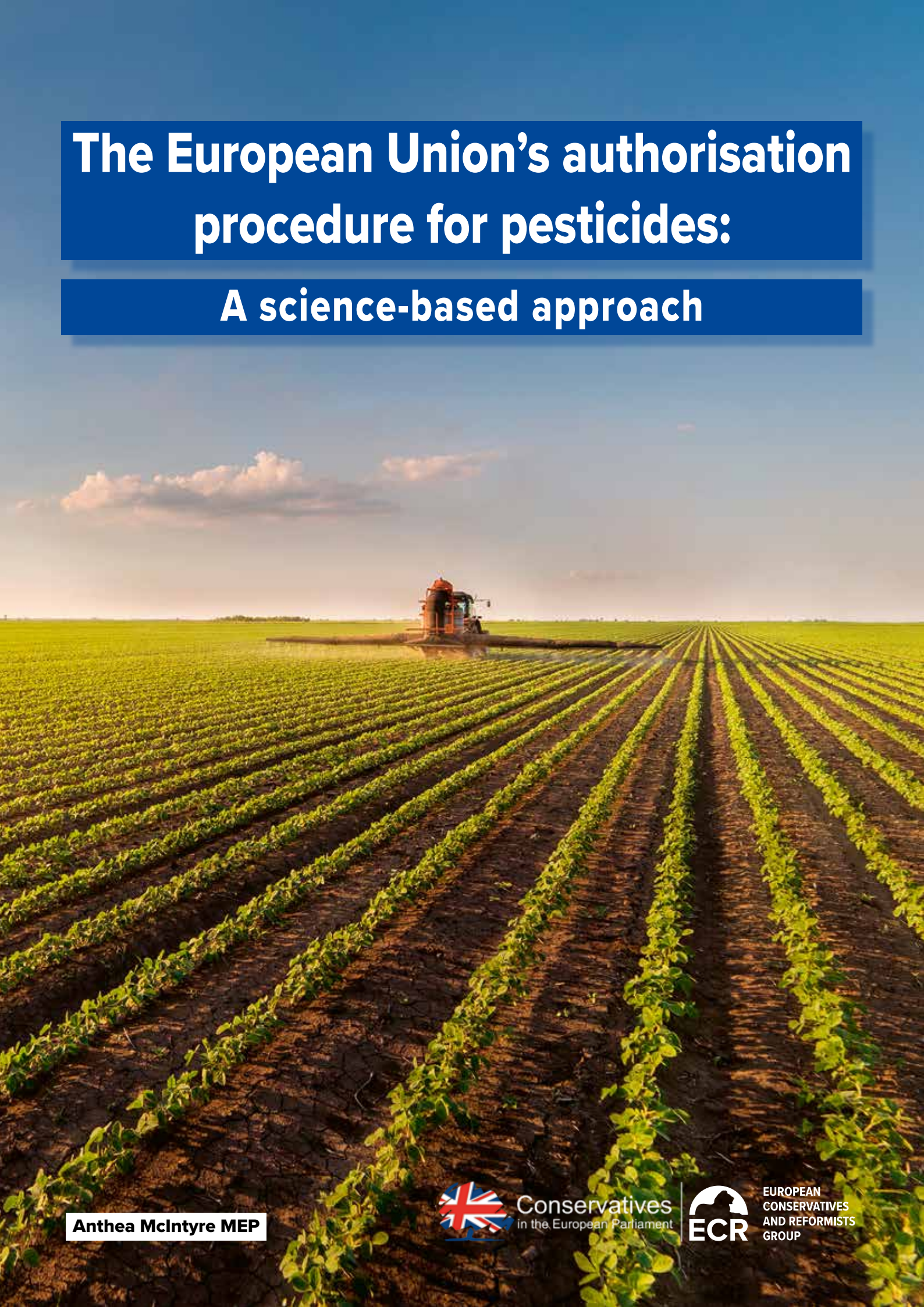
The European Union's authorisation procedure for pesticides:

A science-based approach



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The European Union's approval process for Plant Protection Products is one of the most stringent systems in the world. Yet to read the PEST Committee's report, you really wouldn't think so. Despite hearing from a range of experts and authorities, the report was prepared in a very selective manner, with many of these experts' contributions being completely disregarded.

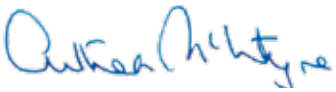
The report was extremely disappointing and reflected poorly on the work of European Parliament. That is why we, the European Conservatives and Reformists (ECR) group, presented many plenary amendments - to ensure that colleagues were able to vote to support the real content of the Committee hearings. I have championed a fact-based and science-based approach to policy-making, and I hoped that the Parliament would see the value of this approach and support the amendments presented by the ECR group - sadly they did not.

Our current system isn't perfect and it can be improved. The EU can act to improve transparency, something the Commission has already done with its legislative proposal to revise the General Food Law. We should encourage innovation - new farming techniques can reduce the need for pesticides. We should support scientific development - new active substances can make older, more persistent chemistry, obsolete.

The Commission, EU regulatory agencies, Member State authorities and Greenpeace, who all gave evidence to the PEST Committee, said it was not flaws in the legislation that needed to be addressed, but improvements in its implementation. This report should have struck a balance and reflected the breadth of expert testimony it heard.

This is why I am publishing an alternative report, to ensure that the voice of rational, science-based reasoning is heard and to truly support farmers who are the ones that will inevitably bear the brunt of further burdensome regulation.

The following pages contain our Key Recommendations, a summary of the PEST report as adopted by the Parliament and our Alternative PEST Report. It goes on to set out the questions we put to the experts together with their answers and then presents the evidence which was given to the PEST Committee by a variety of experts, which was not properly recognised in the official report, or was simply ignored.



Anthea McIntyre
Coordinator & Shadow on the Special Committee
on the Union's authorisation procedure for pesticides

Key Recommendations

- **Science-based approach:** Science must come first, last and always in deciding the safety and effectiveness of plant protection products (PPPs). EU processes for the scrutiny of evidence follow internationally recognised standards, and the insights from the recognised experts, who staff the authorities and agencies across Europe, should not be cast aside. The EU's commitment to science-based policy making should not be undermined but reaffirmed, as it ensures rigour and consistency, and is central to delivering "one of the most stringent systems in the world".

- **Better implementation:** In many submissions and testimonies given to the Committee, experts underlined that the regulatory system for authorising PPPs is fit for purpose. There is, however, room for improvement in its implementation. The Commission's efforts to assess the fitness of the current Regulation in furtherance of better implementation, as a key objective for future policy on PPP approval, is welcomed.

- **Transparency:** The system at present provides a good level of transparency, but improvements can be made. Public trust in the system and its agencies is being threatened by misinformation and it is incumbent on authorities involved to be as transparent as possible in order to allay any fears, legitimate or not. The improvements presented by the Commission in the context of the revision of the General Food Law should be adopted as soon as possible.

- **Precision farming:** Many experts, invited to the PEST Committee, identified obstacles which restrict investment in new active substances and prevent the take-up of new farming techniques. More attention should be paid to methods which promote the use of precision farming techniques and agri-technology more generally, including the expansion of financial incentives.

- **Promote IPM:** In line with the recommendation to improve the use of technology in agriculture, the role that Integrated Pest Management (IPM) systems can play in reducing the use of pesticides is very important. Member States should be encouraged to support their farmers in adopting IPM systems more widely to minimise any negative environmental impacts.

- **Better Regulation:** The regulatory framework for PPPs should support investment through predictability and consistency, linked to the commitment to science-based policy making. Administrative efficiency should also be improved, in order that applications can be assessed in a shorter period.

- **Minor uses:** Experts invited to the PEST Committee by the ECR confirmed that there was still much to be done to incentivise the authorisation of PPPs for minor uses, in order that speciality crops can be adequately protected. It is vital that the derogations currently possible under the PPP Regulation for minor uses are maintained, in the absence of a more systemic approach towards PPPs for these crops. The Minor Uses Fund should be reconsidered in order to provide more effective support with the investment available.

PEST plenary report summary and why its recommendations should have been rejected

Almost a decade after the adoption of the Plant Protection Products Regulation (Regulation (EC) No 1107/2009) and following the controversy over the re-approval of glyphosate, the European Parliament set up a Special Committee on the European Union's authorisation procedure for pesticides (PEST).

Over a nine-month mandate, its Members heard representatives from thirty organisations at eight public hearings. In addition, all the invited panellists have answered approximately 650 detailed questions in writing. The Committee also arranged three fact-finding missions to the European Food Safety Authority (EFSA), the EU Minor Uses Coordination Facility (MUCF) and the International Agency for Research on Cancer (IARC).

Co-rapporteurs from the European People's Party (EPP) Group and the Greens/EFA Group drafted the Special Committee report. 1141 amendments were tabled, and a majority of the Parliament's political groups negotiated 51 compromises. It was adopted in plenary on 16 January 2019 with 526 votes to 66 and 72 abstentions.

Regrettably, however, rather than offer a balanced and thoughtful reflection on the legislative framework governing pesticide approvals, the report purposely vilifies those involved, from EFSA to the national competent authorities, and underplays its effectiveness for controlling pesticides – a regime widely recognised as the world's most comprehensive and precautionary. Contrary to the view from the co-rapporteurs that an "evolution, not revolution" is needed here, the report proposes radical, untested regulatory changes with provisions that duplicate those already in place. The report's key recommendations are as follows.

The report calls on the Commission to consider making EFSA responsible for the risk assessment of all PPPs, at the expense of Member States. It suggests that national authorities are susceptible to undue influence from industry and ill equipped to meet environmental and public health obligations. Such a recommendation risks further delays and does not respect the subsidiarity principle. EFSA will have an increased workload following the newly revised General Food Law, so it is unclear if it will even have sufficient resources to also assess the number of products on the EU market. This is even more perplexing given that the agency was consistently criticised by the PEST Committee for allowing industry to influence its decision to reapprove glyphosate.

It also proposes empowering the Commission to appoint the Rapporteur Member State (RMS), the country responsible for the initial scientific and technical evaluation of an active substance dossier. Furthermore, in the case of a renewal, it calls on the Commission to allocate authorisation to a different Member State from the one that had handled the original approval. These recommendations do not align with an approach that prioritises "evolution, not revolution", and neither are supported by a formal impact assessment. EFSA's Executive Director addressed these concerns before the Committee, stating "in our view it is not that important who the RMS is as we have a European level where we amend, improve, question and scrutinize the first assessment in the peer review process so that the final outcome is always of the same quality". However, the co-rapporteurs have deliberately chosen to neglect this expert testimony.

The report continues with conflicting recommendations on the adoption of risk management measures at the EU and Member State levels. For example, it bemoans the Commission leaving risk mitigation measures, used to approve active substances, to the national authorities, and calls for the executive to have a legally binding role. At the same time however, it acknowledges that these measures are best adopted at the Member State level (in order to account for variations in climatic conditions and different farming methods).

Another contradiction is the report's assertion that the underfunding of national competent authorities risks affecting the quality of the assessments. The PEST Committee has provided no evidence whatsoever to support this claim. On the contrary, the Executive Director for EFSA explained to the Committee that concerns over a Member State's ability to conduct evaluations results in more stringent peer reviews, and extended delays, but not to a lowering of the quality of assessments.

The report also proposes that data requirements for active substances and PPPs must extend to long-term toxicity studies and further routes of exposure, notably via wind and water erosion of soil. This further betrays a lack of understanding about the safeguards under the current legislation, as tests addressing long-term toxic effects of active substances following pre-natal exposure, and up-to-date scientific and technological developments in methods, are already included in the risk assessment. Moreover, introducing these data requirements for PPPs would present major feasibility problems, as there are various sources of pollution over time and across a landscape, and these would need to be accounted for together with other stressors. Identifying multiple sources of residues would be a challenge, but translating the enormous variability of both soil and dust analysis would be largely unobtainable. Indeed, the comparability of PPP data would only be reliable under identical conditions, which of course is highly uncommon within the EU.

Further recommendations include the introduction of bans in public areas, and an end to the use of herbicides for pre-harvest desiccation of cereal crops. These calls for new restrictions are evidently too broad and fail to account for the public good provided by some uses, for example, in controlling allergenic ambrosia artemisiifolia pollen or invasive alien species. Moreover, if a use is demonstrated to be safe and necessary and no other reasonable measures are available, in line with the legal requirements for the authorisation of active substances and the UN Food & Agriculture Organisation's principles of good agricultural practice, then the use of PPPs for desiccation must be allowed. Otherwise, restrictions will become arbitrary and undermine trust in the robustness of the authorisation process.

Lastly, the report's proposal for the Commission's group of chief scientific advisors, the Scientific Advice Mechanism (SAM), to initiate a systematic review of all available studies on glyphosate and its formulations is unreasonable and unnecessary. Glyphosate was re-approved for five years in late 2017, and will be subject to further regulatory evaluations within the next couple of years. The demand for a systematic review would generate additional costs, create uncertainty for farmers, and call the regulation into disrepute by establishing an exceptional parallel evaluation process. Moreover, the added value of an assessment from the SAM is questionable; as it is highly unlikely it would be as rigorous as the evaluations already conducted by EFSA, the European Chemicals Agency (ECHA), and under the Member State peer review.

It is important to stress that the current approval system is not fundamentally broken. The report's conclusions stand at odds with the balance of expert testimony given at the PEST Committee hearings – namely that the legislation is largely robust and fit for purpose, but there are inconsistencies in implementation and the transparency of scientific assessments could be improved. As a result, many of its recommendations would serve only to increase the length of an already long and often delayed procedure for authorisation, stifling innovation and damaging EU competitiveness without delivering any appreciable gain.

Although the report is non-legislative, the Commission is expected to reflect these conclusions in its REFIT evaluation of the legislation, and it will frame the Parliament's work in this area throughout the next mandate. The following alternative resolution is more consistent with the Committee's mandate and better illustrates the insights and evidence given by experts, authorities and interested stakeholders.

The EU's authorisation procedure for plant protection products

The process is the following:
The approval process of **active substances** is as follows:

1. Company "X" submits an application for the approval of an active substance "Y" to any EU Member State. That EU Member State – subsequently called "Rapporteur Member State" (RMS) –is then tasked with the initial scientific and technical evaluation of the active substance.

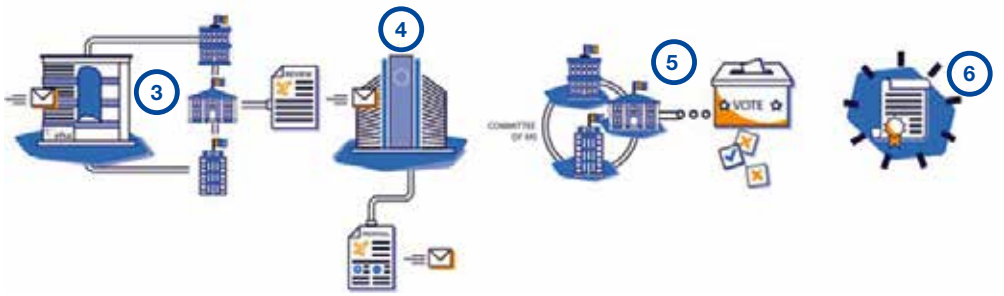
2. The RMS drafts an assessment report for the active substance "Y" and sends it to the European Food Safety Authority (EFSA), in charge of risk assessment.

3. EFSA conducts a public consultation on the assessment report and, together with the EU Member States, carries out a peer review of the assessment report and sends its conclusions to the European Commission

4. Based on EFSA's conclusion, the European Commission, in charge of risk management, makes a proposal on whether or not to approve substance "Y".

