developmental toxicity and neurotoxicity studies are required and may trigger studies with ad hoc study design to address specific concerns; whereas in this context, EFSA is working on an ongoing project to develop non-animal alternatives for screening DNT effects;
- AE. whereas there is concern that the implementation of the Regulation, with regard to the use of animals in testing for hazard identification and risk assessment, is not in line with the 3Rs principle (replacement, reduction and refinement) of Directive 2010/63/EU on animal experiments, as Commission Regulations (EU) No 283/2013 and (EU) No 284/2013, as well as corresponding guidance, have not been updated since their adoption, despite the availability of validated alternative tests and technologies;
- AF. whereas testing for effects on human health involves the use of animals and therefore does not necessarily accurately predict human reactions;
- AG. whereas there is a need to speed up the development and validation of new non-animal methodologies that provide information on the underlying mechanisms of human toxicity, including the pathways that lead to adverse outcomes in humans;
- AH. whereas many third-country agricultural products have a lower level of protection of human and animal health and the environment with regard to the authorisation and use of plant protection products; whereas there is a need to ensure that the EU level of protection is not undermined by imports of agricultural products from third countries;
- AI. whereas illegally imported plant protection products are in circulation and use within the EU, posing a potential threat to public health and constituting unfair competition vis-à-vis plant protection products that are subject to an authorisation procedure in accordance with the current EU legislation;

Application for approval of active substances

- AJ. whereas concern in terms of transparency and conflicts of interest has been raised by several stakeholders about the right of applicants to choose the Rapporteur Member State (RMS) upon first application for approval of an active substance;

- AK. whereas concern in terms of transparency and conflicts of interest has furthermore been raised by several stakeholders 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;
- AL. whereas for new active substances, only 11 out of 28 Member States have been chosen as RMSs by applicants since the entry into force of the Regulation, which illustrates that there are significant differences concerning expertise and staffing;
- AM. whereas France, the Netherlands, Germany and the UK have dealt with about 80 % of all dossiers; whereas Brexit will have a significant impact on the workload of other Member States;
- AN. 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;
- AO. whereas concern has been raised by several 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, who should provide scientific peer-reviewed literature and who should assess the studies;
- AP. 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;
- AQ. whereas for new active substances, normally only data from regulatory studies generated by the applicant are available;
- AR. whereas risk assessment must be based on all relevant available scientific evidence; 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;
- AS. 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;
- AT. whereas, as reported by the Commission in 2015, all Member States have transposed the GLP Directives and have established functioning national GLP compliance monitoring programmes;
- AU. whereas the OECD test guidelines ensure that research is reproducible, consistent and uniform and enable regulators to assess the quality and relevance of a study, to ensure the methodological validity of a study and to facilitate mutual acceptance of data among Member States;

Draft assessment by the Rapporteur Member State (RMS)

- AV. 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’;
- AW. 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;
- AX. 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 concerns have been raised by several stakeholders 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

- AY. whereas the credibility of the Union authorisation system for plant protection products strongly depends on public trust in EFSA, which provides the scientific opinions that are the basis for decisions with regard to food safety in Europe; whereas the decreasing public trust in EFSA is a concern;
- AZ. whereas currently about two thirds of national experts working for EFSA come from only six Member States;
- BA. whereas according to Article 4(1), second subparagraph of the Regulation, the assessment of the active substance must 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;
- BB. 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); whereas after reviewing the available information, including the IARC assessment, EFSA and ECHA, the European agencies responsible for providing scientific assessments which form the basis for EU risk management decisions, concluded that no classification as carcinogenic was warranted pursuant to the provisions of Regulation (EC) No 1272/2008;
- BC. whereas while IARC based its conclusion on published literature in accordance with its working principles, EFSA and ECHA additionally used unpublished studies submitted by the applicant according to Article 8 of the Regulation as the core basis of their evaluation and additionally had access to the relevant raw data;
- BD. 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 concluded that it is not carcinogenic; whereas glyphosate is still under review by the US Environmental Protection Agency, whose draft

ecological risk assessment clearly states that there is potential for effects on birds, mammals, and terrestrial and aquatic plants;

