

PEST COMMITTEE MEETING OF 6 September 2018

**EU AUTHORISATION PROCEDURE FOR PESTICIDES -
AUTHORISATION OF PLANT PROTECTION PRODUCTS
BY MEMBER STATES**

PREPARATORY QUESTIONS

In the context of the PEST Committee meeting of 6 September 2018, a public hearing on “*Environmental impacts of pesticides, including mitigation measures at Member State level*” and “*Stakeholders' recommendations on the current EU regulation on the approval of plant protection products*” with altogether six invited experts will take place.

To prepare for this public hearing, political groups have submitted the following questions. These questions, which address many of the topics at stake, should be answered by the experts invited in writing by 4 September 2018, 12.00 h.

Questions to ALL experts of the 1st panel (Environmental impact & mitigation):

1. What are, in your view, the most likely risks to public health and the environment caused by glyphosate-based herbicides?
2. Are public health and environmental risks adequately assessed at EU level at the moment? If not, what should change? In particular, do you see any problems with the assessment criteria as laid down in the EU legal framework and agency risk assessment guidance documents (of EFSA for example)? Or, are the problems due to the application of those criteria by the scientific agencies?
3. According to several scientific sources (see for example the following [link](#)¹), current criteria for assessing pesticides in the EU authorization are inadequate, because they do not consider the cumulative effects of the use of different pesticides on human health and the environment. How could the current criteria of risk assessment be improved to take better account of the real world effects of pesticide use?
4. Based on your research, what are best practices for mitigating environmental risk of plant protection products?
5. What are important factors for successful mitigation strategies?
6. Birds: Research has shown great impact of PPP on birds, especially migratory birds. Beyond birds, what is the impact of the loss of biodiversity on their prey, predators and others?
7. Bees: We have evidences that LD50 used in assessment is not accurate for bees. Other methods could be used, for instance by quantifying the apparent exposure surface area of honey bees submitted to pesticide treatments by spraying. Moreover, we know now that PPP can also have reprotoxic effects on bees, especially by undermining male fertility.

¹ Schäffer A, Filser J, Frische T, Gessner M, Köck W, Kratz W, Liess M, Nuppenau, E-A, Roß-Nickoll M, Schäfer R, Scheringer M.: [The Silent Spring - On the need for sustainable plant protection](#). Leopoldina Discussions No. 16; 61

8. What improvements could be decided in PPP and active substances assessments regarding effects on bees?
9. Waters: it is now well known that waters are polluted by PPP, among others products. Since decades can be necessary to see the results of pollution on spring waters, what are the expectations for EU waters regarding PPP?
10. Do we have examples of mitigations measures decided by MS and finally implemented at EU level?
11. Neonics: When the EU banned neonicotinoids in April, some scientists feared that there would be a switch to pesticides that would have even more harmful effects on microorganisms such as beetles and spiders. How can such effects be prevented in the approval process? The main example is the active substance sulfoxaflor (that will be banned in France for example), can the active substance sulfoxaflor safely replace neonicotinoids?
12. Seeds: It was also feared that there might be a change from rapeseed to soya, for example, which could have negative effects on pollinator insects. Did you gain experience on this matter in your field of research?
13. Concretely, which consequences do pesticides have on flora and fauna? How do pesticides lead to these consequences?
14. Is it possible to get a PPP in accordance with the sustainable development, that is to say a non-polluting PPP with no impact on environment?
15. Can society both live with no pesticides and guarantee the growing food needs? Which other options are there or will there be in a near future?
16. How is your scientific independence guaranteed in your scientific work, given that many conflicts of interest exist in the question of pesticides?
17. Do you consider that the residues of the active substance, its metabolites, a safener, synergist and the co-formulant contained in it, are studied and assessed sufficiently on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment in order to guarantee one of the purposes of the Regulation 1107/2009, which is the protection of both human and animal health and the environment? Do you see the results reflected in the authorisation assessment at MS level?
18. The Implementation Assessment commissioned by the European Parliament (2018) revealed that "Several stakeholders (PPP producers and PPP users) stated that exposure is not sufficiently considered in the current framework" (p.164/588). Do you consider that the risk mitigation measures, take enough into consideration the non-dietary intake and the exposure of non-target organisms?

Questions to Mr Jeroen P. VAN DER SLUIJS / University of Bergen (Norway):

19. Your "*research seeks to increase our understanding of the phenomenon and dynamics of scientific controversy on contemporary old, new and emerging environmental and health risks*" (see [link](#)).