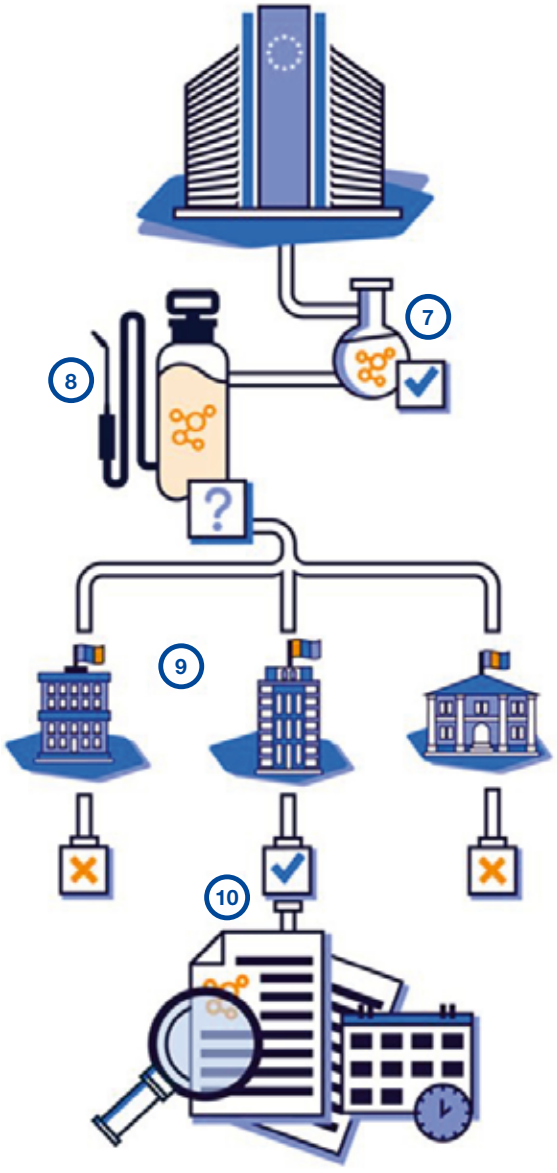
5. A regulatory Committee composed of representatives of all EU countries votes on the Commission proposal for active substance "Y" (more information on Comitology procedure http://ec.europa.eu/transparency/regcomitology/index.cfm?do=F AQ.FAQ)[11].

6. After the Committee has delivered an opinion, the Commission adopts and publishes a Regulation approving or refusing the approval of the active substance "Y".



1 The Commission has adopted on 14 February 2017 a proposal for targeted and limited amendments to Regulation (EU) 182/2011, known as the 'Comitology Regulation'. The aim is to ensure wider political transparency, accountability and ownership by Member States of politically sensitive implementing acts.

The authorisation process of **plant protection products** is as follows:



7. After approval of an active substance at EU level …

8. … plant protection products containing it may be authorised by national authorities in each EU Member State.

9. EU rules allow Member States to refuse or restrict the use of plant protection products, based on the agricultural and environmental circumstances in their territory. For example, some Member States have not allowed the use of such products close to the harvest of cereals or by private consumers (i.e. amateur uses). EU rules also foresee that authorisations granted by one Member State should be accepted in the other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable (principle of mutual recognition)

10. For authorised plant protection products Member States have to enforce their correct use according to their label. The Commission checks the implementation of the legislation in the Member States by conducting audits, following up on any shortcomings and publishing all reports of these audits

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

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 Article 191 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to the 7th General Union Environment Action Programme to 2020[2],
- 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/EEC[3] ('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[4],
- 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[5],
- 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/EC[6],
- 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[7],
- 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[8],
- 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[9] 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[10],
- 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[11],

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1 Texts adopted, P8_TA(2018)0022.
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.
5 OJ L 353, 31.12.2008, p. 1.
6 OJ L 156, 25.6.2003, p. 17.
7 OJ L 55, 28.2.2011, p. 13.
8 OJ L 155, 11.6.2011, p. 127.
9 OJ L 173, 30.6.2016, p. 52.
10 OJ L 208, 2.8.2016, p. 1.
11 OJ L 333, 15.12.2017, p. 10.

- having regard to Commission Communication 2013/C 95/01 in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with the Regulation,
- having regard to its resolutions of 13 April 2016[12] and of 24 October 2017[13] 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[14],
- having regard to its resolution of 7 June 2016 on enhancing innovation and economic development in future European farm management[15],
- having regard to its resolution of 7 June 2016 on technological solutions for sustainable agriculture in the EU[16],
- having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009[17],
- 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[18],
- 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 Commission Report in reply to a further remark from the European Ombudsman in her closing decision,
- 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'[19], published on 12 November 2015 and its 'peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate' [20], 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) on the EU authorisation processes of plant protection products, of June 2018[21],
- 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 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 purposes[22],
- 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,

12 Texts adopted, P8_TA(2016)0119.
13 Texts adopted, P8_TA(2017)0395.
14 Texts adopted, P8_TA(2017)0042.
15 OJ C 86, 6.3.2018, p. 62.
16 OJ C 86, 6.3.2018, p. 51.
17 Texts adopted, P8_TA(2018)0356.
18 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.
19 EFSA Journal 2015;13(11):4302.
20 EFSA Journal 2017;15(9):4979.
21 https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf
22 OJ L 276, 20.10.2010, p. 33.

- 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)[23],
- 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 (A8-0000/2018),

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, currently taking over 11 years, requiring an average of over 200 scientific studies and costing in excess of EUR 220 million to bring a product to the EU market; whereas in 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 human and animal health and the environment while at the same time encouraging competitiveness, stimulating and facilitating research and supporting agricultural productivity in growing sustainable, safe, healthy and nutritious food, all in the fulfilment of the objectives laid out in Article 1(3) of the Regulation;

C. whereas due to the strict nature of Union's legislation, the number of substances on the market has decreased; whereas only 20 new substances out of 43 submitted have been approved and only eight of those have been authorised for use in plant protection products since the entry into force of the regulation; whereas during the preceding two years no applications have been submitted for the approval of a new active substance; whereas this leads to shortages in much needed pesticides for farmers which endangers food supply and health safety in Europe and threatens the attainment of all of the objectives of the Regulation, which includes safeguarding the competitiveness of community agriculture;

D. whereas, nowadays, advanced techniques like 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 and require the support of the Union and Member States;

E. whereas the precautionary principle is an overarching principle for Union policy, as laid down in Article 191 of the Treaty on the Functioning of the European Union; whereas the Union authorisation system for plant protection products has the lowest maximum residue levels and is the only one which uses the 'precautionary principle', which is codified as a specific objective in legislation; whereas the risk management decision according to its Article 13(2) must comply with the conditions of the precautionary principle as laid down in Article 7(1) of Regulation 178/2002; whereas Article 7(2) of Regulation 178/2002 provides that measures adopted on the basis of the precautionary principle shall be proportionate;

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

G. whereas the largest number of guidance documents relates to ecotoxicological studies (category 8) and fate and behaviour in the environment (category 7); whereas there are at least some guidance documents for all categories except for category 2 (physical and chemical properties of the active substance) and 3 (further information on the active substance); whereas the largest number of guidelines relate to toxicological and metabolism studies (category 5) and ecotoxicological studies (category 8), while there are no guidelines for some categories (e.g. 1, 9 and 10) as the nature of these categories does not foresee specific testing;

H. whereas guidance translates the requirements of legislation into practical steps, answering the question of "what must be done", while test guidelines specify the test protocols which must be followed for data generation, answering the questions of "how must tests be done";

I. whereas it is of the utmost importance to fully implement the Regulation in all Member States;

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23 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].

J. whereas the work of the national competent authorities involved in the approval and authorisation process have issues regarding available resources; whereas the Commission found that the evaluator staff in all audited national competent authorities were suitably qualified and trained, and are therefore capable of conducting evaluations of plant protection products to a high standard; furthermore recalls that the safety of active substances is comprehensively assessed through the peer review by all Member States and the EFSA risk assessment;

K. whereas the Human Bio-monitoring programme has been in operation since 2017, and is a joint effort of 28 countries, the European Environment Agency and the Commission, co-funded under Horizon 2020; whereas the monitoring project aims to generate knowledge to inform the safe management of chemicals and so protect human health in Europe; whereas EFSA gave evidence noting the existence of post-marketing pesticide residues monitoring for consumers, which it considers to be the largest programme of its kind in the world; whereas the post-market environmental monitoring carried out to assess exposure (predicted environmental concentrations) are also used in the renewal process for active substances;

L. whereas all stages of the approval procedure should be improved, in order to encourage public confidence in the system regulating plant protection products; whereas the transparency of the authorisation process related to the activities of competent authorities should also be improved; whereas in the report on the transparency and sustainability of the Union's risk assessment in the food chain the Commission has proposed changes to the General Food Law (Regulation (EC) No 178/2002), with the aim of addressing concerns relating to the data and evidence supplied during the evaluation process and increasing transparency;

M. whereas the development and testing of new plant protection products in the authorisation process should ambitiously seek to minimise animal test methods;

N. whereas Commission Regulation 283/2013 setting out the data requirements for active substances should be regularly updated to take into account current scientific and technical knowledge; whereas Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances[24] 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 the existing regulatory framework offers adequate flexibility to ensure that any validated test can be used when provided with sufficient scientific justification;

O. 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;

P. whereas misuse of plant protection products is of concern; whereas prophylactic use of plant protection products can also be of concern where inappropriate, however certain prophylactic applications such as the coating of seeds help to reduce the required total amount of plant protection products; whereas the importance of continuous training and education for farmers in the proper and appropriate use of plant protection products has to be underlined;

Q. whereas according to the 2016 European Union report on pesticide residues in food[25], published by EFSA in 2018, 96,2 % of the samples were within the limits permitted by EU legislation, confirming the high level of compliance of food identified in previous years;

R. 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;

S. whereas there is a separation between the assessment of active substances and possible additives such as safeners, synergists and co-formulants and the products themselves; whereas the national assessments for new products and re-registration consider formulations and mixtures of products;

T. whereas 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';

U. whereas such methodologies are still in the process of being devised, with 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;

V. whereas there is currently a legal obligation to conduct developmental studies and neurotoxicity studies individually, the results of which may trigger studies with ad-hoc study design to address specific concerns, including DNT effects; whereas the increased use of animal testing is unjustifiable in existing scientific practice in accordance with the principle of the Three Rs, to 'Replace, Reduce and Refine' the use of animals in EU legislation; whereas, in this context, EFSA is working on an ongoing project to develop non-animal alternatives for screening DNT effects;

24 OJ C 95, 3.4.2013, p. 1.
25 https://www.efsa.europa.eu/en/efsajournal/pub/5348

Application for approval of active substances

W. whereas some stakeholder groups raised their concern about the right of applicants to choose the Rapporteur Member State (RMS) upon first application for approval of an active substance; whereas the view of EFSA confirms that at the European level the work of the RMS is amended, improved, questioned and scrutinised in the peer review process to ensure that their findings are consistent, repeatable and of the same quality regardless of whether the RMS would be chosen by the Commission, EFSA or the applicant;

X. whereas for new active substances, 11 out of 28 Member States have been chosen as RMS by applicants since the entry into force of the Regulation; whereas there are a variety of reasons which influence the choice of RMS, including an intention to commercialise in that Member State;

Y. 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;

Z. 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;

AA. whereas the EPRS European Implementation Assessment on the Regulation, and evidence given to the Committee, have underlined that assumptions on the quality of a study based upon whether the study was commissioned by industry, public authorities or civil society are highly problematic; whereas the Committee has heard of the risk of free-riding for industry seeking approvals in other jurisdictions were the Union to fund and produce the scientific studies and evidence required for the evaluation of active substances;

AB. 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;

AC. whereas for new active substances, normally only data from regulatory studies generated by the applicant are available, as those active substances are not widely available outside of the producing laboratory; whereas peer-reviewed literature is typically more voluminous for approved active substances and therefore may be used more often in the context of renewals; whereas this is not consistently correct for all active substances, where some active substances may be the subject of more peer-reviewed literature than others;

AD. 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 evaluators consider necessary to take into account during the risk assessment procedure;

AE. 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 allow for reproducibility of the test results, and to enable regulators to assess the quality and relevance of the study; 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 and to facilitate the Mutual Acceptance of Data (MAD) among Member Countries;

AF. 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;

AG. 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;

Draft assessment by the Rapporteur Member State (RMS)

AH. 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’;

AI. 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 each practice is consistent with the obligations of the RMS, namely to check the information provided by the applicant and, where relevant, to correct and amend the information, based upon a critical analysis; whereas EFSA has confirmed that there are no requirements that prevent the RMS from incorporating text directly into the Draft Assessment Report (DAR) where the RMS concurs with the summary or evaluation;

AJ. whereas Parliament acknowledges the misunderstandings raised by some invited panellists regarding the literature review in the risk assessment report on glyphosate by the German Federal Institute for Risk Assessment (BfR); whereas the Parliament is satisfied with the lengthy and repeated explanations given by the responsible national authority and European agencies that the BfR has compiled the DAR in line with standard procedure which allows the RMS after checking the provided information and given it agrees with it to include parts of the application directly into the DAR;

AK. whereas Volume 3 of the Renewal Assessment Report, literature search, does not represent the actual risk assessment of an active substance, but the RMS view on the accuracy of the reporting of the summary results of published literature provided by the applicant; whereas the role of the RMS is to confirm that the search has been conducted properly, to verify its accuracy and to ensure the level of reporting is sufficient for the peer review to be conducted by EFSA and the Member States experts;

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

AL. whereas the decreasing trust in EFSA is a concern that has been expressed by some stakeholders; 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 approvals and risk management;

AM. whereas EFSA's continuous efforts to improve its system to ensure independence and the management of potential conflicts of interests was praised by the Court of Auditors as the most advanced system of the audited agencies in 2012 and has recently been updated in June 2017;

AN. 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);

AO. 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;

AP. whereas the International Agency for Research on Cancer (IARC) classified glyphosate as probably carcinogenic to humans (Group 2A) according to its nomenclature, which is not established as a basis for regulatory decision-making; whereas the European Agencies responsible for providing scientific assessments relevant for EU risk management decisions, EFSA and ECHA, after reviewing all available information including the IARC assessment, concluded that no classification as carcinogenic was warranted pursuant to the provisions of Regulation (EC) No 1272/2008;

AQ. whereas the preamble to each IARC Monograph states that "no recommendation is given with regard to regulation or legislation, which are the responsibility of individual governments or other international organisations"; whereas IARC classifications and assessments by third countries' competent authorities play no formal role in the Union's decision making process;

AR. whereas EFSA evaluated IARC's assessment and the data it was based upon, and drew the following conclusion: "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008";

AS. whereas while IARC based its conclusion solely on published literature in accordance with its working principles, EFSA and ECHA additionally had access to unpublished studies submitted by the applicant in accordance with their obligations under the Regulation, as well as to the relevant raw data, as the core basis of their evaluation;

AT. 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 are in agreement with the assessment carried out by EFSA;

AU. 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;

AV. whereas despite the broad consensus of competent authorities across the globe some stakeholder groups still raise concerns over the opinions by EFSA and ECHA concerning their conclusions in favour of not classifying glyphosate as carcinogenic; whereas those concerns were raised in the presence of EFSA and ECHA, who in turn provided a reasoned explanation of their conclusions;

Commission approval of active substances

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

AX. whereas the decision to renew the approval of glyphosate did not contain legally binding risk mitigation measures at Union level, while the Commission decided to adopt a specific provision in the approval conditions that Member States, when granting authorisations for glyphosate-containing plant protection products, must 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, which were, however, not identified as a critical concern in the EFSA Conclusion, because the assessment in line with Article 4(5) of the Regulation concluded for at least one of the representative uses that the risk was expected to be low;

AY. whereas the European Court of Justice in its ruling in Case T-257/071a states that "In determining the level of risk deemed unacceptable for society, the institutions are bound by their obligation to ensure a high level of protection of public health, safety and the environment. That high level of protection does not necessarily, in order to be compatible with that provision, have to be the highest that is technically possible. Moreover, those institutions may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero risk'";

AZ. whereas the Commission, with the support of the Member States, based on agricultural need and with due consideration of the actual dose and application technology used, approves active substances that EFSA believes could pose high risks to the environment and biodiversity if safe uses could be demonstrated and a cautious safety margin is applied, given that according to Article 4(3)(e) of the Regulation a plant protection product shall have no unacceptable effects on the environment;

BA. whereas the European Ombudsman, in her decision in case 12/2013/MDC of 18 February 2016, takes note of the Commission's statement 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;

BB. 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;

BC. whereas when risks are identified by EFSA in its conclusions on active substances, the Commission often leaves risk mitigation measures to the Member States who have relevant expertise to country-specific needs, notwithstanding the possibility granted to it under the Regulation to impose them at EU level; whereas the European Ombudsman in her decision in case 12/2013/MDC, declares that she understands that the exact definition of mitigation measures should be left to national authorities, in an acknowledgement that this is the most appropriate level of ensuring that these are adapted to specific land, soil and climate conditions and local agricultural practices;

BD. whereas it is appropriate that Member States decide on risk management measures with regard to concerns that are specific to their situation;