- BE. 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;
- BF. whereas concern has been and is still being raised by several stakeholders over the opinions by EFSA and ECHA concerning their conclusions in favour of not classifying glyphosate as carcinogenic;
- BG. whereas it was unfortunately not possible to resolve this controversy in the Special Committee;
- BH. whereas in October 2017, the Commission declared the European Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides' admissible; whereas over one million citizens called on the Commission to propose to the Member States the introduction of a ban on the use of glyphosate, to reform the approval procedure for pesticides and to set mandatory reduction targets at EU level for the use of pesticides;
- BI. whereas the so-called Monsanto Papers and the recent judgment by the Superior Court of the State of California in case *Dewayne Johnson v Monsanto* (case No CGC-16-550128) and subsequent appeal have raised concerns about the independence and conflicts of interest in the evaluation process of glyphosate;

Commission approval of active substances

- BJ. whereas the Regulation lays down a six-month deadline for the Commission, from the EFSA conclusions to the presentation of a draft regulation;
- BK. whereas the decision to renew the approval of glyphosate did not contain legally binding risk mitigation measures at Union level; whereas the Commission decided to adopt a specific recommendation in the approval conditions that Member States, when granting authorisations for glyphosate-containing plant protection products, should pay particular attention to the risk to terrestrial vertebrates; whereas a high long-term risk was found for almost all uses of glyphosate for non-target terrestrial vertebrates, including mammals and birds;
- BL. whereas ECHA concluded that glyphosate causes serious eye damage and is toxic to aquatic life with long-lasting effects;
- BM. whereas it is not clear under what conditions the Commission and the Member States consider a risk to be unacceptable for the environment;
- BN. 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 must have no unacceptable effects on the environment;
- BO. 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;

- BP. 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;
- BQ. whereas, based on the follow-up report submitted by the Commission in February 2018 with regard to ten active substances examined in the context of the Ombudsman's inquiry, the confirmatory data procedure has led to two active substances, haloxyfop-P and malathion, that would otherwise have been restricted, remaining on the market for an extended period of time;
- BR. whereas data gaps in the case of low-risk biological pesticides primarily occur because the data requirements are designed for chemical plant protection products, and are thus unsuitable for low-risk biological ones;
- BS. 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;
- BT. whereas it is appropriate that Member States decide on risk management measures with regard to concerns that are specific to their situation;
- BU. 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; whereas the lack of availability of low-risk plant protection products makes integrated pest management implementation and development more difficult; whereas this lack of availability is caused by the lengthy evaluation, authorisation and registration process;
- BV. whereas nowadays, advanced techniques such as precision farming and robotics may be used for the accurate monitoring and elimination of weeds or harmful insects at an early stage; whereas advanced techniques are still underdeveloped in the European Union and require the support of the Union and the Member States;

Authorisation of plant protection products by Member States

- BW. whereas plant protection products should be thoroughly assessed in accordance with current scientific and technical knowledge 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;
- BX. 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;

- BY. whereas, when granting authorisation to plant protection products, particular attention should continue to be paid to the risk for ‘vulnerable groups’; whereas the Regulation defines vulnerable groups as persons needing specific consideration when assessing the acute and chronic health effects of plant protection products; whereas these include pregnant and breastfeeding women, the unborn, infants and children, the elderly, and workers and residents subject to high pesticide exposure over the long term;
- BZ. 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;
- CA. 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 this delay is unacceptable in view of the impact of these substances; whereas certain Member States have developed their own negative lists of co-formulants, in the absence of such a list at Union level;
- CB. whereas the absence of these EU lists makes the thorough risk assessment of plant protection products more difficult;
- CC. 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; whereas the aim of the procedure of mutual recognition by Member States was to simplify procedures and increase trust among the Member States; whereas the application of the mutual recognition procedure is regarded as an important tool to increase work sharing and ensure compliance with deadlines while guaranteeing optimum protection, and is important for the functioning of the internal market;
- CD. 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;
- CE. whereas 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;
- CF. whereas Commission Regulation (EU) No 283/2013 requires studies on long-term toxicity to be carried out; whereas Commission Regulation (EU) No 284/2013 currently requires toxicological studies on operator, bystander and resident, as well as worker exposure, several long-term and chronic toxicology studies for animals, and studies on fate and behaviour in soil, water and air, including route and degradation in air and transport via air, but not on the long-term toxicity of plant protection products;
- CG. 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 safer plant protection products and non-chemical methods such as those defined in Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides¹;