In what way could the risk communication be improved to avoid diverging reports?

20. How do you respond to claims that the IUCN Task Force on Systemic Pesticides, for which you were head of the scientific committee, had predetermined its conclusions on neonicotinoid pesticides to support an advocacy campaign before even starting its work

on its Worldwide Integrated Assessment (WIA)²? Do you consider the work of the Task Force on Systemic Pesticides to be consistent with the principles of academic scientific integrity?

21. In 2010 you took part in an “*international workshop on neonicotinoids*” at the Université de Paris-Sud, the “*resumé*” of this meeting can be found publicly on the internet. In this resumé it was agreed to publish research papers with the aim of calling for a ban on neonicotinoids and of launching an NGO-campaign against those substances. The separation of (scientific) risk assessment and (political) risk management in Regulation 1107/2009 is internationally recognised. In this regard, could you share your opinion on the role of science in assessing and managing risks of pesticides?
22. What is your view on the importance or consideration that the Commission gives to environmental aspects/risks when deciding whether or not to approve an active substance? In your opinion, is their approach in line with legislative requirements, such as Article 4 of Regulation 1107/2009? Is it sufficient to protect the environment? Please give examples to back up your answer.
23. In relation to the evaluation of the inspection unit of SANTE, according to the Commission's report to the Ombudsman in 2018 following the complaint 12/2013/MDC (<https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/press-releases/report-sante-on-confirmatory-data.pdf>, see page 12)

"In 2015, the Commission undertook a survey of all Member States on the authorisation of PPPs. The responses to the survey showed that the majority of the Member States did not comply with the legal requirements laid down in the Regulation (EC) No 1107/2009 regarding deadlines for the authorisations of PPPs.

In 2016 and 2017, audits on the authorisation of PPPs were conducted in 7 Member States: Germany, the United Kingdom, Luxembourg, Portugal, France, Lithuania, and Spain. Audit reports can be found on the Commission website. The audits confirmed that the national re-evaluations of PPPs on the market, which must take account of the EU approval Regulations and their related conditions, are significantly delayed. In three Member States there were significant numbers of PPPs still authorised which had not been evaluated in accordance with EU agreed uniform principles^{19,20}. In these Member States the percentage of authorised PPPs that had not been evaluated in accordance with the uniform principles ranged from 9% to 33%."

What is your evaluation on how this situation may affect the environment?

24. One of the purposes of Regulation 1107/2009 is “*to ensure a high level of protection of both human and animal health and the environment... The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.*” (recital 8, addressed in article 4)
25. Based on your work and research, do you consider that this aim of the regulation is fulfilled, and therefore the authorisation and use of pesticides in the EU do not cause any harmful effects on animals or any unacceptable effects on the environment? In your opinion, do you consider that the current authorisation and use of pesticides allows a high level of protection of the environment and its ecosystems?

² <https://risk-monger.com/2017/01/15/beegate-revisited-iucns-anti-neonic-pesticide-taskforce-an-expose-into-activist-science/>

26. On Residues: According to Regulation 1107/2009, pesticide residues, or mixtures of pesticide residues should have no harmful effects on humans and animals and no unacceptable effects on the environment and each active substance (or its metabolites) has to fulfil the following conditions (Annex II, 3.7 and 3.8): it should not be considered a POP, a Persistent Bioaccumulative and Toxic (PBT), very persistent, very biocumulative, an endocrine disruptor to non-target organisms, to have unacceptable acute or chronic effects on bees or to have unacceptable impacts following ecotoxicity testing among others.

In your opinion do you consider that the current system ensures that all the above criteria are fulfilled? Do you know of any cases where these criteria are not fulfilled?

27. A recent study found a 75% decline of insect biomass in proximity to agricultural sites (Hallmann et al, 2017), another found that more than 400 million of birds have disappeared in Europe (Inger et al. 2014), whereas an average of 33% of all birds have disappeared in France (French National Museum of Natural History, CNRS, 2017). All these studies attributed the observed decline in populations of species, at least in part, to intensive agriculture and the use of pesticides. In your perspective, what is the significance of these observations in relation to biodiversity and ecosystem services? Do you consider these changes alarming? And if yes, what political action would you propose as necessary?

28. A meta-analysis study in 2014 (Malaj et al. 2014) studied more than 2000 European freshwater sites and found that in 42% of the sites, aquatic ecosystems (using as reference invertebrate, fish and algae) were under chronic chemical risk, and pesticides were the major contributors. Is it true that the use of pesticides in agricultural areas are putting our freshwater ecosystems at risk? What are the long term consequences of such impacts?