BE. whereas there is a need to support the accelerated approval of new low-risk plant protection products due to a current lack of availability of such 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 EPRS European Implementation Assessment on the Regulation notes that it is generally recognised that the number of active substances that are available is substantially decreasing; whereas low-risk substances should be encouraged and may constitute an alternative to certain substances;

BF. 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

BG. 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;

BH. whereas the procedure for authorisation of plant protection products, and in particular the data requirements for risk assessment, already takes into account the actual use of plant protection products;

BI. 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;

BJ. 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;

BK. 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, in terms of the single market, of the procedure of mutual recognition by Member States in a particular geographical region was to simplify procedures and increase trust among the Member States; 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 for users; stresses that these delays seriously hinder the market introduction of efficient and safer innovative products;

BL. 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;

BM. 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 its long-term toxicity;

BN. whereas the use and identified cases of emergency authorisations granted under Article 53(2) of the Regulation is steadily increasing in some Member States, while decreasing in others; 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, and in these cases the effect of substitution should be investigated; whereas in the most recent audit report, the Commission noted that in the Member States, systems for emergency authorisations were effective in evaluating the justification for granting this type of authorisation for limited and controlled use;

BO. 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, with regard to the application dose, method and technology;

BP. whereas a Commission audit on the evaluation of the authorisation of plant protection products in Member States concluded that the majority of Member States fail to comply with almost all legal deadlines under the Regulation and that delays in granting regular authorisation, especially for minor uses, lead to an increased number of emergency applications; whereas an inability to tackle pests, particularly for speciality crops, endangers the quality, diversity and sustainable production of food crops in the EU; whereas the risk to production has been calculated to total more than EUR 1 billion, including production loss and additional costs for farmers; whereas risks will only become more acute, as populations increase and pressures on land use intensify;

BQ. whereas it is accepted that innovative technologies need to be applicable to all farming types, whether conventional or organic;

BR. whereas the need to invest in research and development has been widely identified; whereas the outcomes of research programmes should lead to the efficient transfer of knowledge from the laboratory to the farm; whereas there is a need for research programmes to be focused on improving the sustainability of agriculture, reducing production costs and increasing competitiveness;

BS. 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;

General observations

1. Considers the EU to have the most stringent system in the world, and welcomes the continued improvement of the Regulation, particularly the forthcoming review of the General Food Law (Regulation (EC) No 178/2002) in the legislative proposal; considers that even the most stringent systems can always be improved, including in its implementation;
2. Stresses that the EU is world-leading in its separation of the roles of risk assessor and risk manager, which is internationally-recognised best practice, while elsewhere the risk assessment and risk management roles are often combined and/or carried out within the same entity;
3. Stresses the importance of a regulatory framework that encourages competitiveness, facilitates research and stimulates innovation in order to develop better and safer plant protection products, while at the same time securing the availability of a broad range of plant protection products; believes that future reviews of the regulatory framework should encourage the authorisation of plant protection products compatible with sustainable agriculture systems, which are environmentally and scientifically sound, effective and affordable, and which support food security; considers future reviews should also take due account of non-target impacts, notably on bees and other pollinators and other insects beneficial to farming, such as the natural predators of pests;
4. Stresses the importance of a science-based approach in authorising active substances, transparency and effective risk communication to ensure the acceptability of risk management decisions and consumer trust; notes that improving transparency and risk communication are two key objectives of the recent Commission proposal to reform the General Food Law, and welcomes this opportunity to strengthen trust in the approval system;

5. Welcomes the recommendation of the Scientific Advice Mechanism (SAM) that the Commission should 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, including with a view to the Union's responsibility to contribute to food security for a growing world population in line with Sustainable Development Goal 2 (SDG2), 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, taking into account that non-use of plant protection products also confers risks; plant protection products keep transport corridors and urban areas free from weeds, which act as refuges for vermin, and control invasive species such as Japanese knotweed, which threaten building foundations, flood defences, and biodiversity; considers that the risks and benefits to the environment of alternative non-chemical techniques should also be assessed;
6. Welcomes the Commission's interpretation of the precautionary principle, as expressed in the REFIT evaluation of the General Food Law, that it is not an alternative to a risk management approach but rather a particular form of risk management; recalls that this view is also supported by Union court rulings;
7. Calls on the Member States to allocate sufficient resources to the agencies responsible for the assessment of active substances and plant protection products and to ensure independent, objective and transparent assessments based on scientific evidence;
8. Calls on the Commission and the Member States in their role as risk managers to base their assessments on comprehensive risk assessments founded on the best available scientific evidence; further calls on the Commission and Member States to duly apply, intelligently and within context, the precautionary principle, in line with Article 7(1) of Regulation (EC) No 178/2002, when following an assessment of the available information and the possibility of harmful effects on health is identified but scientific uncertainty persists; urges the Commission to communicate systematically, and in detail, on how this principle has been taken into account and how risk management decisions are made;
9. Notes that there have been concerns about the fulfilment of the precautionary principle, however, cases like Commission Implementing Regulation No 781/2013 on fipronil, Commission Implementing Regulation No 485/2013 on neonicotinoids (EC April) as well as the disapproval of 22 substances since entry into force of 1107/2009 and having the lowest MRLs demonstrate that the precautionary principle is respected;
10. Considers that greater attention should be paid to the risk of misuse and inappropriate use of plant protection products, including prophylactic application methods, and the effects thereof on the environment and on the build-up of resistance;
11. Recognises that the prophylactic use of plant protection products can in many cases reduce the need for further chemical or non-chemical intervention, and on balance can be positive from an environmental perspective; understands that in some instances there are no plant protection product alternatives to treat the emergence of weeds, or established pest or disease populations, and thus prophylactic use is the only option to prevent reductions in crop yield and quality; further acknowledges that some plant protection products, due to their mode of action, must be applied before the emergence of weeds if they are to be effective; therefore believes that appropriate use of prophylactic applications should remain part of the available variety of treatments and protections in the farmer's toolbox;
12. Calls for the creation of an effective post-market vigilance system to monitor the impacts of the use of plant protection products on agricultural productivity, as well as human and animal health and on the environment as a whole; considers that the Health and Food Audits and Analysis Directorate of the European Commission could play a role in this regard;
13. Welcomes EFSA's ongoing project to model DNT effects; takes note of the fact that required developmental toxicity and neurotoxicity studies already now may trigger studies with ad-hoc study design to address specific concerns; calls on the Commission to assess options of ensuring that active substances and other components in plant protection products be assessed for DNT effects;
14. 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;
15. Calls on EFSA and the Commission to improve their communication in order to inform the public in an appropriate and easily understandable way about the need for plant protection products in the production of safe, affordable food alongside any proven impact on human health and the environment; this should include an explanation of the difference between hazard and risk, acceptable risks and established safe uses, and contextualise the hazards and risks of plant protection product use with other household chemicals and substances; recommends that this information be easily accessible and inform users of possible risk mitigation measures;

16. Expresses its concern that Council Regulation (EC) No 834/2007 provides no equal scientifically robust and thorough regime for the assessment of effects on human health, animal health and the environment for the authorisation of substances for plant protection in organic production; notes that the principle of separating risk assessment and risk management is not applied in that regulation;
17. Highlights the potential that precision and smart farming techniques and technological innovation can have in optimising pest control in a more targeted and sustainable manner and the potential efficiency that could be realised through the use of precision and smart farming technologies, which would lead to a significant reduction in the quantities used and would also reduce the environmental impact; points out that these advanced techniques are still underdeveloped in the European Union; calls on the Commission and Member States to finance programmes for research, innovation and development of these practices;
18. Calls on the Commission to develop a standardised EU-wide IT platform or database to support the sharing of post-market monitoring data;

Application for approval of active substances

19. 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;
20. 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);
21. Welcomes that, as reported by the Commission in 2015, all Member States have transposed the GLP Directives and have established functioning national GLP compliance monitoring programmes; 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;
22. Welcomes the Commission's proposal on the transparency and sustainability of the EU risk assessment in the food chain;
23. 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;
24. Stresses the need to require applicants to provide all studies to the RMS, including the raw data, in a machine-readable format;
25. Understands that scientific peer-reviewed open literature, where available, and GLP-based studies are both equally valid as contributions to the assessment that should be given consideration and are weighted according to the relative quality of the studies and their relevance to the application under consideration;
26. Recalls that from a scientific point of view it is irrelevant who conducts and pays for the study as long as it is designed, carried out and reported according to scientific standards;

Draft assessment by the RMS

27. Recalls that the RMS should strictly apply Article 9 of the Regulation, so as to ensure that applications are complete before they are deemed admissible;
28. 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;
29. 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';
30. Recommends that when passages are taken from the application dossier the RMS should make a clear distinction between the assessment of the authority and the assessment of the applicant;

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31. Calls on the Commission and the Member States to ensure that key tests regarding human health, animal health and the environment and up-to-date scientific methods are included in the risk assessment; recalls that the applicant dossier is required to include studies on the effects on non-target soil meso- and macrofauna as well as studies on the fate and behaviour in soil, water and air; notes that Commission Communication 2013/C 95/01 remains the most comprehensive source of guidance documents and test guidelines, while several of the documents listed may have been superseded and should be updated; calls on the Commission to duly update its overview on up-to-date guidance documents and test guidelines;
32. Calls on the Commission to better integrate post-marketing monitoring systems within the assessment of the long-term effects on human and animal health and on the environment;
33. 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;
34. Recalls that Commission Regulation (EU) No 283/2013 requires studies on the long-term toxicity; further recalls that Commission Regulation (EU) No 284/2013 currently requires toxicological studies on operator, bystander and resident as well as worker exposure, several long-term and chronical toxicology studies for animals, and on fate and behaviour in soil, water and air including route and degradation in air and transport via air; calls on the Commission to evaluate whether these data requirements under Commission Regulation (EU) No 284/2013 are up-to-date with current scientific and technical knowledge to assess the long-term toxicity of the pesticide product and further routes of exposure, notably via wind and water erosion of soil;
35. 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 impact of the Regulation on food production, as well as 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;
36. Calls on the Commission to ensure that EFSA guidance notes are sufficient and workable for the risk-assessors, and to ensure consistency and predictability for applicants by providing relevant assessments of their impact; believes that it is necessary that these are approved by Member States before their use; calls on the PAFF Committee to consider any pending guidance, including the updated bee guidance used by EFSA in its recent review of three neonicotinoids against the agricultural need and environmental impact of withdrawing the chemistry;
37. 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 once proved suitable for use in the regulatory approval process; calls for research in relation to other routes of exposure in addition to the nervous and thyroid systems to be prioritised and measured against agricultural need as well as negative impacts on the environment from withdrawing the chemistry;
38. Calls on EFSA and ECHA to increase the user-friendliness of the information provided on their websites;
39. 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;
40. 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;
41. Expresses its concern that in recent debates, the European Union's current science-based evaluation system for plant production products has been increasingly called into question; stresses the importance of maintaining and further strengthening a system which is scientifically robust, objective, and based on peer-reviewed evidence, derived from an open, independent, and multidisciplinary scientific approach in authorising any active substance, in line with the EU's risk analysis principles and the precautionary principle as established in the General Food Law;
42. Insists that the procedure for the re-approval of active substances must take into account the practical use of plant production products, as well as scientific and technological progress in this area; points out that the complexities in the current evaluation and authorisation system lead to deadlines being missed and undermine the effective working of the entire system;
43. 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, whilst supporting and promoting enhancement in sustainable food production;
44. 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;
45. Calls on the Commission to refer to its Scientific Advice Mechanism (SAM) when preparing proposals for improving the implementation of the current regulatory framework, including the outcome of the ongoing REFIT evaluation of the Regulation;

Commission approval of active substances

46. Calls on the Commission and the Member States to increase the overall transparency of the procedures, including by providing detailed minutes on the comitology discussions and the respective positions, in particular by explaining and justifying the decisions of the PAFF Committee;
47. Calls on the Commission to assess the use of the confirmatory data procedure and limit the application to the 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 providing applicants with reliable timelines for authorisation; stresses that complete dossiers are essential for active substance approvals;
48. Notes that following the decision of the Ombudsman in case 12/2013/MDC the Commission re-assessed ten substances where confirmatory data applied, and none were withdrawn following the finalisation of the assessment;
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 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;
51. 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;
52. 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;
53. 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

54. Welcomes the idea and targets of the zonal authorisation system and recalls that this system should, in principle, lead to an authorisation of plant protection products that is more time- and cost-efficient for all parties concerned; regrets that despite the aim of avoiding double assessment, the work of the PEST Committee has shown that there are differences in how the zones apply the mutual recognition procedures; demands that the Commission and Member States act to improve the functioning and effectiveness of the zonal system, by strengthening coordination and fully implementing mutual recognition; calls on the Commission, in this regard, to undertake an in-depth assessment of the zonal system;
55. 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;
56. 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;
57. Calls on the Member States to minimise their national data requirements, in the interests of greater predictability and efficiency;
58. Urges the Member States to meet the deadlines and comply with provisions relating to mutual recognition in order to ensure predictability for applicants and facilitate introduction to the market of innovative plant protection products;
59. 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;
60. Calls on the Member States to strictly apply legal deadlines with regard to the elements of the authorisation of plant protection products in general and particularly with a view to minor uses; underlines that a better adherence to legal deadlines should contribute to reduce the need for emergency authorisations under Article 53;
61. 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;

62. Calls on the Commission to fully use its control rights under Article 53(2) and (3), to ensure that derogations and extensions are consistent with the Regulation, namely that they are: limited to a period not exceeding 120 days; for limited and controlled use; and used where a measure is necessary because of a threat which cannot be contained by any other reasonable means;
63. 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;
64. 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;
65. 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;
66. 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;
67. Calls on the Commission and the Member States to promote the development and use of 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; therefore calls on the Commission to assess options to stimulate innovation in this field;
68. Regrets that there are no products on the market to replace copper-based fungicides, so that the best alternative actually is the use of pest-resistant varieties; Emphasises that special attention and support should be given to plant protection products for minor uses, as there is currently little economic incentive for companies to develop such products; welcomes the setting-up of the Minor Uses Coordination Facility as a forum for improving coordination between Member States, grower organisations and industry in developing solutions for minor uses;
69. Considers it important to reduce farmers dependence on pesticides as much as possible, noting that production of food and feed operates in a competitive, international environment;
70. 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);
71. Regrets the increased use of and availability on the market of illegal and counterfeit plant protection products; calls on 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;

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

ECR questions and answers at PEST hearings

During the nine months of the PEST Committee's mandate, a wide range of experts, stakeholders and relevant EU agencies addressed the Committee. To prepare for these hearings and exchanges of views, political groups were able to submit questions to each of the panellists. These questions, which address many of the topics at stake, were answered in writing and can now be easily accessed on the Committee website: http://www.europarl.europa.eu/Committees/en/pest/home.html.

In order to illustrate Parliament's concerns with the authorisation procedure, and to the detriment of the special Committee's mandate, not all of the evidence presented in Committee was included in the final report. The questions and answers, taken from various PEST Committee hearings, which have been excluded in the final report, are set out below. These Q&A interventions were with the following nine guest speakers.

On 7 June 2018, the PEST Committee heard from Sir Paul Nurse, Member of the Scientific Advice Mechanism's Group of Chief Scientific Advisors, which provides the Commission with high quality, timely and independent scientific advice on specific policy issues critical to the development of EU policies or legislation.

On 19 June 2018, Vytenis Andriukaitis, the Commissioner for Health and Food Safety, made his intervention at the hearing on the Commission's approval of active substances. As ever, a strong champion of science-based policy making he provided an important overview of the work done so far to tackle the issue of transparency. The Committee also heard from Bob Diderich, Head of Environment, Health and Safety Division at the Organisation for Economic Cooperation and Development (OECD), which promotes policies to improve the economic and social well-being of people around the world. Finally, the Committee heard from Violette Geissen, Professor of the Department of Soil Physics and Land Management at the Agriculture University, Wageningen.

On 28 June 2018, Pekka Pesonen, Secretary-General of the EU's farmers union, Copa-Cogeca, highlighted that administrative burdens are leading to the concentration of agrochemical companies and leaving European farmers with fewer tools to control pests and diseases.

On 30th August 2018, the PEST Committee provided a comparative analysis of the authorisation procedures in three OECD countries: Australia, Canada and the USA. Speakers included: Chris Parker, Managing Director of the Australian Pesticides and Veterinary Medicines Authority; Richard Aucoin, Executive Director of the Canadian Pest Management Regulatory Agency; and Richard Keigwin, Director of the Pesticide Re-evaluation Division, American Environmental Protection Agency.