- CH. whereas recent reports have highlighted significant declines in biodiversity with regard to birds and insects, in particular bees and other pollinators; whereas, in the last 27 years, a decline of over 75 % in total flying insect biomass in protected areas has been observed²; whereas agricultural intensification (e.g. pesticide usage, year-round tillage, increased use of fertilisers and frequency of agronomic measures), which was not incorporated in that analysis, may form a plausible cause; whereas agricultural intensification has been associated with an overall decline in biodiversity in plants, insects, birds and other species; whereas biodiversity and robust ecosystems are of fundamental importance, particularly bees and other pollinating insects, to ensure a healthy and sustainable agricultural sector;
- CI. whereas the ban on all outdoor uses of three neonicotinoids (imidacloprid, clothianidin and thiamethoxam) is welcome; whereas these bans should not be undermined by undue Article 53 derogations;
- CJ. whereas other systemic plant protection products should be restricted as much as possible, including for seed treatment, if they pose a danger to human health and the environment;
- CK. whereas the use and identified cases of emergency authorisations granted under Article 53(2) of the Regulation are increasing within the EU; 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;
- CL. whereas systematic delays in the authorisation processes could also lead to an increasing use of emergency authorisations; whereas recourse to Article 53 derogations for minor uses to address special situations other than actual emergencies is not viable or appropriate; whereas EFSA should investigate the effect of substitution as well as the availability of non-chemical methods;
- CM. whereas special attention should be given to plant protection products for minor uses, as there is currently little economic incentive for companies to develop such products;
- CN. 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

¹ OJ L 309, 24.11.2009, p. 71.

² See Hallmann, C.A., Sorg, M., Jongejans, E., Siepel, H., Hofland, N., Schwan, H., et al. (2017) 'More than 75 percent decline over 27 years in total flying insect biomass in protected areas'. PLoS ONE 12(10): e0185809.
<https://doi.org/10.1371/journal.pone.0185809>

the Regulation as such and its implementation need to be improved for it to achieve its purpose;

2. Takes note of the Commission's ongoing REFIT evaluation of the Regulation;
3. Stresses the importance of ensuring independent, objective and transparent scientific assessment of active substances and plant protection products;
4. Calls on the Commission and the Member States to allocate sufficient resources and appropriate expertise to the assessment of active substances and plant protection products and to ensure independent, objective and transparent assessment in light of current scientific and technical knowledge;
5. Calls on the Commission and the Member States to ensure full and uniform application of the hazard-based cut-off criteria for active substances that are mutagenic, carcinogenic or toxic for reproduction, or that have endocrine-disrupting properties;
6. Calls on the Commission and the Member States in their role as risk managers to duly apply the precautionary principle when, following an assessment of the available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, by adopting provisional risk management measures necessary to ensure a high level of protection of human health;
7. Urges the Commission to communicate systematically on how this principle has been taken into account and how the risk management decision has been made;
8. 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 sustainable food production, including the role of plant protection products therein; believes that such considerations should take into account, among other factors, quality, safety, availability and affordability of food for consumers, fair income for, and long-term sustainability of, agricultural production, climate change, and the short-term and long-term risks and benefits to human and animal health and the environment associated with different scenarios for the use of plant protection products, including integrated pest management and a non-use scenario;
9. Considers that, within the EU system, greater attention should be paid to the widespread use, and prophylactic use when inappropriate, of plant protection products and the effects thereof on human health, animal health and the environment, as well as to the build-up of resistance in the target organism;
10. Stresses the importance of full implementation of Directive 2009/128/EC, given its link to the authorisation system, in particular the provisions with regard to integrated pest management and adequate training for farmers therein; points out that Parliament's ongoing work on this matter may be referred to for further details;
11. Calls on the Commission and the Member States to ensure consistency of purpose between the approval of active substances and authorisation of plant protection products under this Regulation and the purpose of Directive 2009/128/EC;
12. Calls on the Commission and the Member States to no longer approve active substances or plant protection products for desiccation;