29. What recommendations do you have on how to improve the current functioning or design of the EU pesticides approval process in order to ensure the highest possible level of protection of the environment and health as well as a high level of public trust in the process? Please feel free to also include areas which may not have already been covered in PEST hearings to date.

30. You promote a worldwide-integrated assessment of pesticides. Such an approach is interesting, because it is essential to have a systemic way of looking. Scientifically speaking, all data and parameters have to be considered to measure correctly the impact of a phenomenon. Moreover, the systemic approach shows that this is the entire planet, as a whole, which is concerned. The problem goes beyond the borders. However, the political aspect is necessarily a part of this problem. What do you think about principles such as subsidiarity or westphalian sovereignty? Which political framework do you suggest to aim a worldwide-integrated assessment of pesticides?

Questions to Ms Noa SIMÓN-DELSO / Belgian Bee Keeping Center for Research and Information (CARI):

31. Your focus is on soil: Could you please elaborate and explain the different impacts of mechanic plant protection and non-mechanic (chemical and organic) on biodiversity especially with regards to worms. (ploughing vs herbicides)?

32. How do you see the development with precision farming tools? Will there be an effect on soils?

33. What do you think is the impact of having more than 90% of beekeepers in Europe being amateurs in terms of pathogens and viruses control? Do you see a possible impact on wild pollinators' populations?
34. The Commission's own survey of EU Bee Keepers and Member State Reference Laboratories indicated that factors of most concern with regards to honeybee health were Diseases, Varroa, Viruses and Nosema with pesticides relatively of much lower concern. So why has your research continued to focus on the role of pesticides rather than these other factors?
35. Scientific studies conducted by industry for pesticide registration must comply with the OECD Principles of Good Laboratory Practice (GLP) as well as International Test Guidelines to ensure the data is reliable, reproducible, and that the study methodology is robust and fit for purpose. Can you explain the quality controls for academic studies used to achieve the same outcome? For example, what safeguards are in place to ensure that there is no contamination of pollen and nectar samples during the collection and analysis process for neonicotinoids?
36. As part of your campaign for a full ban on neonicotinoids³, did you conduct an evaluation as to whether the replacements for neonicotinoids would provide improved safety for bee health?
37. In your view, is the current risk assessment performant enough to protect pollinators? And what about the rest of the entomofauna?
38. In your view, is there a possible positive coexistence between agriculture and pollinators?
39. A document from 2005 (see Appendix I, text highlighted in yellow) suggests that the Commission considered environmental issues as a "minor issue" only, and was proposing to stop banning pesticides for environmental reasons only. What is your view of this position, also in light of art.4 of Regulation 1107/2009? Has this consideration of environmental issues changed in recent years and what policy statements would you refer to highlight your answer?
40. In relation to the evaluation of the inspection unit of SANTE, according to the Commission's report to the Ombudsman in 2018 following the complaint 12/2013/MDC (see Appendix II, page 12)

"In 2015, the Commission undertook a survey of all Member States on the authorisation of PPPs. The responses to the survey showed that the majority of the Member States did not comply with the legal requirements laid down in the Regulation (EC) No 1107/2009 regarding deadlines for the authorisations of PPPs.

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What is your evaluation on how this situation may affect the environment?