The final speaker, John Chinn, Chair of the Board of Crop Health and Protection (CHAP), spoke during the hearing that took place on 6th September 2018. CHAP is one of four agri-tech Innovation Centres set up by the UK Government, which seeks to understand the problems associated with crop health and protection, and then engages with Research Scientists to find solutions.

Q: Anthea McIntyre (ECR).7 June 2018
Chair, I would like to address my question to Sir Paul Nurse. I wanted to ask a question about the Scientific Advice Mechanism (SAM) report, which recommends a tiered approach to PPP (plant protection product) authorisation, involving a mandatory first-stage limited rollout.
Given the lack of new substances and products entering the market, does Sir Paul consider there is a danger that a further extension of the process and period of approval could act as a further deterrent to investment, which would not be outweighed by the additional evidence gathered for consideration?

A: Paul Nurse, SAM.
I think our objective was to try and simplify the process, at least in avoiding different levels that can give rise to conflicting evidence. If that takes more time – and I do not see why it should – but it comes to the correct answer, then I think that is something we just have to live with. But I do not think it automatically follows that it should take longer, especially if we can simplify the processes involved.

Q: Anthea McIntyre (ECR).7 June 2018
Do you think you can simplify the processes?

A: Paul Nurse
We have given suggestions as to how that might happen. I think these would have to be worked through by those whose trade and occupation this is. I hope that we are not living in an ethereal world with our report, but I personally think, and I think the Group as a whole thought, that we could simplify, we could get more effective outcomes, and that can only be good for the management of this issue.
I think it is worth emphasising that this is quite a complicated area. I mean it is not a simple area to deal with, and if we do need to take more time I think we just have to live with that – if we keep with us the confidence of the public and of society as a whole, which I think is critical for this.

Q: Anthea McIntyre (ECR).19 June 2018
Commissioner, thank you very much for your presentation and for being here today. My first question is: with the introduction of the new proposal on the General Food

Law and the REFIT exercise that is currently under way regarding Regulation (EC) No 1107/2009, is it fair to say, first, that the Commission is aware that there are weaknesses in the system that need to be addressed, and secondly, that it is already in the process of making the necessary improvements?

My second question is about transparency. At our previous meetings, representatives from both the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) agreed that more transparency would be a positive improvement to the system. So how are the views of the European agencies integrated into the revision of legislation? For example, do they benefit from a privileged position in the process of consultation as compared with outside entities? And is addressing transparency the only way to restore trust in the system in your view, or are there other ways that could also improve trust?

A: Vytenis Andriukaitis, Commissioner for Health & Food Safety.

Ms McIntyre asked us several questions. I can first confirm the points I will set out below. What we proposed was a revision of the General Food Law. Granting earlier access to industry started in the risk assessment process with new guidance on what information from industry studies can be claimed as confidential. We also introduced a verification process on the quality of industry studies as regards compliance with relevant studies and ensured the further involvement of Member States' authorities in EFSA's activities. This is a result of the consultation process and so it reflects the views and expectations of civil society. This is also what I intended to explain in my opening speech.

You mentioned transparency. It is one way of improving trust, but not the only way. First of all we need to restore trust using all instruments for transparency, there is no doubt about this but, second, we need to improve EFSA's scientific capacities. Third, we need to have more instruments if some cases are controversial between different scientists: how can we improve the system of arbitration to achieve results between different scientific opinions? And we could also ask EFSA to commission additional studies in the controversy. That will also help us to restore trust.

It is not only a matter of transparency. It is also about human resources. How can we support EFSA from a financial point of view to have enough human resources and to attract more scientists from the outside? And we should also have greater possibilities to include more Member States in the same process so that they are also part of the decision-making process.

And finally, risk communication. If you continue with a cacophony such as today's you have no chance of achieving anything because you can see different actors, different approaches, different messages, misleading information, a lot of different interpretations, and then finally you see distrust in science. It is the same. We need to draw attention especially in the area of risk communication, because it is about the possibilities for restoring trust.

Q: Anthea McIntyre (ECR).19 June 2018

I would like to put a question to Mr Diderich please. Mr Diderich, to help my understanding, in your second slide you told us that there are about 1 000 new chemicals every year. And yet I know that since Regulation (EC) No 1107/2009 has been in force – we are in the seventh year of its application now I think – only eight active substances have been approved, authorised and brought to the market. There have been 57 applications submitted for actives. Going back to the eight active substances that have been brought to the marketplace four are conventional chemicals and four are low-risk substances. I know under the previous legislation, which was Council Directive 91/414/EEC, I understand that there was an average of 8.6 new substances each year, and under Regulation (EC) No 1107/2009 the average is about 1.2. Can you help me square the circle with those very low figures I've just talked about compared with your 1 000 chemicals?

A: Bob Diderich, Head of Environment, Health and Safety Division, OECD.

The figure that I mentioned is for all types of substances, not just pesticides, so it includes industrial chemicals, biocides, pesticides, pharmaceuticals and so on, and the bulk of those are really industrial chemicals. The reason why there's so little pesticides is, of course, the incredibly high cost of developing the active ingredient and testing the full dossier for the authorisation, whereas for industrial chemicals the requirements before putting on the market are much lower–the barriers to putting on the market are much lower, and therefore the number of new chemicals that are coming out of research and are being put on the market is so much higher. It's really about the cost of the dossier and the research involved in developing the different types of chemicals.

Q: Anthea McIntyre (ECR).19 June 2018

Can I ask, as this is the Pesticide Committee, if you could tell me – if that figure was just for pesticides – what number would replace the 1 000?

A: Bob Diderich

It would be more in the 10 to 100.

Q: Anthea McIntyre (ECR).19 June 2018

I would also like to address questions to Professor Geissen. First of all, I have to say I am a big fan of Wageningen. I think you have done some marvellous work and I have been particularly interested recently in the work done on plant breeding techniques and the new era, because it seems to me that what you are saying about reducing the use of pesticides, and indeed producing crop varieties that are resistant, relies on us accepting new breeding techniques, because that is the way forward. One of the important things in this Parliament is to get people to understand that new breeding techniques should be welcomed from a scientific point of view and not just treated as if it meant

making everything GM and frightening 'Frankenstein food', so well done on that. In the UK, we are particularly keen at the moment on conservation farming – particularly minimum tillage (min till) and low tillage (low till), which have really shown an improvement in the soil health. If you look at a field which hasn't been ploughed up and you dig a piece of soil, the number of worms and the fibre in that soil is really good, so to pursue those methods we really need to have the use of glyphosate. And while I completely agree with you on the introduction of technology and either micro sprays so you only put a drop where it is needed and the development of robots – because I am completely convinced that is the way to go – we are not there yet and I wanted to see your reaction to continuing to use glyphosate.

A: Violette Geissen, Professor, Department of Soil Physics and Land Management, Agriculture University, Wageningen.

I think especially for conservation farming, which surely has a good impact on soil because it is not ploughed and so that avoids soil compaction. Actually, it is combined with a high application of glyphosate.

But there are other possibilities, and these techniques are already in the market. You can, for example, in combination you can grow the winter crop, let's say if you have weeds or something like this, you grow a winter crop. You let it freeze in the winter and you leave it on the soil surface and you just work in a small strip where we sow wheat, for example. Then you do not need glyphosate.

Then, when the wheat is higher and, let's say, after four weeks use finger weeders, these are new technologies. These finger weeders take these weeds out of the rows from the wheat or you can make mixed cropping: wheat plus bees. These are very new technologies that we are trying and with success in the Netherlands. And there are currently four European projects running on this and crop biodiversity in the fields. And what's important is in this case is to have to have the whole food chain developed for this crop diversification system.

Conservation tillage. It's a good beginning, but we could modify it to a way that it is really sustainable and there is where the food chain, as you have to have people who you can sell these products to. We are developing this now in different European projects with a kind of success.

Q: Anthea McIntyre (ECR).28 June 2018

We are aware that there is a real threat of anti-microbial resistance in veterinary medicines. It is very well documented. But far less attention is being paid to the increasing accounts of pesticide-resistance in plant pests and diseases and the need for a variety of plant protection products.

If the number of products that's available continues to decrease –and we know that they've only been about eight new products in the last few years, and that results in fewer alternatives, what do you estimate will be the impact on European agriculture and food security and are we in fact decreasing the environmental protection that we're all seeking to achieve?

A: Pekka Pesonen, Secretary-General, Copa-Cogeca.

Thank you very much for the question. Since you mentioned anti-microbial resistance, we have that particular case very much on our agenda for the moment. We know that we have a limited number of antibiotics available and, in particular, we haven't seen any new antibiotics introduced in this sector for a number of years, as far as I recall. Therefore this is a very current and relevant question, especially for anti-microbial resistance and the use of these particular products.

When it comes to pesticides and building up resistance, the whole concept of integrated pest management is to ensure that we have a range of actions – not only chemical or biological, but also physical, everything: crop rotation – as I mentioned, normal agronomic practices to diversify as much as possible in order not to repeat the treatment of the same parcel of land for instance, in the same manner.

We are trying to avoid monoculture for simple agronomic reasons. We can't always completely avoid that for the very same reasons. Typically, in some regions in Europe we have to use more or less the same areas to cultivate, for instance, feed for livestock for natural reasons. So we have to find a solution there. But, even in that case, we need to employ different methods – preferably every year, every crop cycle–so that we don't build up these resistances against any particular product because in the long run – quite rightly so, as you indicated – we would be losing these products because the effectiveness of the substance will be lost.

Therefore, in the long run, the fewer alternatives in the global integrated pest management set up we have, the more likely it becomes that we cannot fight pests and disease and eventually that would lead to a deterioration of our security objectives. This is exactly what the European and global farming community is worried about because we are expected to deliver probably twice as much food in the long run because of the increasing population and, in particular, the requirement of citizens of non-European citizens for high-quality proteins. So Europe is not the sticking point here, but the global food security, in which Europe leads the way.

Q: Anthea McIntyre (ECR).30 August 2018

Chair, I would like to put a question to Dr Parker regarding the written questions that we posed about public versus private funding for scientific research. I would just like to clarify some of the responses.

Do you consider that the private nature of funding of research is in itself a problem or conflict? And concerning EU public funding of research, which is one of the things that is being considered, apart from the benefit that you identified of some free research – you identified that in your response–do you think that this would deliver different results or would the underlying science remain the same?

A: Chris Parker, Managing Director, Australian Pesticides and Veterinary Medicines Authority.

Thank you for the question. Our view is that it is up to

applicants to prove to us that products are safe and efficacious. Our view is that it is their responsibility and their cost, they are the ones looking to participate in the marketplace in Australia and it is up to them to provide the scientific evidence that is required for a product to be registered. Our job is to ensure that we have the quality of scientists available who are able to review that information, based against the best scientific principles and based on risk, and make a decision.

Q: Anthea McIntyre (ECR).30 August 2018
Can I just come back on that and see if I can push you a bit further. Would you be concerned by the, no, put it the other way round: if the European Union decided that it was going to publicly fund all research rather than go the route of the private funding that currently happens, would that give you greater confidence in the findings?

A: Chris Parker
How the European Union chooses to get the scientific information it requires to register products is a matter for the European Union. I am not going to be drawn into a value judgment about science, other than to reiterate that our job, as the regulator in Australia, is to ensure that we have the scientific capacity and ability to be able to ensure that products are safe and efficacious. I don't believe it is reasonable to ask me for a value judgment on whether one type of science, public or private, would be better. Science is science and it needs to be evaluated in the appropriate manner by a sophisticated regulator such as the Australian Pesticides and Veterinary Medicines Authority.

Q: Anthea McIntyre (ECR).30 August 2018
Thank you. I guess this is a question to everybody, but what I would like to do is ask for some clarification on the different processes of renewal and reassessment. How do they differ in practice? Is it that the intermediate renewals – every five years or whatever in different countries – require a practical analysis or are they just limited to a paperwork assessment? How do the renewals align with the re-evaluation cycle, and is it the same process of renewal and reassessment for both the active substance, and for the individual products based on the substances?

A: Chris Parker
Australia's re-evaluation process is based on new scientific evidence. We do not have a regular re-evaluation of products. What we do have is, where we have new scientific information that we believe is relevant to a product that we have previously registered, then that product goes through a formal review process and that formal review process has the same robustness around it as would the application for a new chemical. So, each of the different components, from toxicity all the way through to trade, through chemistry, of all the different formulations that are out there, are all considered, as is the full evaluation of human health aspects as well.

A: Richard Aucoin, Executive Director, Canadian Pest Management Regulatory Agency.
In Canada, as I mentioned in my opening remarks, we have a statutory obligation to re-evaluate all pesticides on a 15-year cycle. So when we initiate the re-evaluation, that includes a full re-evaluation of the active substance as well as all the end-use products that contain that active substance. That risk assessment and risk management is very much conducted in the same manner as a substance before it enters the market.

A: Richard Keigwin, Director, Pesticide Re-evaluation Division, American Environmental Protection Agency.
In the United States, the approach is very similar to what my colleague from Canada described. We evaluate the active ingredient every 15 years, along with its associated end-use products. For all ingredients – active ingredient or inert ingredient –we also have an adverse effects reporting system. If new information becomes available to us that suggests that the toxicity or the exposure from the chemical may be different than what we previously assessed, we will undertake a new assessment to see if that new information changes our previous scientific conclusion.

Q: Anthea McIntyre (ECR).30 August 2018
If I could just come back actually to both Dr Parker and to the last speaker. Let us start with the USA. Will the court ruling in California mean that you will do a reassessment of glyphosate, a re-evaluation? And if I could just ask Dr Parker – if it had been an Australian court, would that cause you to do a re-evaluation of glyphosate in Australia?

A: Richard Keigwin
Thank you for the question. In the United States we are currently in the re-evaluation process. The public comment period on our draft risk assessment recently concluded and we are evaluating those comments and that information now. Then, based upon that evaluation and those comments, we will determine what mitigation might be necessary and will issue a proposed risk management decision for public comment either later this year or early in 2019.

A: Chris Parker
In regard to glyphosate, we looked extensively at the International Agency for Research on Cancer (IARC) report, we looked extensively at the available science, and we did not believe that there was adequate scientific evidence to provide for a review of glyphosate going forward. The Member is asking me a hypothetical question about a hypothetical court case potentially in Australia–or not in Australia. I am really not able to answer that question. It is completely hypothetical and it would not be useful for me to speculate on something that has not occurred.

Q: Anthea McIntyre (ECR).30 August 2018

I just want to say how very refreshing it is to hear that three very important and substantial countries base their decisions on scientific evidence and an assessment of risk. In the EU, very sadly, we have got ourselves completely hung up on the precautionary principle, and it bears no relation to common sense. If we extended the precautionary principle to all the other aspects of our lives, we would never build anything other than bungalows, because staircases can be a hazard. You can fall down them. If you are really applying the precautionary principle to building standards, as I say, you would only ever have bungalows.

But – in this Committee particularly, but in the EU – we insist on regulating everything on the basis of the precautionary principle, hence the great desire among some colleagues to ban glyphosate and ban all chemicals. I know from discussions with colleagues that there are people who would ban chemicals, whether they are safe or not, just on the grounds that they are chemicals.

Since I don't have very many opportunities to ask questions to such sensible and valued representatives, the question I would like to ask is this: In your own countries, do you see ways in which you would like to change or improve the processes you use to authorise chemicals, such as those we are talking about?

A: Chris Parker

It is a challenging question for me to answer because I operate under a set of legislation that is provided by the Parliament through the Department of Agriculture. I do my duty in accordance with that legislation, but I would note that currently before the Australian Parliament there are some changes to the legislation, some of which will improve some of our processes. But these are obviously yet to be passed by the Australian Parliament.

As I said in my opening statement, we recognise that the world is changing and that there are new technologies out there. We need to be an adaptive and flexible regulator to be able to accommodate the new technologies and the changing environment that is out there. Therefore, we are constantly looking to improve at the regulation that we do, but all based on that risk and science-based approach.

A: Richard Aucoin

In Canada, we too are always open to changes in business practices and making sure we have an efficient process. We always want to make sure that we are looking forward to as much transparency as possible. We always know that there is more work that we can do in the area of transparency.