13. Calls on the Commission and the Member States to no longer allow the use of plant protection products in areas used by the general public or by vulnerable groups, as defined in Article 12(a) of Directive 2009/128/EC;
14. Calls on the Commission to introduce specific measures for the effective protection of vulnerable groups into the Regulation, in order to, without delay or derogation, put an end to the application of pesticides over long distances in the vicinity of schools, childcare facilities, playing fields, hospitals, maternity hospitals and care homes;
15. Calls on the Commission to take the necessary action to ensure that sales statistics concerning pesticides are publicly available per active substance and per Member State, and that pesticide use statistics are further improved so as to provide full information for the environmental risk assessment as well as the comparative assessment under the Regulation;
16. Calls for the creation of an effective post-market vigilance system to systematically monitor the real-life impacts of the use of plant protection products on human and animal health and on the environment as a whole, including in the long term; stresses that post-market vigilance for plant protection products should ensure effective data collection and communication among all stakeholders, and be transparent and publicly accessible; calls on EFSA and ECHA to develop harmonised guidelines for effective post-market vigilance in this field;
17. Calls on the Commission to develop a standardised EU-wide IT platform or database to support the sharing of post-market monitoring data, and considers that post-market monitoring data and other available monitoring data should be used in the authorisation process;
18. Calls on the Commission to accelerate the implementation of the pilot project 'Environmental monitoring of pesticide use through honey bees', which will, inter alia, allow the implementation of EU legislation in terms of pesticide application and authorisation to be evaluated;
19. Calls on the Commission to conduct an epidemiological study on the real-life impacts of plant protection products on human health;
20. Calls on the Commission to further develop and implement approaches to address the combination effects of chemicals by promoting integrated and coordinated assessment across all relevant EU laws;
21. 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, therefore, on the Commission to assess the options to ensure that active substances and other components in plant protection products are assessed for DNT effects, fully taking into account reliable animal-free human-focused mechanistic methods for DNT hazard assessment;
22. Considers it essential that research and innovation continue to be developed in the Union, and therefore calls for Horizon Europe, other Union financial instruments and the Member States to provide sufficient funding to promote:

- (a) independent research on the effects of plant protection products on human and animal health, the environment and agricultural production;
 - (b) research into alternatives to plant protection products, including non-chemical methods, and low-risk pesticides, with a view to presenting farmers with new solutions for sustainable agriculture, and research into agro-ecological and precision farming techniques with a view to minimising external input and optimising pest control in a targeted and sustainable manner;
23. Calls on the Commission to consider the importance of a regulatory framework that encourages innovation and research in order to develop better and safer plant protection products and alternatives;
 24. Recalls that access to safe and efficient plant protection is essential to enable farmers to prevent naturally occurring food-borne contaminants such as carcinogenic mycotoxins, which put the safety of our food at risk;
 25. Points out that the crops and the soil and climate conditions in the Member States, and in particular in the outermost regions of the European Union, are very diverse and specific; calls for this diversity to be taken into account in the authorisation processes;
 26. Calls on EFSA and the Commission to improve their risk communication in order to inform the public in an appropriate, understandable and easily accessible way; considers that it is important to improve public knowledge about hazard and risk and acceptable and unacceptable hazards and risks, raise awareness of the level of compliance with MRL values across Europe and inform users of possible risk mitigation measures;
 27. Calls for full implementation of the 3Rs principle;
 28. Calls for the application of non-animal tests and technologies in the testing of active substances, safeners, synergists, other co-formulants and product formulations, and for the assessment of cumulative and mixture effects of active substances and plant protection products, wherever such tests and technologies are available;
 29. Calls for Commission Regulations (EU) No 283/2013 and (EU) No 284/2013 to be updated whenever validated alternative tests and technologies are available;
 30. Calls on the Commission to include scientific and technological developments for new approach methods in regulatory science with a view to improving the predictivity of regulatory testing and replacing the use of animals;
 31. Calls on the Commission to explore opportunities to require submission of relevant human data, for example data generated during clinical trials conducted during testing of medicinal products, to the open-access database envisaged in the ECHA/EFSA call for tender, so that human data can be used to validate non-animal methodologies under development;
 32. Calls on the Commission and the Member States to ensure effective controls of the agricultural products imported from third countries with a view to ensuring a high level of protection and a level playing field for European food production;
 33. Calls on the Member States and the Commission to engage in increased efforts to stop

the trade of illegal plant protection products, as these products undermine the objectives of Union legislation in this area;