³ <http://science.sciencemag.org/content/360/6392/973.1>

41. One of the purposes of Regulation 1107/2009 is *“to ensure a high level of protection of both human and animal health and the environment... The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.”* (recital 8, addressed in article 4)
42. Based on your work and research, do you consider that this aim of the regulation is fulfilled, and therefore the authorisation and use of pesticides in the EU do not cause any harmful effects on animals or any unacceptable effects on the environment? In your opinion, do you consider that the current authorisation and use of pesticides allows a high level of protection of the environment and its ecosystems?
43. On Residues: According to Regulation 1107/2009, pesticide residues, or mixtures of pesticide residues should have no harmful effects on humans and animals and no unacceptable effects on the environment and each active substance (or its metabolites) has to fulfil the following conditions (Annex II, 3.7 and 3.8): it should not be considered a POP, a Persistent Bioaccumulative and Toxic (PBT), very persistent, very biocumulative, an endocrine disruptor to non-target organisms, to have unacceptable acute or chronic effects on bees or to have unacceptable impacts following ecotoxicity testing among others.
- In your opinion do you consider that the current system ensures that all the above criteria are fulfilled? Do you know of any cases where these criteria are not fulfilled?
44. A recent study found a 75% decline of insect biomass in proximity to agricultural sites (Hallmann et al, 2017), another found that more than 400 million of birds have disappeared in Europe (Inger et al. 2014), whereas an average of 33% of all birds have disappeared in France (French National Museum of Natural History, CNRS, 2017). All these studies attributed the observed decline in populations of species, at least in part, to intensive agriculture and the use of pesticides. In your perspective, what is the significance of these observations in relation to biodiversity and ecosystem services? Do you consider these changes alarming? And if yes, what political action would you propose as necessary?
45. A meta-analysis study in 2014 (Malaj et al. 2014) studied more than 2000 European freshwater sites and found that in 42% of the sites, aquatic ecosystems (using as reference invertebrate, fish and algae) were under chronic chemical risk, and pesticides were the major contributors. Is it true that the use of pesticides in agricultural areas are putting our freshwater ecosystems at risk? What are the long term consequences of such impacts?
46. What recommendations do you have on how to improve the current functioning or design of the EU pesticides approval process in order to ensure the highest possible level of protection of the environment and health as well as a high level of public trust in the process? Please feel free to also include areas which may not have already been covered in PEST hearings to date.
47. Can you explain how pesticides have an effect on bees, pollinators and other key organisms for ecosystem?
48. The EU has partly recognized the impact of neonicotinoids on pollinators or other organisms such as earthworms. What about other classes of pesticides, in particular Glyphosate, considered genotoxic and carcinogenic for animals by the IARC?

**Questions to Mr Ettore CAPRI / Catholic University of Sacred Heart Piacenza,
Faculty on Agriculture:**

49. You are involved in EFSA. In what ways could the EFSA process be improved from a scientific point of view?
50. Is there a 'fit-for-purpose' evaluation of the mitigation measures used by Member States to manage theoretical risks identified during the risk assessment process? And if so, could you explain the theory and practice of this evaluation?
51. Could you explain the architecture and aims of the MagPIE project?
52. What were MagPIE's major findings?
53. To what extent is it possible with toolboxes such as MagPIE to determine optimal PPP application and to support an integrated pest management approach?
54. The publications on pesticides where you stand as a first or last author are not related to the risk caused by pesticides on human/animal health or the environment. Among others, the topics of your research are linked to the sustainable use of pesticides directive or risk indicators. Neither are related to pesticide risk assessment. Your work has been partly funded by the pesticide industry and you have collaborated with the pesticide industry-funded ILSI. How do you justify your application to the EFSA plant protection products panels?
55. How can be it sure that the study framework enables to get consistent results, given that conclusions change according to initial hypothesis, the size of the sample, the parameters retained etc.?
56. Which statistical framework do you advice to make a consistent assessment of the pesticides' impact on waters, soils, forests and airs?
57. The MagPIE project lists the mitigation measures of the PPP in order to get a toolbox that politicians or other stakeholders will be able to use. Is it possible, currently or in a near future, to cancel the negative impact of pesticides thanks to some mitigation measures, or does it stay some negative effects?

**Questions to ALL experts of the 2nd panel (Stakeholders recommendations on
Regulation (EC) 1107/2009):**

58. Which elements of the current EU authorization process for PPPs are, in your view, most problematic and should be changed? In your answer, could you please differentiate whether problems are caused by the flaws in the legislative framework or by its implementation? If applicable, what should be changed in EU legislation? If applicable, what should be changed in the implementation process?

(The analysis and proposals below are largely drawn from a document prepared by "Citizens for Science in Pesticide Regulation", a coalition of NGOs, scientific and legal experts led by PAN Europe, to be presented to the public on September 5th 2018).

The EU pesticides regulation explicitly prioritises the protection of human and animal health and the environment. However, the rules are not implemented properly and the regulatory system is allowing private interests to be given priority over health and the environment.

Major conflicts of interest persist in the EU's pesticides regulatory system. The data used by EU regulators mainly consists in studies provided by applicants with a vested interest in exaggerating the safety of their products and dismissing concerns. These studies' raw data is never published (only summaries), and only partly and reluctantly disclosed when requests are made, preventing scientific scrutiny on the work of EFSA. Moreover, through its lobbying, industry remains heavily involved in designing the methods for risk assessment. The pesticides panel of the European Food Safety Authority (EFSA), which also has a heavy role in designing such methods, has since its beginning included people with financial ties to the agrochemical industry. The members of EFSA's peer review process are EU and national public officials whose identity is largely unknown, and, in the case of national officials, whose political independence from their governments cannot be guaranteed.