Of course, we are always going to continue to use the best science available. One area that we could improve a lot on is our risk communication. A lot of the discussion around hazards versus risks and the precautionary principle would perhaps benefit from much clearer risk communication with our respective publics.

A: Richard Keigwin

I agree with the comments from my colleagues. What I would add is that we constantly strive to improve our process. Not only is it something that we are statutorily required to examine, but it is something that we encourage our own staff to explore. We also routinely invite feedback from the public on how we can continue to improve the process that we utilise to make the decisions that we make.

Q: Anthea McIntyre (ECR).06 September 2018

I would like to address a question to Mr Chinn. I have to say I found the presentation fascinating because I think it is really helpful to this Committee to hear someone with practical experience, with an encouraging future for us, because I think we are very concerned to see how we can improve the environment and how we can reduce the use of pesticides, so Mr Chinn has given us some very practical ideas.

I have two questions. You said we are developing more targeted plant protection products which will have a reduced impact and I think, as far as I understand, that needs to be linked to new technology. I would just like to ask you to expand a bit more on what can be achieved and how that will work, but I have a concern. I didn't hear you calling for the regulatory process to be reduced or not to not have rules, what I understood you to say is that we needed to speed things up, and put that way it seems that we could be benefiting from safer, more effective, 'lower risk pesticides' I think you said, if we could just get them through the system. I would be interested to hear your comments on that and generally on the idea of new chemistry and new technology.

A: John Chinn, Chair of the Board of Crop Health and Protection (CHAP).

If we start with talking about targeted chemistry, we generally know at a fairly early stage in the chemical's development, which part of a plant's pathway it will interrupt to cause the death of the plant, and having that knowledge will help us to make an opinion on whether this is likely to be a safer chemistry or less safe. I believe that the regulatory authority could fast-track chemistry that appears to be safer, because that is exactly the chemistry that we need to get out on farms as quickly as possible.

When we come to new technology, there is an overlap between new technology and targeted hosts, because in my example of the nematodes we used to control vine weevil in our blueberries, the nematode is a live animal, basically. It is a grub, and we can apply that to the crop, and the grub specifically looks for vine weevil larvae, leatherjacket larvae or slugs, and those are the only three hosts that it invades. That way of controlling a problem to me seems absolutely the way that we should be trying to go.

I would like to really clear up what I see is sometimes a misunderstanding of the difference between a biopesticide and a biological agent. A biopesticide is a pesticide that has been derived from a plant. Some of these biopesticides can be extremely nasty. I don't believe there is anything nice about a natural poison that makes it better than a synthetic poison. They are all poisons.

Biological agents are like my nematodes, and they are much more specific.
In terms of new technology finally, the way that we are going where we can put cameras on the sprayer boom and we can specifically treat individual weeds or diseased plants will hugely reduce the amount of pesticide that we need to apply. I just can't think that that is anything but good for the farmer, economically, and good for the environment, and certainly it will result in hugely-reduced residue levels in the food.

Q: Anthea McIntyre (ECR).06 September 2018

I would just like to put one more question to Mr Chinn. You talked about 'a poison is a poison', and there are some things that are better than others to spray, and yet there seems to be a move to say that synthetic chemicals are bad but anything that is a natural substance is okay. So it is okay to use copper on vineyards, because that's a natural thing, but it's not okay to use glyphosate. I just would like to hear your views on that.

A: John Chinn

I have some quite strong views, bearing in mind that copper is element number 29 on the periodic table, and you only have to go to element number 33 to get to arsenic. If we use the same logic, do we really think we might spread arsenic on our vineyards? Strychnine is a most horrible poison. It is naturally occurring; it comes from the seeds of the nux-vomica tree. It occurs naturally, but it is a most dreadful poison. So just because something is a naturally occurring poison, that it in way makes it better than a synthetic poison.

Evidence from PEST Committee hearings

Commissioner Vytenis Andriukaitis: Health & Food Safety

EU authorisation of pesticides - Commission approval of active substances

Tuesday 19 June 2018, 15.00 – 18.30, European Parliament, Brussels

European citizens expect safe food, and rightfully so. However, while ensuring that food safety remains an imperative, it is no longer sufficient in itself. Increasingly, citizens have concerns about how their food is produced, about the sustainability of the food system and about environmental protection. The governance of our food system is also becoming more open and inclusive, with a call for greater transparency in the risk analysis as well as the greater engagement of citizens in the decision-making process, facilitated by digital innovation and social media.

We can only meet these expectations if we can together learn lessons from recent challenges and move forward in the interest of all citizens. In this context, this special Committee is important, so I thank you for your invitation and the opportunity to speak with you. Let me stress one point: this Committee and I share the same goal, namely to maintain food safety, protect citizens' and animals' health, and safeguard the environment. To help achieve these goals, the EU has the most stringent regulatory system of pesticides in the world. It requires first a comprehensive scientific evaluation conducted by the Member States and the European Food Safety Authority and, if safety has been demonstrated, approval of active substances at EU level. However, the final products are then approved by the Member States.

Let me be quite clear that the Commission has removed – and will continue to remove – active substances from the market if they are not safe. Since the regulation in 2011, the Commission has taken 22 non-approval or non-renewal decisions based on scientific evaluations. In fact, the approval criteria are so strict that many companies have decided not to submit their substances for renewal, because they don't expect them to pass this test. This is true of 18 substances.

The Commission does not hesitate to restrict the use of certain substances when warranted. The recent decision to prohibit the outdoor use of three neonicotinoid substances proves this point. Nevertheless, I am aware that, despite all our efforts, some Members of the European Parliament claim that the Commission is not courageous enough to ban substances when there is a negative risk assessment from the European Food Safety Authority (EFSA). I would like to put the facts right and give a concrete example. My services are organising an appeal Committee in July for four active substances that I would like to ban, following an EFSA negative risk assessment: diquat, malathion, pymetrozine and thiram. Unfortunately, Member States do not support my proposal: so many of them want to keep their products on their markets. So the issue remains uncertain. This, I hope, shows my determination, but also the difficulties of the Commission's task.

The legislation adopted by Parliament and the Council is very stringent. At the same time, there is no such thing as a perfect system, so we should always look to refine this process, to modernise it and to incorporate lessons learned. The Fitness Check of the General Food Law and the recent European Citizens' Initiative on glyphosate both called for greater transparency of EU risk assessment in the food chain and reinforcement of the system's sustainability.

I have proposed the revision of the regulation on the General Food Law with these goals in mind. Some of you were there when I presented the revision to the Committee on the Environment, Public Health and Food Safety (ENVI) last April, but allow me to briefly outline the proposal again. It seeks to make improvements in four key areas. First, it increases the transparency of the risk assessment by ensuring that scientists and citizens have access to key information at an earlier stage, with the exception of confidential information. Second, specific measures will improve the quality and reliability of the scientific studies. For example, a register of studies commissioned by industry will be established, and EFSA will be able to provide general advice on what is required from the industry before an application for an authorisation is submitted. In exceptional circumstances, the Commission can ask EFSA to commission additional verification studies. The proposal aims to strengthen the involvement of Member States, the European Parliament and NGOs in EFSA's governance structure, without impeding EFSA's independence. Third, it strengthens communication between the Commission, EFSA, Member States, stakeholders and the general public. I am confident that this proposal will result in significant benefits and will improve citizens' trust and confidence in the process. I am not the only one to think that. I was very happy when Helmut Burtscher-Schaden from Global 2000, one of the initiators of the citizens' initiative but also a like-minded friend, dedicated his important book, 'Die Akte Glyphosat, Top Secret' to me with the following words: 'Dear Commissioner Andriukaitis, on 4 March 2016, you stated that all studies should be disclosed because of an overriding public interest. On 11

March 2018, you came up with a strong legal proposal. Thank you for that'. We are very clearly not far apart. We live on the same planet – the one and only planet we share and cherish. We need to work together to make this proposal a reality, to make sure that there is no leeway and no suspicion that corporations use the weaknesses of the system and endanger our health. As Helmut writes on the cover of his book: 'Smoke & mirrors in the pesticides approval process'.

The ENVI Committee has started working on this proposal, and I call on all of you to support this initiative so the legislative process can be finished within the current legislative term. But this is not the only area we are looking to improve. We are using the Regulatory Fitness and Performance Programme to evaluate our pesticide legislation. This includes both the regulation on plant protection products and the regulation on pesticide residuals.

I want to take this opportunity to welcome Parliament's focus on these issues. In addition to this Committee's forthcoming report, Members of European Parliament Pavel Poc is examining the implementation of the plant protection regulation, and Parliament's research services have already produced a study on this topic. We also have the Scientific Advice Mechanism's opinion on pesticides and the findings of the audits conducted by the Commission's services in the Member States. Let me assure you that all of these outputs will feed into the Commission's analysis as we move ahead.

In addition, I have myself had many discussions on our system. This is why I would like to respond to some concerns that I have noted in the list of questions you have sent me and in the meetings I have had with some of you. I am aware of criticism as regards a repetitive extension of the approval of substances. Indeed, here I am bound by the letter of the law. If the Rapporteur Member State is late in finalising its assessment, the whole EU procedure is delayed, and this, unfortunately, happens from time to time. In such cases I cannot withdraw a substance from the market, because it is the authorities and not the company who are to blame for the delay. That would be unfair and illegal. I have no choice but to extend the approval. That is not satisfactory, and they have written to Member States to ask them to fulfil their duty and accelerate their work – unfortunately with little success. Another criticism concerns the overuse of confirmation information. I do not know why people use the term 'overuse'. This possibility is provided for in the legislation, and we are using this procedure strictly in line with the regulation, which says that confirmatory information may be requested 'where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge'. I have responded to the Ombudsman on this issue. As a result of scientific progress we develop new guidance documents, and our procedures are very slow, so sometimes it is important to be strict and ask for more information from the companies, to take account of progress in science.

Finally, I would like to react to the comments that our guidance documents are too often delayed. This is indeed true of the Bee Guidance Document, again despite all our efforts. The reality is that these documents need to be endorsed by the Member States, and here again it is sometimes difficult to find a solid majority. Maybe the answer would be to depoliticise such documents and leave them to scientists alone. I would welcome your views on this.

The 2009 Directive on the Sustainable Use of Pesticides also seeks to reduce the risk of pesticides to health and the environment. In order to deliver on its potential, the directive needs to be implemented rigorously, and that requires investment by all of us. Last year, a Commission report on the implementation of the directive found that, despite all Member States adopting a national action plan, there were wide variations between the different plans, in particular regarding measurable targets and timetables for the action areas. This needs to change. Member States are currently reviewing their national plans. The revised plans must include clear, measurable goals. This year the Commission is conducting audits in four Member States on the implementation of the directive, and further audits are planned in 2019 and beyond. We are also working with Member States to develop harmonised risk indicators to monitor trends in the risks and impacts of pesticide use.

You, as Members of the European Parliament and as members of this Committee, play a crucial role, so I want to take this opportunity to ask you to focus the debate on national action plans in each of your individual Member States. Reducing the risk associated with pesticides is also a goal of the new Common Agricultural Policy proposal, which was published on 1 June. It is worth noting that some aspects of the Directive on the Sustainable Use of Pesticides are now included in the rules of conditionality. This means that direct payments could be reduced if farmers do not comply with them. Further indicators have been set on the sustainable use of pesticides, and Member States will be evaluated against this.

Honourable Members, I want to thank you once again for your engagement and the important work undertaken by this Committee. I look forward to your report and I assure you that your conclusions will be taken on board – but please be precise, be detailed and be specific. We will continue to work tirelessly on increasing transparency, building trust and improving the sustainability of our food safety system.

Bernhard Url: European Food Safety Authority (EFSA)

Executive Director

EU authorisation procedure for pesticides - EFSA opinion on draft assessment reports and ECHA classification of active substances

Thursday 7 June 2018, 14.00 – 17.30 European Parliament, Brussels

Chair, thank you very much for inviting us here again to the Special Committee on the Union's authorisation procedure for pesticides (PEST). This is now the third time we are in contact with you. We are trying to do our utmost to support your work. We did this in April and then we had the pleasure to welcome you in Parma for a two-day meeting and this is now the third time we talk to you.

In our past appearances here, and also in Parma, we talked a lot about procedural issues, how we assess pesticides and active ingredients within EFSA. We talked about methodologies, about the evidence we use, about the experts, the expertise we use, how we use studies from industry, from scientific literature, and how we apply the weight of evidence approach.

We also talked about the people, the role of experts, that we use in the peer review process, also EFSA's panel structure and how we collaborate with Member States' authorities in this two-step procedure. And a third part of what we tried to outline to you was the whole issue about independence of the data, the methodologies and the people, transparency of the process, and then we also focused for quite some time on allegations in the room that we hope, at least, we were able to explain to you, to showcase to you, how our scientific work is done, and that the allegations brought forward were not based on factual evidence.

Today I would like to focus on different issues and not go back to those issues, although obviously we are ready to answer your questions if there are any open still. Today I would like to start with a comparison on classification that we have done together with the International Agency for Research on Cancer (IARC). With this we would like to show you that first of all, classification is a complex scientific process.

What you see here is a comparison of 54 pesticides that were assessed by both systems – the IARC system and the European system – over many years. And you see here that out of these 54, in 29 cases we came to an equivalent classification proposal. But in 25 cases, we came to different classification proposals between IARC and the European system. And if you look at these 25 cases, you will see that in 14 cases the European classification proposal was, so to speak, more strict, more severe or more conservative, than the one proposed by IARC. And in 11 cases it was the other way round, and one of these 11 cases is glyphosate.

I think there are some messages in this slide, important messages, that on average the EU system is, you could say, more sensitive or more conservative with regard to classification. You can also see in this slide that the system works, that there is not a systematic bias in one or the other direction; the system works and glyphosate is just one case out of 54 cases.

I think it also shows that the allegation that was brought forward in the past that the EU system was scientifically unsound or flawed is not supported by this evidence.

It is also interesting to note that until glyphosate happened, nobody was interested in these differences. It is only now, because of glyphosate, that suddenly we say: how can it be that there is a difference? If I try to put myself in your position as policymakers, this divergence is not helping policymakers. It creates uncertainty, ambiguity, so we should try to find ways, or try to find explanations, as to why these differences occur. I think the session today will also give us an opportunity to dive into this, especially because our colleagues from the European Chemicals Agency (ECHA), the authority for the classification of chemicals, are with us today.

Turning the discussion now to how can the system be improved. We have spent a lot of time on looking at how the system has worked up till now, but how could the system be improved? There is one proposal now on the agenda; it is now entering into the co-legislation process. It is an amendment of the General Food Law, amendment of Regulation (EC) 178/2002, which we very much welcome.

We are very grateful to the Commission that following the EU Citizens' Initiative, the Commission has been very reactive and very fast in putting on the table a legislative proposal for new measures on transparency, and also to update the governance model of EFSA, aligning it with the other European agencies, for an approach, for a more coherent risk communication, between the risk managers, the agencies, and also the Member States, and this, according to the Commission proposal, would also be supplemented by an additional budget.

Of course, we have a conflict of interest here, we are biased. As Executive Director of EFSA obviously I would say it would be very useful to have these additional measures on transparency, additional measures to increase the reliability of studies and data use, but also the additional budget we need to implement this new Regulation.

What we have also done on our own initiative, without having in mind legislative changes, is that we further strengthened our conflict of interest policy and implementing rules. Here we are in constant dialogue also with the European Parliament to update and strengthen the conflict of interest rules, also now for experts appointed by Member States. We have been in close collaboration for many years with our colleagues in ECHA in Helsinki, but now there is also a proposal in the making that the alignment of the processes between risk assessment by EFSA and classification by ECHA in a timely manner will come forward.

I find this a very important step forward so that we do not have this time gap where, on the one hand, EFSA is doing risk assessment and maybe one or two years later ECHA does the classification. It is really important that we bring this into alignment.

Then we work with our internal Member States' Pesticide Steering Network on how to improve the process between Member States and EFSA in the work on pesticides, and we also try to contribute to, and we have published a technical report in, the REFIT exercise that is going on now with regard to pesticide legislation. So from our side also we are investing money and resources into improving the system. It is a continuous improvement system.

When it comes to scientific initiatives, and we have outlined this to the PEST Committee, especially in Parma, we know that we need progress in science on many different fronts. I shall mention here just the cumulative exposure and the cumulative risk assessment with regard to pesticides where EFSA is doing, I think, breakthrough work, together with the Member States, but we cannot continue, or we cannot foster this work in the way we would like to do, because of resource constraints.