Application for approval of active substances

34. 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 criteria for an independent, objective and transparent assessment: expertise, resources, absence of conflict of interest, relevance for the product, technical capacity and ability to achieve scientifically robust and reliable outcomes within the given timeframe, together with a comprehensive peer review process and a stakeholder consultation, on lines similar to the system for re-approval of active substances;
35. 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;
36. Calls on the Commission to ensure that only Member States that can guarantee a high quality of assessment and that have effective procedures for assessing conflicts of interest become RMSs;
37. Calls on the Commission, with the support of 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);
38. Further calls on the Member States to responsibly carry out their auditing of GLP-certified laboratories, and calls on the Commission to create a Union verification system for Member State audits led by itself;
39. Takes note of the Commission's proposal on the transparency and sustainability of the EU risk assessment in the food chain and thus welcomes the opportunity to improve the current situation in this respect;
40. Considers it important that applicants should be required to register all regulatory studies that will be performed in a public register, and allow a comment period during which stakeholders are able to provide existing data to ensure all relevant information is taken into account; stresses that the provisions regarding the public register also include registration by the certified laboratory of the start and end dates of the study, and the publication of the control data, to be included in a register of historical controls, including the methodology of tests that will be performed, while respecting the protection of personal data; considers that only regulatory studies that have been registered may be submitted with an application;
41. Stresses the need to require applicants to provide all studies to the RMS, including the raw data, in a machine-readable format;
42. Calls for public access to be granted to the above studies, including all supporting data and information relating to applications for authorisation, in a machine-readable format and in their entirety in order to ensure transparency, thus allowing for timely independent scrutiny while protecting personal data and ensuring that those who

requested the studies can only use them for non-commercial purposes, so as to safeguard the relevant intellectual property rights;

43. 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, to be assisted by EFSA;
44. Stresses that scientific peer-reviewed open literature, where available, should be given the equivalent weight in the assessment as GLP-based studies; considers that they are both valid as contributions to the assessment and should be weighted according to the relative quality of the studies and their relevance to the application under consideration;
45. Calls on the Commission to assess whether it would be appropriate to no longer require the applicant to assess the data to be provided as part of the application, instead assigning this task to the RMS;
46. Calls for an independent reassessment of the current rules for the literature review so as to ensure that all relevant studies are considered;

Draft assessment by the RMS

47. 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;
48. Stresses that the assessment should include a thorough evaluation of the raw data, as well as data related to final product formulations as available at that stage of the evaluation; 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; points out that dismissing data reporting adverse effects should be based only on scientific evidence-based justification, for example the proper application of relevant OECD guidance documents;
49. Calls on the Commission to assess how best to ensure that active substances are assessed on the basis of the most frequent uses, the most frequently used formulations, their dosage and relevant exposure scenarios;
50. Calls for all assessments to be based on a systematic review of all available evidence and for full transparency regarding the use of 'weight of evidence';
51. Recommends that the RMS should limit reproducing paragraphs to a minimum and only to justified and duly reported 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

52. Calls on the Commission and the Member States to ensure that key tests (e.g. up-to-date ecotoxicological tests for soil organisms, assessment of environmental concentration and residues in dust, wind, air and water, and tests addressing long-term toxic effects, in

particular for vulnerable groups) and up-to-date scientific and technological developments in methods are included in the risk assessment;

53. Calls on the Commission to duly update its overview on up-to-date guidance documents and test guidelines;
54. Calls on the Commission to facilitate and enhance the completion of the harmonisation process regarding the data requirements and methodologies, in particular in the field of guidance documents on ecotoxicology and environmental fate and behaviour;
55. Calls on the Commission to set maximum residue levels for soils and surface waters using, inter alia, the data collected through post-market environmental monitoring;
56. Calls for MRLs for food and feed to be set sooner and with more efficiency, and for greater coherence to be ensured by standardising the assessment periods between the MRLs and approval or renewal;
57. Calls for the data collected through post-market environmental monitoring to be used to verify the accuracy of Predicted Environmental Concentrations (PECs) in environmental fate models;
58. Calls on the Commission to propose amending Commission Regulation (EU) No 284/2013 to include data requirements regarding the long-term toxicity of the plant protection product and further routes of exposure, notably via wind and water erosion of soil, using up-to-date modelling;
59. 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 levels of active substances, formulations and mixtures in surface waters, soil, wind and dust;
60. Considers that the guidance documents should provide sufficiently clear orientations for risk assessors to guarantee a high quality assessment and ensure predictability and consistency for applicants;
61. 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;
62. Calls on EFSA to further update the bee guidance independently of the adoption of the pending guidance to take into account other pollinator species as well as mixture effects and technical feasibility;
63. 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;
64. Calls on EFSA, the Commission and the Member States to apply an extra safety factor when calculating the 'safe' doses of exposure, with a view to addressing potential