The Monsanto Papers, internal Monsanto documents disclosed in cancer litigation in the USA, show how industry can actively subvert science. It is now clear that industry must be kept at arm's length from safety testing, risk assessment and risk management, and this is not the case today in the EU.

In a context where EU and national research policies increasingly force public-private partnerships between academia and business in the name of innovation, the consequence of the above is that, today, EFSA is at the receiving end of an economy of regulatory data production that it does not control, and has little capacity to either perform the in-depth analysis it would need or access enough independent experts.

The result of these failures, both in the regulation itself and in implementing it, is a rapid collapse of biodiversity (birds, bees, butterflies, frogs, and insects) in agricultural areas and serious harm to humans, in particular farm workers. In addition to its failure to protect health and the environment, the current system also fails to protect food security for future generations, since biodiversity, pollinators, and soil fertility – the building blocks of a productive and resilient agriculture – are put at risk by pesticides.

To correct the situation, several steps must be taken:

- In terms of risk management, the European Commission and Member States should prioritise public health, the environment and sustainable agriculture:

- 1. The European Commission shall only propose the approval of a pesticide if all uses proposed by industry are considered safe by EFSA and no safer alternative (substance or practice) is available.*
- 2. The Sustainable Use of Pesticides Directive must be respected: pesticides must be used only as a last resort when all other non-chemical alternatives have been applied and have failed.*
- 3. The European Commission, as risk manager, shall operate transparently and with accountability. It must fulfil its obligation under the pesticide regulation to prioritise public health and the environment over all other considerations, such as international trade or corporate profits. The decision-making process – the discussions between the European Commission and the Member States, or any other entity – shall be public.*

4. *To enable EU farmers to improve their practices without being ‘punished’ by markets; the European Commission shall not place them in a position of unfair competition and shall therefore ban imported products that contain residues of non-approved pesticides, or that contain residues of any pesticide exceeding permitted levels, with no exceptions.*

- *In terms of the data used in the risk assessment process, it is essential to ensure that decision-makers rely on data that is complete, public, up to date, and free from industry bias*

5. *Safety testing of pesticides shall be carried out by independent laboratories and not by the pesticide industry itself. The process shall be paid for by an industry-supplied fund that shall be managed by an independent public body such as EFSA, although the commissioning of studies and their evaluation should not be done by the same institution.*

6. *To prevent cherry-picking of favourable data, all safety studies must be registered in advance. As long as industry has to supply them in the framework of its applications, no industry-funded safety study that is not registered shall be used in support of regulatory authorisation of a pesticide.*

7. *All experts involved in risk assessment shall be subject to a strict conflict of interest policy and rules. Any ties to commercial interests will exclude them from the process. Should an expert with a conflict of interest be considered to offer useful expertise, he/she could be invited to a hearing but should not have any role in the drafting and deliberation phases of the risk assessment.*

8. *Existing guidelines on risk assessment shall be fully reviewed by independent scientists because in many cases they were designed and promoted by industry and are biased in favour of industry interests.*

9. *EU-funded research programmes shall prohibit industry-linked individuals from joining projects that design or evaluate risk assessment methodologies.*

10. *The data required on pesticides to assess whether they should be authorised need to be updated urgently, because major health effects are not adequately covered, such as immunotoxicity, endocrine disruption and developmental neurotoxicity.*

11. *Industry dossiers shall only be accepted into the authorisation process when all required data are delivered, including all independent peer-reviewed publications related to health and environmental effects of the pesticide. Pesticides that do not fulfil all the requirements of the regulation must be banned.*

12. *Formulations of pesticides as sold and used (and not just the isolated active ingredient) shall be tested and assessed for crucial endpoints, e.g. mutagenicity, carcinogenicity, developmental toxicity, and endocrine disruption.*

13. *The cocktails of pesticide residues to which EU citizens are exposed every day must be taken into account when calculating “safe” daily exposure levels. Until this is implemented, an additional “safety” factor of 10 shall be applied in all pesticide risk assessments. An additional safety factor shall also be applied to concentrations of pesticides found in the environment.*

14. *All the results and data of all pesticide safety tests shall be published on the internet in a consistent and searchable format.*

15. *National authorities shall conduct routine independent post-approval monitoring of the effects of pesticides on health and the environment. The monitoring shall be paid for out of a fund supplied by the pesticides industry but managed by an independent body. There must be no contact on these matters between the monitoring authorities and industry.*

If the EU regulation were properly implemented and risk assessment methods were overhauled to be scientifically rigorous and objective, a number of pesticides that were previously deemed safe would be shown to endanger human health and/or the environment and would have to be banned or restricted.