We are working with many partners on a more refined landscape-based risk assessment model for pesticides. This would also improve protection of the environment, consumers and bystanders, and non-target organisms a lot, and this leads to the whole question of how we can keep our methodologies updated. EFSA is a scientific organisation. We want not only to follow the progress of science, we also want to drive the progress of science, but there I have to come in again with the question of resources.

I am very grateful to the Chair of this Committee who after the visit to Parma spoke out very vocally, saying that EFSA needs more resources to improve and to bring forward our scientific work on pesticides. I would like to repeat this also here in this House as you, the co-legislators, have a major influence on how the future budgets for EFSA, including in terms of science, and not only in terms of the 178 proposal. That's more for transparency, for accessibility of data for governance, but here we are talking about hard core science and we are not funded in a way that we can bring this science forward as we would like to do.

Björn Hansen: European Chemicals Agency (ECHA)

Executive Director

EU authorisation procedure for pesticides - EFSA opinion on draft assessment reports and ECHA classification of active substances

Thursday 7 June 2018, 14.00 – 17.30 European Parliament, Brussels

Chair, I too am very happy to be here, for the first time in this setting, as head of the European Chemicals Agency (ECHA) and I am proud to be able to fulfil my duty as Head of Agency and as a civil servant contributing to democracy in action in clarifying issues in the case of glyphosate.

I think the fact that we are getting together to discuss this issue and to discuss ECHA's work is a clear indication that the machinery works. We have done our work; there have been questions about our work; and now we are sitting together to clarify this in a discussion, with the aim of learning from it and improving where possible and necessary. So I am very much looking forward to the debate afterwards.

I would like to start by talking about what ECHA is, to go into some of the activities that we do and then to look at glyphosate. ECHA is a chemicals agency which was established about ten years ago in Helsinki. We implement the scientific, technical and administrative tasks allocated to us in four pieces of legislation: the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, the Classification and Labelling Regulation, the Biocidal Products Regulation and the Prior Informed Consent Regulation, which implements the Rotterdam Convention. We are also being given additional tasks under the Waste Framework Directive, just adopted, and the Commission is recommending, in its proposal, that we take on tasks under the Persistent Organic Pollutants (POPs) Regulation.

We deal with a number of chemicals and a number of interesting topics within that area. You can see that glyphosate is clearly one of them, but we, like the European Food Safety Authority (EFSA), have done work on bisphenol A. We have done work on tattoo inks and we have done work – and are doing work – on micro-plastics and on some other general scientific issues surrounding the chemicals area. Then we come to glyphosate, where we have produced an opinion through our scientific Committee, the Committee for Risk Assessment, in the context of the Classification and Labelling Regulation.

The conclusions of our Committee for Risk Assessment were that the chemical does have one toxic property for human health – which is to do with eye damage – and that it is toxic for the environment, but we did not conclude that it is toxic for a number of human health endpoints, in particular the ones that this session is about. I would like to explain a little bit about the general framework of classification and labelling, then apply that to what we have done on glyphosate, and also to put that work in the general context of the work we and our predecessors in the European Chemicals Bureau, and the Commission before that, have been doing for the last 30 to 40 years on classification and labelling.

First of all, the Classification and Labelling Regulation, which we implement from the scientific, technical and administrative side in the European Chemicals Agency, looks at the hazards of chemicals, and sets out rules on how to determine the hazards of mixtures, based on the hazards of the chemicals in them. The legal basis of the regulation effectively implements a UN agreement, the Globally Harmonised System. In this slide you see the symbols that are the labels on chemicals and chemical products, which, with this Globally Harmonised System, have now been harmonised across the world and across different uses, be they by consumers or workers or in transport. We are implementing the criteria of this Globally Harmonised System through the regulation at EHCA.

The way it works is, in general, through a four-step procedure. This involves the test houses which do tests; the industries which pay for and contract out the tests; and, usually, Member States which assesses the results; as well as a scientific Committee, in our case in EHCA, which reviews what the Member States have done. The test methods which the test houses apply are methods that have also been agreed internationally. This is done in order to reduce animal testing, but also to ensure that a test done in one region can be accepted somewhere else. So the test methods applied by the test houses are internationally agreed and there is an audit system, also internationally agreed, to audit the test houses, which is called Good Laboratory Practice. So the test houses are audited by Member States in a network under the umbrella of the OECD.

The Member States' job, in preparing a classification and labelling proposal, is to assess the results of the tests financed by industry, with full access to the full study report and also with knowledge about the auditing of the test houses which performed the testing. They then put a

proposal together in a document, where they compare all the data with the criteria, and they send that to the European Chemicals Agency, where our Risk Assessment Committee of experts assesses or reviews what the Member State competent authority or the evaluating Member State has written or concluded in their report.

That discussion leads to a unanimous agreement. We then present that in an opinion to the Commission, which in turn presents that result to a comitology Committee. In essence, this step-wise approach is one which is applied in science very broadly: a scientist does some work, puts his or her results into a scientific publication that then gets reviewed by peer scientists in order to be published in a peer-reviewed journal. That is the type of system we have in a step-wise approach, all the way from the test house up to the Committee vote.

In the case of glyphosate, we had quite a number of studies produced by GLP laboratories, which we had to assess and, in doing that assessment, we have to compare data using the criteria in the Classification and Labelling Regulation. The Classification and Labelling Regulation is one which is evidence-based so, basically, you look at the data to see if there is or is not sufficient evidence there to fulfil the criteria. So there is a certain threshold above which you need to have evidence in order to have a classification.

In the case of glyphosate, there was a lot of information and a lot of data and, indeed, there was some data which gave an indication of positive results. There was also some data which gave an indication of negative results. In this complex situation we apply a so-called 'weight of evidence' approach which tries to understand whether the positive results have consistency in terms of all the data that is there. In the case of glyphosate – in looking through all the data and looking at the consistency and all the information we had – the Committee for Risk Assessment concluded, with all the experts there, that they did not feel – or did not see – that this data, looked at in its totality, was sufficient to fulfil the criteria in the Classification and Labelling Regulation, and therefore that was our opinion going to the Commission.

This case of glyphosate is one of many. There are about 4 000 substances in Europe that have been classified in this way over the past 40 years. We in ECHA alone have done almost 300 harmonised classification and labellings over the past 10 years. Of these 300, about 30% included substances that were identified as carcinogens, so it is possible to have enough evidence to fulfil the criteria as a carcinogen according to the CLP Regulation.

Andreas Hensel: German Federal Institute for Risk Assessment BfR

President

Hearing on EU authorisation procedure for pesticides - Application for approval of active substances and Draft assessment reports

Tuesday 15 May 2018, 15.00 – 18.30, European Parliament, Brussels

Chair, I will speak in one of the working languages here in Parliament, in German. I am happy to have been invited, as we now have the opportunity to explain here briefly how Germany works in a rapporteur system in the plant protection sector. We also have Mr Backhaus, a colleague from the Julius Kühn Institute for Plant Health here with us today, who is also part of the institutional landscape, and who is occupied with plant protection in Germany.

We think – and this will also be part of the discussion today – that many misunderstandings regarding plant protection product authorisations often result not from scientific divergences, but rather from discussions on how the method itself is organised – we are therefore very happy to have been invited here for that purpose – and how plant protection should be organised in the future so that it is carried out in Germany with the appropriate level of quality and with a satisfactory outcome for the consumer.

Unlike pollutants, plant protection products have a big problem. We have two divergent subjects requiring protection here. On the one hand, there is food safety and crop reliability for farmers, on the other hand there is the question: how much plant protection product residue should be permitted in food? The parliaments, including the European Parliament, are the ones who have determined that certain concentrations of plant protection product residues are indeed permitted in food. The precautionary principle in the authorisation of plant protection products is evident in that we – and I would estimate, that we are altogether about a thousand scientists in the associated authorities here in Europe – look in the authorisation procedure itself to see the concentrations at which this does not lead to any adverse effects for consumers. And this authorisation procedure itself is, I think, entirely presentable internationally and also very efficient.

Perhaps a very brief word on communication. Of course it is always a bit problematic if someone says: 'Well of course there is residue there, and you, the consumer, have to eat it.' However, it is not the approving authorities who are responsible for this, but rather the parliaments who say: 'We will weigh up these subjects of protection, and we will also organise the processes.' This is why I am here today, to tell you how the processes are organised, at least in Germany.

Contrary to what is widely reported, the Federal Institute for Risk Assessment is not responsible for the authorisation of plant protection products in Germany, rather, we work exclusively in the area of preventative health care. Like the European Food Safety Authority, we are a result of the BSE crisis. In other words, after BSE (mad cow disease), there were deliberations, also in Germany, about how consumer protection could be organised, and the BfR was established on the foundation of solid predecessor institutions. We were established in 1876 as an Imperial Health Department, but twin subsidiaries were created in 2002: the Federal Office for Consumer Protection and Food Safety, for management decisions of the Federal Government, and the German Federal Institute for Risk Assessment as an independent scientific authority with its own law on establishment. This means that we are also independent from our own government. And independent means independent, in all questions of risk assessment. Independent in active research that we conduct to improve our risk assessment, and also independent in our risk communication. That is because the basic idea is that we can speak freely if there are problems relating to consumer protection.

We have about 17 national reference laboratories for research. We are very happy to have these, because we can determine the quality of the data ourselves, and this might be one of my take-home messages. The first important thing is: Underlying the quality of a risk assessment is data, and the better the data are, the better the risk assessment.

The BfR itself – if I can state key figures in this way – now has almost 1 000 employees, about two thirds of whom are scientists and research assistants with a budget of about 100 million, and we are active in all areas related to consumer protection or consumer interest. This means that we are not just there to say when something is dangerous for consumers or presents a risk, but we are also there to say how this should be evaluated. The guidelines and standards are rooted in our department.

Very briefly in summary. We are not only responsible for plant protection products and biocides, but also for all questions of

food safety, and food additives, then in the area of biological safety, for all food-related microorganisms – viruses, bacteria, bacterial toxins or parasites – and also for the non-food sector, i.e. cosmetics, toys, tattoos and so on. A further area is the chemical sector under REACH, i.e. European legislation of chemicals. That would be under a different technical supervision in a different ministry, but also within the scope of our evaluation. So this means ECHA and EFSA are with us as corresponding authorities.

We have our own risk communication which also researches awareness, for example, of consumers, sociological and psychological problems, and – I should probably also indicate – also an experimental toxicology that is looking into the alternative to animal testing. It sits well with us since it concerns which animal testing can be used, in which form as regards regulated substances or testing of regulated substances. How they can be used, or whether they can be replaced. We believe that it is a very good match for us.

Within the Federal Institute for Risk Assessment, there is a department – and at this point I'd like to introduce my neighbour here, Dr Solecki, the Department Head, who has been in the job roughly since the discovery of plant protection products, so for about 40 years. The organisation – as you already know – is so, that the active substances themselves are authorised in Europe. This means that there is a RMS with a co-rapporteur, which, for glyphosate, are Germany and the Republic of Slovakia, and then there is the zonal approval procedure, which is where authorisations of plant protection products – that is, the active substances plus everything else included – are then granted on national level. So for example in this case – we have written this out for you – this would be 37 products in Germany.

Active substance testing is one of the basic requirements for the question which plant protection products will be authorised? Because if the active substance has not been appropriately tested, no authorisation will be carried out for the plant protection product.

At the same time, we work alongside the ECHA, from the viewpoint of intrinsic substances, intrinsic toxicity, i.e. the hazard of chemicals. The ECHA does this with its Committee for Risk Assessment, and this Committee has been looking into glyphosate for many years now too.

What is the process, how can you picture it? It starts with an applicant. They approach you, so for active substances, they approach the Commission. There is a rapporteur who is determined by the Commission for renewing approvals. For new active substances, the applicant can choose for themselves. Then, in a public consultation it is examined whether there are other details that we need. The EFSA did this in this case. Then the process begins. The EFSA organises the process itself. There is one Member State and one co-rapporteur, which is Germany in the case of glyphosate. A risk assessment report is created, which is then finally publicly discussed again, so everyone in the world is given the chance of commenting on it again. And an overall conclusion is then made, and the conclusion itself is then presented to the Commission, which can then decide on it in the Standing Committee for Plants, Animals, Food and Feed.

The question of zonal authorisation is a separate consideration. There are different zones in Europe with different plant protection products. The procedure for this is designed differently. So, in this case, the national state is asked when a draft is required for a particular active substance. Data is sought externally, and then finally an authorisation is issued on the national level, or not.

Perhaps one more thing to prevent misunderstandings. The coordinating authority in Germany is the Federal Office for Consumer Protection and Food Safety, and the BfR is also there exclusively to evaluate human and animal health. Not only consumers affected by residues are included, but also, for example, users and bystanders, i.e. those who are present when applying the plant protection product. This is also evaluated by us. The Julius Kühn Institute can introduce itself, and the Federal Environment Agency is responsible for the environmental aspect in Germany.

Now we come to the question that is often asked. How many do you do now? On average, BfR conducts a total of 3 500 risk assessments annually. Of course the number concerning pesticides is much lower. This is also related to the very significant total cost of authorisation. To illustrate, from 2012 to 2018, Germany processed 21 active substances as rapporteur and 16 as co-rapporteur. Perhaps we should take another look at this. 13 are currently in evaluation. Of those for which decisions have been made and which relate to active substances, we, the BfR have positively evaluated three, rejected four of the active substances, and one substance has been withdrawn by the applicant company itself.

As a whole, you can say: in Germany about 1 000 applications, right now exactly 1 073, of which 545 are in process, 299 have been approved, 109 have been rejected and 120 were withdrawn by the industry. These figures are just for you to see that not everything goes through, but that it is indeed very critically assessed. Germany is one of the states with the greatest number of staff in the area of plant protection product approvals. There are about 350 to 400 of us, as an estimate, who are active in this sector in Germany.

Regarding glyphosate: perhaps as regards procedure, coming back to the question of the regular process. This started in 2011 with the approval renewal. There had been one previously, which was also processed by BfR. I suspect that this is why the Commission assigned approval renewal to us too, or assigned it to Germany. The risk assessment report was completed by 2013 and then given to the EFSA. And here it is also clear that this risk report, which is often discussed, is not the BfR risk assessment report, but rather the EFSA risk assessment report and the Commission's and the 28 Member States respectively. Because ultimately, if we have completed our risk assessment, all 28 member states have adopted it in form and content. That means, in our current discussion, and also going forward, we must always

be clear that we are not talking about a BfR draft, but that of the Commission or the member states themselves.

You can see that the regular process was concluded in 2015. Then an IARC publication on the carcinogenicity of glyphosate came out in March 2015, and something was done which was unique in plant protection product authorisation procedures. The Commission stopped the process and said: we will wait for this IARC monograph. We waited and when it was published an addendum was created by the BfR, in which we analysed the data and then evaluated them accordingly. In September 2015, expert meetings were then held with the relevant observers. The IARC and the American authorities were also present, the WHO. And in 2017, the RAC opinion was given, i.e. the hazard assessment of the ECHA, which, incidentally also concluded that not only did the risk assessment of glyphosate show that it was not a carcinogen, but the hazard assessment also showed that glyphosate is not cancer causing.

It will not surprise you, and most of you know this, that the question for humans probably relates to a monograph of IARC, which is not shared by – you could say – all risk assessment authorities and approval authorities worldwide.

There are various reasons for this. We may also be able to discuss this later. But there is no agreement in this case. We believe that we worked correctly. You can also read this in our 4 500 page report at any time.

I would maybe like to mention one aspect, since it is often said: Yes, we need to do more studies on glyphosate. Glyphosate is easily the best researched plant protection product active substance in the world. If you see how many studies have been conducted on it. Please look at the right-hand side. These are the studies to be conducted in accordance with European regulations that the Parliament has given us – we are entirely in your hands. That would cost 4 455 animals in the end. If you go to the left, you will see the number of animals that have actually been used to date – and these are only the studies, those that have been used in GLP and OECD studies, and not, for example, those also used in other toxicity studies or subchronic studies, not to mention studies from universities or the like. You can see that it is almost a scandal in itself that people still say: we need another study. If you look at it, the number being used for argument at the moment, it is already clear that the data situation is as good as you will find almost anywhere.