mixture toxicity in cases of high remaining uncertainty which could not be decreased by additional tests of mixtures;

65. Calls on EFSA and ECHA to increase the user-friendliness of the information provided on their websites and to facilitate data mining;
66. Calls on the Member States to ensure that they are properly represented in EFSA by independent national experts; recommends that the Member States engage with EFSA in constructive ways;
67. 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;
68. 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;
69. 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 and other scientists to participate in its work;
70. Calls for EFSA and ECHA to be allocated sufficient funds in order to carry out their 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, and also in view of the additional workload anticipated for those agencies;
71. Highlights that the credibility of the plant protection product authorisation system strongly depends on public trust in European agencies; underlines that transparency in the scientific assessment process is important to maintain public trust; further welcomes EFSA's continuous efforts to improve the system and the most recent update of its independence policy in June 2017, with a view to ensuring independence and the management of potential conflicts of interest;
72. Calls on EFSA to ensure that all experts who participate in the assessment make a publicly available declaration of interests and to exclude the participation of experts with conflicts of interest from all stages of the peer review process;
73. Proposes the establishment of an independent monitoring committee within EFSA, tasked with analysing potential conflicts of interest;
74. 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;
75. Calls on EFSA to ensure that it has the necessary expertise to fully assess the availability and application of non-chemical methods;
76. Calls on the Commission's Scientific Advice Mechanism to act on request as a mediator in scientific controversies concerning active substances;

77. Calls on the Scientific Advice Mechanism to initiate a systematic review of all available studies concerning the carcinogenicity of glyphosate and glyphosate-based formulations with a view to assessing whether it would be justified to review the approval of glyphosate in accordance with Article 21 of the Regulation;

Commission approval of active substances

78. Strongly regrets the numerous delays at Member State and Commission level before and after peer review by EFSA, in particular the delays in the assessment of substances that meet the cut-off criteria, and urges the RMSs and the Commission to meet their deadlines as laid down in the Regulation;
79. Stresses the need to ensure political accountability for the adoption of implementing acts using the comitology procedure; 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 and by making public the votes of the Member States;
80. Calls on the Commission and the Member States to endorse an independence policy and to ensure that Members of the Standing Committee on Plants, Animals, Food and Feed have no conflicts of interest;
81. Calls on the Commission and the Member States to strictly apply Article 4 of the Regulation and to adopt clear scientifically based criteria for what constitutes unacceptable effects on the environment, taking into account real-life exposure (acute and chronic) to multiple plant protection products;
82. 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; considers that the protection of public health and the environment must take the highest priority, while at the same time applicants must be provided with reliable timelines for authorisation; stresses that complete dossiers are essential for active substance approvals; regrets that the derogation by confirmatory data procedure has led to at least two active substances that would otherwise have been restricted remaining on the market for an extended period of time;
83. 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;
84. 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, while supporting Member States in identifying risk mitigation measures relevant to their country-specific situation, taking into account the agronomic, climatic and environmental conditions in their territories;
85. Calls also on the Commission to ensure that post-market monitoring will assess the effectiveness and efficiency of the implemented mitigation measures;

86. 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;
87. 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;
88. Calls on the Commission, in accordance with its resolution of 15 February 2017 on low-risk pesticides of biological origin and its resolution of 13 September 2018 on the implementation of the Regulation, to submit a specific legislative proposal to amend the Regulation outside of the ongoing REFIT procedure, with a view to enabling a rigorous high-quality fast-track evaluation, authorisation and registration process;
89. Calls on the Commission to improve transparency by establishing a webpage displaying the timeline and stages of the approval of each active substance, indicating the RMS, EFSA and ECHA decisions, PAFF Committee decisions, the duration of the licence and other relevant details;