What data are there? Our risk assessment report – this is the four and a half thousand pages – I hope that you have read it all. It has taken a lot of work to complete. As it is always said that we copied it from someone, I have taken the liberty of separating out the page about which it was said that these are the ones that were lacking. In the end, the risk assessment is on the left-hand side, while the studies or the literature overview for the non-guideline studies are on the right-hand side. These are the studies that we request from the applicants, and that is also laid down by law. The purpose is to summarise the publicly published literature. This means that the applicant must submit this literature, and in addition the rapporteur must check if there are other studies that have been published. This is also important to know, because sometimes the studies that come from applicants are not complete, or the questions are formulated differently, or the studies do not relate to the active substance, but to plant protection products that have completely different effects. In addition, there are also guideline compliance studies. These are the studies that are requested from a regulatory point of view. The toxicological endpoints have been in discussion for about 40 years, that includes the defined toxicological endpoints. Here the legislator requires that it is published in accordance with OECD guidelines and under GLP conditions, as amongst other things, there are no publications in the scientific world for new active substances, only these studies that are requested of the applicant. That means that the quality that is required roughly corresponds to the harmonised standard of all assessment authorities worldwide and among other things, includes toxicology, residues and also corresponding analytic methods. This is the routine from which most data come. And these studies are also essential, as it is the raw data that are later consulted and not a summary, as is commonly seen in publications. These raw data are the foundation of the risk assessment. This also means that if you view the whole literature, this part of the literature is of great importance. With glyphosate, it must be stated that there has never been, I believe, an active substance for which so many new publications were added on approval renewal. We are now at about 1 000 publications, which all have to be viewed and evaluated. So that means that these studies are viewed and checked for correctness and plausibility. And those that seem relevant or are also relevant in a meta-analysis and fulfil the criteria accordingly, are then included for the evaluation.

The important thing is to point out that at this point no risk assessment has yet taken place, but the aim is only to estimate whether the party making the application has expressed the correct state-of-the-art in science and technology. Therefore, this has nothing to do with plagiarism or anything, but is rather just a question of whether the status of the literature has been correctly reported. The actual risk assessment is based on the original data and studies that the respective applicant must present.

Maarten Trybou: Plant Protection Products and Fertilisers service, Belgium

Head of the Pesticides Unit

EU authorisation procedure for pesticides - Authorisation of plant protection products by Member States

Thursday, 28 June 2018, 14.00 - 17.30, European Parliament, Brussels

Good morning, and welcome. I shall try in 10 minutes to explain the authorisation procedure in Belgium. First of all, I must explain the complex political situation in Belgium. We have a federal state, but in addition to that, we have three regions: the Flemish Region, Wallonia and the Brussels Capital Region. We also have four communities that are determined by the language spoken there, i.e. a Dutch-speaking, a French-speaking, a German-speaking and a Dutch-and-French-speaking Community. So you have the federal state that is split up into, shall we say, two large regions, with the Brussels Capital Region in the middle. Next to that, there is also a question of language use, which means that the communities do not have exactly the same borders as the regions.

When it comes to plant protection products, powers are divided between the various authorities. At federal level, we are responsible for placing products on the market: placing products on the market is therefore our competence. We also represent Belgium at European level in all cases. We are responsible for worker protection and for food safety. The regions in turn are competent with regard to everything that pertains to agriculture, environment, waste and in this case specifically, for the use of both plant protection products and alternatives to plant protection products. They are therefore entirely competent in terms of use. The communities for their part are competent with regard to education and in the field of public health.

How are we organised at federal level? On the one hand, we have the federal ministry of Public Health, Food Chain Safety and Environment. The federal public service or FPS has a DG for Animals, Plants and Food, which also includes the Plant Protection Products and Fertilisers service, and to which I belong. We are responsible for the assessment of products. We evaluate requests that we receive for plant protection products, maximum residue levels and active substances.
We are organised around a national authorisation Committee, the 'Erkenningscomité', where advice is given to the competent minister. In the national authorisation Committee, all advice is gathered and a final decision is proposed to the competent minister who will then grant authorisation. We therefore not only evaluate applications, but also deliver authorisations. We also determine the position that Belgium will take when voting on active substances in the European Commission's standing Committee on food safety, both for voting on the authorisation or non-authorisation of active substances and for determining maximum residue levels.

In addition, we draw up a national action plan as stipulated in the Directive on sustainable use of plant protection products. We are responsible for the federal part and for the overall coordination at national level together with the regions, for which we will eventually draw up one national action plan. Finally, we also issue certificates for the use and sale of plant protection products, again as stipulated in the Directive on sustainable use, according to which a certificate of competence is mandatory for anyone who uses and sells plant protection products for professional purposes.

Other sections of the federal government also have certain powers. The DG Environment of the same FPS Public Health has an inspection service, which is in charge of controlling everything that falls outside of the food chain, and that is used for and by the general public, e.g. in horticulture. Any usage that does not concern the food chain is therefore controlled by this inspection service.

There is also another inspection service, a parastatal entity of our FPS Public Health, namely the Federal Food Safety Agency or Food Agency. It consists of a number of directorates-general that together are responsible for all use, storage and conservation of plant protection products. These DGs carry out most of the controls, since plant protection products are of course mostly found in the food chain and are therefore controlled by these entities. They only check requirements, conditions of use, labelling conditions, etc. that are imposed at federal level for the authorisation of plant protection products. For this, they establish a monitoring programme each year, to analyse plant protection products on the market, as well as plant production residues. They serve as the Member State contact point for everything that pertains to the control of plant protection products. They also have their own separate Committee's that do audits, a scientific Committee as well as an advisory commission where specific scientific questions can be asked. But again, only with regard to control and inspection. Finally, they are also in charge of certification for sprayers. In conjunction with the regions, the arrangement is that all sprayers must be

checked and verified every three years in accordance with a number of legally specified parameters.

Besides these federal bodies, a number of scientific bodies have also been set up at federal level. Sciensano is for instance a scientific institution that investigates everything pertaining to plant protection products, but also agriculture and food safety. There is also the Superior Health Council, which answers specific scientific questions regarding public health. You will see here a schematic diagram which is also mentioned in the last report to the former FVO or Food and Veterinary Office, which is now the Directorate F of the European Commission. It is a schematic representation of how we are organised at federal level.

As I said, there are also competent bodies at regional level. These are organised into regional ministries of the Environment and of Agriculture, where they can impose general measures to protect the environment and to promote agriculture. They are also competent to monitor the legislative provisions that they have laid down. Whereas the federal authorities have the power to impose product-specific conditions, i.e. very specifically for one authorisation and one product at a time, regions may also impose general measures that in principle apply to the overall use of plant protection products. Consequently, they are also responsible for everything regarding integrated pest management, as this includes plant protection products. They, therefore, also monitor cross-compliance within the scope of subsidy schemes for agriculture and follow up to check if these conditions are being met.

In addition, they establish a national action plan for plant protection products as specified in the Directive on sustainable usage. Finally, they are also represented in our national authorisation panel that grants authorisations for plant protection products. This is a structure that we set up to include regional powers in the granting of authorisations for plant protection products. We therefore decide together–at federal and at regional level–on the conditions under which plant protection products may be released on the market.

I shall look in somewhat more detail at the federal authorisation procedure for plant protection products. These are the different types of applications that we receive. There are applications for the products, the plant protection products themselves, for placing them on the market. We also receive applications for the evaluation of active substances, for maximum residue levels. We take care of the evaluation and authorisation of plant protection products for which we have set up a national authorisation procedure.

Here you will see in more detail the different types of applications that we receive. We deal with zonal authorisations, or rather, not zonal authorisations, but zonal evaluations. An evaluation is carried out by a rapporteur at zonal level, which is then taken up by other Member States of one of the three zones in Europe. In addition, we may of course also receive interzonal applications that apply to all of Europe, for all three zones simultaneously. These will pertain to the use of plant protection products under cover or under protected conditions, without exposure to the environment. The understanding here is that only one investigation is necessary, as the environment and typical agricultural conditions of the various Member States have very little impact on the risk assessment in such cases.

We also do the renewal for all these authorisations. Applications for the expansion of application methods are handled, and many different types of applications, e.g. to change the composition, labelling, application method, the active substance that is used, restrictions on use, etc.

We also have parallel importation certificates. Parallel trade was legally established through European legislation. For this, separate applications must be submitted that are also processed by our service. There are also test products. We give authorisations for the use and importation of these. In total, we receive and investigate about 1 000 applications each year.

For active substances, there are applications for entirely new active substances, where we may act as rapporteur or co-rapporteur. Approvals for active substances have to be renewed, and there too, we may act as rapporteur or co-rapporteur. We participate in the peer review set up at European level: based on the draft assessment reports of the RMS, a consultation is organised between peers at European level where they will comment together on the evaluation by the rapporteur. We also comment on the draft assessment reports of other Member States. All of this is meant to ensure a harmonised evaluation, and also to achieve greater acceptance of the evaluation that is done by the rapporteurs. We therefore try to comment together with all Member States and to ensure that everyone sets up their evaluations in the same way.

At national level, we also evaluate the technical equivalence of active substances. This implies that we will check whether other manufacturers than those who submitted the application at European level are equally able to produce a similar active substance. It must be equivalent both in terms of impurities and of the method, so that the risk assessment that has been done, could also be applied to it.

Sometimes restrictions are imposed on active substances at European level. These may also be adjusted, if a specific application is received from the notifier. As a RMS, we will also handle this type of application. In the past, a great deal of confirmatory data also used to be required for the approval of active substances. This is a neat way to push authorisations through even if certain data are missing. These data must of course be investigated afterwards. This would in turn require a European procedure in order to get a clear assessment. Sometimes we also act as rapporteur for these. Finally, what is referred to as adverse data can also be submitted. These are new data that point to a risk or problem. Manufacturers are obliged to submit such data if they are aware of them, and these must then be investigated.

We also investigate maximum residue levels, i.e. new levels or revisions or extensions for minor crops. I shall explain the authorisation procedure to you in short. Applications are received by managers. These are then investigated by

evaluators and submitted to our authorisation panel following a full assessment by our experts. The panel provides an opinion which our service will communicate to the applicants. For this, we have three teams of evaluators that are mobilised both for plant protection products and for active substances, for the purposes of human toxicology and residues, ecotoxicology and behaviour in the environment, and physicochemical characteristics and action. This facilitates exchange and allows a more flexible use of evaluations. There are also two application manager teams that lead applications in the right direction, both for authorisations and authorisation renewals, and for the extension of existing authorisations.

Chris Parker: Australian Pesticides and Veterinary Medicines Authority

Managing Director

Public Hearing on EU authorisation of pesticides - Comparative Analysis of Authorisation Procedures in OECD Countries

Thursday 30 August 2018, 14.00 – 17.30, European Parliament, Brussels

In Australia, agricultural and veterinary (agvet) chemicals are regulated under a cooperative statutory scheme. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent statutory authority responsible for assessing and registering pesticides and veterinary medicines proposed for supply in Australia. Our regulatory responsibility extends from registration and manufacturing through to the point of sale. Compliance and monitoring powers in our legislation provide a mechanism for the APVMA to undertake post-market surveillance and testing to ensure the continued safety and effectiveness of registered products.

The Australian Government works in partnership with state and territory governments to assess and manage risk, from those important first steps of product commercialisation right through to how agvet chemicals are stored and used. State and territory governments are responsible for regulating and monitoring how chemicals are used. Together we support Australia's AUD 59 billion agricultural industries with safe and effective agvet chemicals that underpin farm-gate productivity by security management, environmental sustainability and animal health and welfare.We have a risk-based and scientific approach. The products we regulate are, in many cases, intrinsically hazardous. Pesticides, herbicides, fungicides and parasiticides: these are all designed to protect the environment, animals and agricultural crops from pests and diseases. The APVMA regulates agvet chemical products using a structured process combining scientific methodology, legislation and risk assessment to ensure the products are safe to use and they do not adversely affect trade.

We use regulatory science methods to understand the risk profile of agvet chemical products and to determine the likelihood of harm occurring – to people, animals, the environment and the agricultural industry – from the use of these agvet products. This assessment considers both the toxicity, otherwise referred to as the hazard, and the extent of the exposure of the product. Risk management measures are proposed to mitigate the risk of harm occurring. If management measures can be applied and the agvet product used safely the product will be approved for the use according to the label directions.

Many actives and products we register have the potential for harm but a harm that can be minimised and brought within safe levels when the appropriate risk mitigation measures are put in place.

Australia has a contemporary and responsive regulatory framework and we recognise the value in continuous improvement. Industries develop and grow, our environment and climate changes and within the context of a global digital economy we seek to reform our regulatory framework. We do this in partnership with government, industry, stakeholders, and to reform the legislation and build regulatory agility, while maintaining the appropriate protections for human health, animals and the environment.

Agricultural and veterinary chemicals in Australia play an important part in our economy. Besides supporting the AUD 59 billion worth of agricultural production, the direct sales of agriculture and crop protection products topped 3.2 billion in Australia in 2016. It is an industry that employs over 1 700 people directly in the manufacturing processes and another 7 500 indirectly through the input supply for crop protection products. While Australia's veterinary medicines sector is smaller in scale, it is a significant contributor and it has grown to exceed AUD 1 billion worth of value.

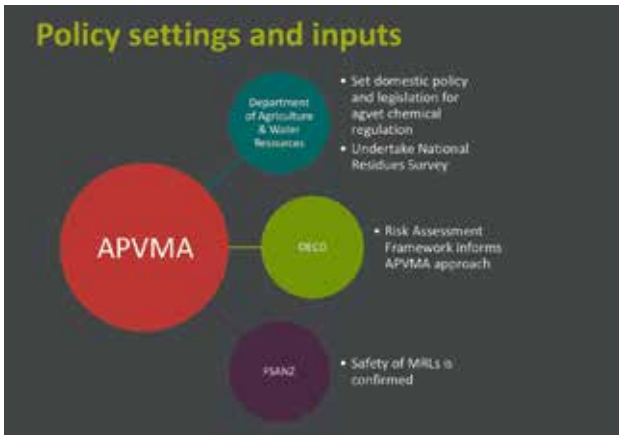
There is strong demand in Australia for new crop protection and animal medicines and it is important that the APVMA delivers a regulatory service that is responsive and can support safe innovation in our agricultural sector. The opportunity that Australia shares with other nations is to work collaboratively, to share the load on assessing risk and in doing so unlock productivity gains in regulation and support productive agricultural industries.

Our participation in joint global reviews has yielded benefits for Australia, and for our regulatory counterparts, and I recognise the contribution of APVMA scientists and those from Canada and New Zealand who conducted the first ever trilateral joint review of veterinary medicine in 2016.

We are also encouraging the use of international assessments and data in the applications submitted in Australia. In the 2017/18 financial year, the APVMA used international data assessments from other regulators to inform the decisions on 28 product applications and 19 applications for minor use permits. We hope to build on this work and with ICT improvements in our own systems and a proactive approach encourage applicants to submit international data and assessments for their Australian registrations.

Through continual engagement and dialogue at international fora, such as the OECD, we seek to share the Australian regulation context and discover further opportunities for international harmonisation. Biosecurity pests and diseases do not discriminate. They cross borders, causing damage to animal health, impacting agricultural productivity and trade. While Australia is fortunate to be free of many plant pests and diseases, we share the goal of protecting humans, animals, industry and the environment from harm.

Regional environmental differences will continue to influence our individual regulatory decisions, yet through enhanced harmonisation and international cooperation, our robust regulatory decisions informed by science and evidence, and based on risk, can support global outcomes.



Written Overview:

Australia notes that the European Union takes a hazard-based regulatory approach to assessing pesticides (agricultural chemicals). This means that agricultural chemicals are assessed primarily on the intrinsic potential for harm (hazard), rather than the likelihood that harm may arise from the approved use and safety precautions for the agricultural chemical (risk).

It is correct that agricultural chemicals, like industrial and other chemicals, may be hazardous and have the potential to cause harm. Australia's regulatory system therefore has regard to the potential risk posed by agricultural chemicals and adopts a risk and science-based approach to use.

Australia's system for regulating agricultural chemicals is a shared responsibility between the Australian and state and territory governments. The APVMA is the independent Australian Government agency that regulates agricultural chemicals up to and including the point of supply. State and territory governments have regulatory responsibility after products are supplied for use. This includes the storage, use and possession of agricultural chemicals.

The APVMA is responsible for registering agricultural chemicals before they can be supplied in Australia. The legislated process for registering agricultural chemicals, as set out in the Agricultural and Veterinary Chemicals Code Act 1994 which specifies that the APVMA can only register an agricultural chemical if it is 'satisfied' that an agricultural chemical is safe, effective, will not unduly prejudice Australia's trade of commodities and the label for the product contains adequate information to ensure its safe and effective use. The APVMA uses the latest scientific developments, alerts from overseas regulators, or any other relevant information, including health and environmental information, when assessing an agricultural chemical for registration.

Australia acknowledges the risks posed by the misuse of agricultural chemicals to human health and the environment. Legislation regulating the supply of agricultural chemicals recognises that the health and safety of human beings, animals and the environment is the first priority of the system for regulating chemical products and their constituent components. The legislation must also be implemented in a manner that promotes community confidence in the regulation of chemical products and their constituent components. Assessment processes are open and accountable, and provide opportunities for public involvement and participation. This provides the context in which chemicals can be used safely, to enhance the productivity of our agricultural sector, and protect our communities from pests and diseases.

Richard Aucoin: Canadian Pest Management Regulatory Agency

Executive Director

Public Hearing on EU authorisation of pesticides - Comparative Analysis of Authorisation Procedures in OECD Countries

Thursday 30 August 2018, 14.00 – 17.30, European Parliament, Brussels

Thank you very much, Chair, for the opportunity to speak with you today about how pesticides are regulated in Canada.

I am head of the Pest Management Regulatory Agency (PMRA), which is a branch of Health Canada. This is the federal department of health. Our primary mandate is to protect human health and the environment and our approach to pesticide regulation is built on this mandate.

The Pest Control Products Act is the federal legislation that governs how pesticides are regulated in Canada and only pesticides that are authorised under this legislation can be manufactured, imported, sold or used in Canada. Additionally, Canada's provinces and territories administer complementary regulatory systems designed to protect people and the environment. Constitutionally the provinces may add more restrictive conditions on the use of pesticides, but cannot allow less restrictive conditions.

Before a pesticide can be authorised for use in Canada the health and environmental risks must be shown to be acceptable, and as with most OECD countries, the registrants are required to provide an extensive battery of scientific studies that characterise the nature and extent of health and environmental risks posed by the product. These studies are required for the technical grade active ingredient and a specific data set is required on the end-use products as well, which are all assessed at the federal level by PMRA.

The studies must follow internationally accepted protocols, such as the OECD protocols, and are reviewed by PMRA's scientific evaluators. Based on an assessment of the toxicity and an assessment of the potential exposure that people or the environment may have, we determine whether the product can be used without posing unacceptable risks – health or environmental risks. PMRA also establishes in law maximum residue limits that represent the amount of pesticide residues that may remain on food crops.

Once a pesticide is granted approval in Canada it becomes subject to a series of post-market risk management controls under the legislation. This includes statutory, cyclical, re-evaluations and special reviews of all registered pesticides, and includes compliance and enforcement activities, and includes regulatory actions where needed if, for example, health or environmental incidents or adverse effects are noted.

The pesticide label itself is a legal document that details the conditions of use that allow the risks to be managed. As with any potentially hazardous product, the regulations or the label directions themselves do not guarantee compliance and as a result, PMRA seeks to minimise any incidents of non-compliance by imposing very clear label directions and restrictions and by implementing compliance programmes that involve monitoring and enforcement across Canada.

PMRA also monitors areas of developing science related to the safety of pesticides through the public scientific literature, by networking with other OECD regulators, working closely with EU Member States and institutions such as EFSA, and through participation in international fora, for example the OECD and Codex, to update and harmonise accepted protocols for the testing of pesticides and biocides.

New science and information are taken into account during our re-evaluations, which are initiated on each existing active substance, and products, every 15 years. Special reviews are another mechanism under the Pest Control Products Act to determine the continuing acceptability of registered pesticides. These special reviews may focus on addressing specific aspects of concern, such as the concerns raised by another OECD member country's decision to prohibit all uses of an active ingredient.

Our legislation requires that the registrants report all unexpected or unintended effects related to their products to PMRA. These incident reports help us identify any potential risks to health or the environment from the use of pesticides and to take corrective actions if and when necessary.

I would also like to point out that all our major decisions under our legislation are preceded by a full public consultation process, including publication of our risk assessments and our risk management proposals, and before any final decision is made we take into account all the comments and information that we have received, and in our decision we publish the nature of that information received and how it was taken into account in the final decision.

All the test data that is provided to us as part of an authorisation can be inspected, upon request, after a decision is made.

All of our work is being carried out in the context of increasing global alignment and cooperation. Canada's regulatory model, we believe, has allowed us to form strong partnerships, including with countries such as the US and Australia, and EU Member States and institutions such as EFSA, to play a major role in developing collaborative approaches to joint pesticide reviews – and we have had considerable experience doing global scientific reviews with many different partners around the world – and to promote international regulatory alignment. This not only benefits health and environmental protection but, I believe, increases public confidence, which is hugely important.

Chair, this concludes my presentation and I am certainly pleased to answer any questions that you or the Committee have.

Jean-Philippe Azoulay: European Crop Protection Association

Director General

Hearing on EU authorisation procedure for pesticides - Application for approval of active substances and Draft assessment reports

Tuesday 15 May 2018, 15.00 – 18.30, European Parliament, Brussels

I would like to start by thanking you, on behalf of our industry, for the invitation to come and take part in this hearing today. The issue of pesticides and how they are approved in Europe is of utmost importance for now and the future. We understand and are listening to the concerns that exist, and we want to play our role in helping to find solutions. For those of you unfamiliar with the European Crop Protection Association (ECPA), we represent 23 member companies, which go from large multinational companies to much smaller, regional SMEs, and which are all involved in the development and commercialization of crop protection solutions.

Before introducing myself, I would like to introduce my colleague Emma Jenkins who joins me today as a regulatory expert from one of our member companies. Emma has 23 years of experience of the crop protection sector, and is here as acknowledgement of the complexity of the EU approval system, and to be sure we can answer to the best of our ability any detailed questions you have about the system and our industry's role in it.

And of course I should then introduce myself: My name is Jean-Philippe Azoulay. I am the director general of the European crop protection association, a role I have held since September 2016. My background is in industry, where I have worked for 30 years, with experience in four different industrial sectors. 15 of these years have been spent in the Crop Protection industry in various positions, including four years as General Manager for a region covering Europe Middle-East and Africa for one of the research company members of ECPA. In that time I have been privileged to see and experience first-hand the realities of agriculture. I have been on small farms in Zambia and Kenya; in the greenhouses of Almeria in Spain; the vineyards of Burgundy and the cereal fields of Denmark and Russia. I have seen the challenges facing farmers.

I know this industry well. I have seen the many exciting developments it has brought forward, and the things it has made possible. I have worked with many great people. From the leadership of these organisations to the scientists working to discover new substances – people who are leaders in their fields - all people who are incredibly committed and incredibly passionate about supporting global agriculture. In Europe alone, 27 000 people work for our industry. For someone who does know the industry so well it is often difficult to reconcile the internal impression of our industry with the external reputation. I can see very clearly the significant challenges we face in terms of reputation and image with the public, and also with many of the members of this Committee. I really want to change that.

Collectively as industry, we have been slow to acknowledge the concerns expressed by Society, and as a consequence, we have been slow to respond to these concerns. Historically we have put a lot of effort and resource in to our operations, stewardship, Research & Development – where we invest over 6 billion Euros a year - or manufacturing. We have put nowhere near enough effort in to explaining what we do, why we do it, and the fundamentally positive reason that pesticides exist. We have taken for granted that our products are useful to produce safe, affordable, sustainable food, and we have spent more time complaining about the negative aspects of the EU authorisation system than communicating on its positives. That's not to say we don't still complain about the EU authorisation system. It is inefficient and unpredictable – two things that make it very difficult for businesses to operate and to invest for the future. Whether that system meets its stated objectives is one thing that we will leave to be judged by this Committee; but one thing I think is very clear, aside from the specifics of the system, is that the biggest challenge that exists is the perceived lack of trust in that system. A lack of trust is to the benefit of no one. We all have an important role to play in addressing that, but we recognise there is no silver bullet.

This is why we are so pleased to be able to be represented here today: Even if we are only users of the regulatory system, and even if we often complain about its shortfalls, or maybe in fact because of it, we hope that through our written questions and through our answers today, we can reassure you about our role as the crop protection sector in that system.

It's worth recalling that food production in the form of agriculture was born roughly 12'000 years ago, around 10'000 BC. For 11'950 years, eating was about managing scarcity and food safety. In the last 70 years, particularly in

Europe, eating has been about diversity and quality. Food safety has become a given. A given that we have collectively failed to celebrate. One only has to read the annual EFSA report on residues, or the annual report on the EU Rapid Alert System for food and feed safety, to see what the key threats to our food system are. Pesticides is not one of them. Commissioner Andriukaitis for one, in speech after speech refers to the fact that Europe can be “proud to have the safest food in the world”. Yet one would be forgiven if you follow the public debate for having the impression that the reality was quite the opposite.

This is not to say that crop protection cannot be improved and that the system is perfect. We can and should always strive to do things better. Safer products, diverse food production models, can and should be developed and encouraged. We understand the expectations from Society to accelerate these changes, to reduce the impact of agriculture on the environment. We also understand the need to reassure users and the general public about the impact of our products on their health. And as industry, we are committed to continuing our efforts in that direction: ensuring the safety of our products is the main pre-occupation of our companies. Our industry invests billions each year developing ever safer ever better products for Europe’s farmers. One example of those continued efforts is the recent announcement of a global commitment to Transparency by our industry. Our member companies have unanimously pledged to facilitate the disclosure of safety-related data on a voluntary basis. This is an important sign that we want to be part of the discussion, and we are ready to play our role. There is always more that can be done – science evolves, societal expectations change - and we are ready to work across all parties and interests to ensure progress can be made.

Once again I wanted to thank you for the invitation to speak to you today. This is a complex issue. There is no zero sum. But it’s important that we are all part of that discussion from civil society groups to industry to decision makers. We must find common solutions to the problems which will affect our common destiny.

John Chinn: Centre for Crop Health and Protection

Chairman

A stakeholder's recommendations on the current EU regulation of the approval of plant protection products

Thursday 6th September 2018, 14.00 – 18.00, European Parliament, Brussels

Good afternoon
Ladies and Gentlemen.

My name is John Chinn and I am a partner in a family farm in the UK where we grow a range of horticultural and arable crops.

I am here this afternoon in my role as Chairman of the Centre for Crop Health and Protection, one of four Agri-tech Innovation Centres set up by UK Government. We seek to understand the problems associated with crop health and protection, and then engage with Research Scientists to find solutions. Appropriate and innovative use of Plant Protection Products is central to our work.

The world population of 7.6 billion people is forecast to increase to 10 billion by 2050. The great challenge of the 21st century is to produce more agricultural goods from the same area whilst protecting biodiversity.

25% of the European landscape is used for the production of permanent and arable crops, providing a livelihood for 12 million farmers and workers and helping to feed the EU population of 512 million people. We must eat, therefore we must farm.

The UN Food & Agriculture Organisation estimates that 'without crop protection tools farmers could lose as much as 80% of their harvests to damaging insects, weeds and plant diseases'.

Plant protection products combat both weeds and plant pests and diseases that compromise the cultivation of food and feed. Weeds may be poisonous to humans and animals, and pathogens such as Fusarium moulds are the cause of some of the most severe fungal diseases in European crops and produce toxic secondary metabolites called mycotoxins which very successfully survive the transition from field to fork and can cause chronic and sometimes fatal effects on animals and humans. The use of plant protection products to control injurious plant pests brings a direct benefit to human and animal health and will remain crucial in sustainable farming systems, however, advancements in:

- new more targeted chemistry
- the use of biological control agents
- targeted application technologies
- progress in plant breeding and genetics

can all combine to ensure the production of safe, healthy, nutritious, affordable food with ever better care for the environment.

To illustrate how scientific and technological developments promise a better tomorrow, I can give a few examples:

a. We are developing more targeted plant protection products which will have a much-reduced impact on non-target organisms and the wider environment. On my farm we used to use chlorpyrifos (an organo-phosphate) to control vine weevil larvae in our blueberries but it also killed earthworms – in many ways sterilising the soil. Now we avoid this ecological damage by introducing nematodes to the crop that specifically invade only the larvae of vine weevil, leatherjackets and slugs. A hugely successful development of a biological control agent with very targeted hosts, which helps to maintain a living, healthier soil. We are developing the ability to apply plant protection products only to our

target site – be that a weed or a diseased plant. By fitting cameras to our crop-sprayers we can identify, target and spray down to the level of individual weeds or diseased plants. This will decimate pesticide usage on farms bringing financial and environmental benefits.

b. The Centre for Crop Health and Protection has developed Crop Monitoring stations that automatically collect disease spores and DNA sequence them. This can save unnecessary use of plant protection products when there is no disease present, and inform us of the strain of any pathogen detected so that we can use the most suitable plant protection product to avoid resistance issues whilst minimising impact on the environment.

Since the agricultural revolution of the 18th century we have seen continual increases in the size and power of farm machinery. With this came increased cultivations and a resultant increase in crop yields. However, mixing air into soil oxidises the organic matter which we depend on to maintain fertility and support the microbiome. As a result, over the years we have witnessed increasing degradation of our soils and a plateauing of crop yields. Many progressive farmers are now literally replacing the plough with glyphosate. This no-till strategy prevents soil erosion, preserves biodiversity and reduces greenhouse gas emissions. It builds soil organic matter, enhances the soil biome and is an essential tool for sustainable agriculture. BUT the system is dependent on glyphosate!

This year, in the UK alone, thousands of hectares of newly planted oilseed rape are being ploughed up due to crop failure or are being sprayed with indiscriminate insecticides because of flea beetle damage following the ban on neonicotinoids. With thousands less hectares of oilseed rape now coming to harvest, there will be a huge reduction in the area of these early flowers available to bees. It is an open question whether any environmental damage from the use of neonicotinoids is greater than the environmental damage from banning their use.

The EU approval process for plant protection products is one of the most stringent in the world. It currently takes over eleven years, requires an average of 200 scientific studies and costs more than 250 million euros to bring a product to the EU market. Rigorous testing and application protocols are very effective in protecting the public and the environment, however little attention has been given to its other aim of effectively supporting productive and competitive agriculture and horticulture.

The fact that the regulation has just started its eighth year and, in that time, has only brought the equivalent of about one new active to the market per year, demonstrates that the approach is failing to deliver for growers. For a regulation committed to help innovation and support the industry, this is a categorical failure that is stifling the availability of safer, more effective and lower risk pesticides. This is particularly keenly felt in our smaller horticultural industry where the UK has access to even fewer actives that most countries in the EU.

If the current regulation is ever to deliver on its objective to safeguard European agricultural production and competitiveness, then an urgent and major re-think of the regulation is required.

Under the Precautionary Principle, the European Commission may ban the use of a plant protection product, if the risk associated with its use cannot be determined with sufficient certainty as identified by a scientific and objective evaluation. This requirement has been particularly challenging to prove and so the Centre for Crop Health and Protection has built an e-flows mesocosm at the National Agri-Food Innovation Campus, near York in the UK. The mesocosm is an outdoor experimental system that examines the natural environment under controlled conditions. In this way mesocosm studies provide a link between field surveys and highly controlled laboratory experiments. The mesocosm includes controlled watercourses and other features to record impact on field edges. This is exactly the sort of development that our industry needs to take, and is taking, to generate public confidence around the use of plant protection products.

The collection of even the very best data about pesticides (on exposures, effects, distributions or persistence) will never answer the concerns that some people have about their use, and non-rational myths do force social and political changes. Scepticism about received truths has long been a common attitude in opinion formers. EU regulators need to rise above this.

With the arrival of Artificial Intelligence and automation, farming is on the brink of a technological revolution that will greatly reduce our use of plant protection products, but as we work towards a better tomorrow, we need the regulators to speed the approval of new more targeted chemistry. Legislation needs to balance the impact on improving crop productivity against a science-based risk-assessment - rather than just hazard awareness. Consider household bleach, a highly toxic and hazardous product, yet on an appraisal of the benefits from germ control and the ability to wear rubber gloves when handling the product, it is approved and can be found in most households. Can we draw comparisons to the approval process for plant protection products?

There is no ‘holy grail’ answer to healthy food production. Within the EU our food is all nutritious and safe, but some production systems won’t be affordable for everyone and not being able to afford food will affect peoples’ health and longevity.

Thank you.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