Authorisation of plant protection products by Member States

90. 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, restriction or refusal thereof, and to revise the limitations for refusal of authorisation;
91. Considers the mutual recognition procedure as vital for sharing the workload and facilitating compliance with deadlines; regrets the delays in the assessments by the Member States examining the applications for authorisation and 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;
92. Urges the Member States to meet the deadlines for the evaluation of plant protection products and the provisions relating to mutual recognition, as laid down in the Regulation;
93. Calls on EFSA to establish harmonised guidelines for the assessment of plant protection products and on the Commission subsequently to adopt them;
94. 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 not be done from data obtained on active substances, unless this is

scientifically justified and confirmed as reliable by post-market monitoring;

95. Calls on the Commission to submit a detailed report to Parliament within 2 years on the national practices of risk assessment and risk management of plant protection products;
96. Calls on the Member States to ensure that any decision on the authorisation of plant protection products is based on a proper risk assessment of the real-life exposure, acute and chronic, of vulnerable groups, and for the corresponding EFSA Guidance to be amended accordingly;
97. 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;
98. Calls for public access to be granted to the above studies, including all supporting data and information relating to applications for authorisation, in a machine-readable format and in their entirety in order to ensure transparency, thus allowing for timely independent scrutiny while protecting personal data and ensuring that those who requested the studies can only use them for non-commercial purposes, so as to safeguard the relevant intellectual property rights;
99. Calls on the Commission to assess whether it would be appropriate to make EFSA responsible for the risk assessment of plant protection products, while maintaining that the actual decision on the authorisation of plant protection products should take place at national level, in order to take account of country-specific situations;
100. 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 to grant derogations under Article 53 of the Regulation only where existing requirements are strictly complied with;
101. Considers that the system of inter-zonal mutual recognition must be improved;
102. 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 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;
103. 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 justified emergency situations;
104. Calls on the Member States to ensure that public consultation of relevant stakeholders is undertaken prior to the granting of any emergency authorisation under Article 53, without creating unnecessary delays in the granting of emergency authorisations and ensuring that all relevant stakeholders are informed in a timely manner whether the emergency authorisation is granted or refused;
105. 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;

106. Calls on the Commission to finalise methods to determine when certain derogations should be applied, if at all, in particular as regards ‘negligible exposure’ or ‘serious danger to plant health’;
107. Calls on the Member States to inform each other, the Commission and the public 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;
108. Calls on the Commission and the Member States to improve their data exchange on safer plant protection products which could replace plant protection products containing candidates for substitution, in order to facilitate the comparative assessment of plant protection products;
109. Notes that research into copper usage in areas where it is used as part of long-standing practice shows that there are effects on the microbiology of the soil; agrees that copper should be seen as a transitional material used for plant protection purposes and that its use should be phased out as soon as better alternatives become available;
110. Calls on the Commission and the Member States to promote the development and use of sustainable and ecological alternatives to plant protection products, integrated pest management measures and low-risk pesticides, as an important measure for reducing the adverse impacts of pest management; acknowledges the need for more research into and development of these products; calls on the Commission, therefore, to assess options to stimulate innovation in this field;
111. Calls on the Commission to propose amending the Regulation in such a way that the use, but also the placing on the market, of low-risk plant protection products is made easier for operators on the procedural level; considers that clarification is needed, in particular, concerning the placing on the market of basic substances;
112. Calls for transparent and fair access to active substances for SME-sector plant protection product formulators;
113. Calls on the Commission to conduct an analysis of the impact of the requirements of current legislation regulating the authorisation and trade of plant protection products and biocidal products in terms of human resources and economic capabilities available to SME producers, and whenever changes are made to existing regulations; stresses that the results of such analyses must be made available for public consultation;
114. 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;
115. Calls on the Commission, EFSA and the Member States to ensure that all relevant stakeholders, including the public, are included in any stakeholder activities on pesticides, as provided for in Directive 2003/35/EC and the Aarhus Convention;
116. Calls on the Commission and the Member States to ensure that the requirements in the Regulation for the prioritisation of non-chemical methods are properly implemented;

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