The above-listed improvements would lead to a higher level of protection for health and environmental protection. Given the numerous non-chemical alternatives for plant protection based on ecological methods, they would also stimulate innovation in agriculture in a more sustainable direction. As a result, food security could be guaranteed not only for the present but also for the future, by protecting the basic requirements for agriculture: biodiversity, soil health and water quality.

59. Is the Commission reform [proposal](#)⁴ on the reform of the General Food Law (Regulation 178/2001) published in April sufficiently addressing the problem of lack of transparency (including access to documents (e.g. raw data) held by EFSA)? If so, why? If not, why?

The Commission's proposal goes in the right direction but has seemingly been written too fast: it could be seen as replacing the existing access-to-documents regime, notably under the Aarhus convention, which would actually worsen data transparency rather than improving it. These elements in the proposal must be amended.

Furthermore, the draft report of Ms Sommer (EPP) worsens the situation by suggesting, among other problematic elements, that the data should only be published after EFSA has published its scientific opinion, which would largely defeat the purpose of the whole initiative by preventing scientific scrutiny on industry applications when it is most relevant.

60. The IARC opinion and the BfR/EFSA opinions have conflicting views on the risks associated with glyphosate (i.e. on its carcinogenicity). Situations of conflicting scientific opinions are not uncommon in science advice for policy-making. At the same time, such scientific conflicts present a challenge both for regulators and for the broader public and the latter's trust in regulation. How could situations of divergent scientific opinions on a particular regulatory issue be addressed? Which institutional mechanisms of mediation of scientific conflicts would work best at EU level? (see, for example, the proposal of the Group of Chief Scientific Advisors, [Scientific Opinion 5/2018](#))⁵ to use the Scientific Advice Mechanism for that purpose).

Divergences in science are not uncommon and should not necessarily be resolved by other means than the continuation of scientific research.

In the case of a divergence over a scientific opinion that is important for regulatory purposes, though, the obvious starting point should be to first evaluate the respective data sets, procedures and methodologies followed by the authors of each opinion to evaluate these opinions' trustworthiness. In the case of the divergence between IARC and BfR/EFSA over glyphosate, an obvious conclusion was that IARC's methods of only using publicly available data and exclude

⁴ https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en

⁵ https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf

conflicted experts from its panels was more trustable than that of BfR/EFSA, which were working on unpublished data provided by interested industries (who were threatening EFSA of legal action if it would disclose it) and evaluated by (largely) anonymous governmental officials whose political independence from their respective national governments could not be guaranteed. The argument that EFSA's opinion would be more reliable because it had access to more data is severely undermined by this data being provided by industry and, as the Monsanto papers have shown, sometimes having been written by Monsanto employees themselves while pretending to be authored by independent scientists.

61. a) What changes, if any, should be introduced to the principle of reversed burden of proof, as currently applicable in the PPP authorization procedure, whereby the applicant provides all the evidence, on which the risk assessment is based? In your answer please also consider the feasibility of any reforms in this regard in terms of public finances and other practical and legal issues.

Cf. the list of reform suggestions listed under question 58. In a nutshell, it is very important that industry keeps the burden to demonstrate that its products can be used safely, in particular financially, but that it has no longer any control over the production and evaluation of risk assessment data and methodologies. Moreover, because each company needs to do its own studies, many studies are done redundantly. It is therefore likely that such a reform would not only increase the trustworthiness of risk assessments but would also diminish the overall cost of pesticides risk assessment by removing of duplicated studies.

Another point is that these studies are paid individually by industry, and their high cost favours large companies and drives markets concentration. The system should therefore be reformed in a way where the cost of regulatory data production is covered by a tax on industry's sales, or similar, to redress inequalities; the regulatory data would be produced by independent laboratories once these have been given samples of the product to test by the interested companies; the data would be published entirely, and then evaluated by EFSA.

- b) Does the Commission [proposal](#) to change the General Food Law Regulation address this problem sufficiently?

Not really, because the proposal mainly deals with data transparency aspects. The introduction of a mandatory register for all regulatory studies as proposed by the Commission would however very meaningful to fight cherry-picking by industry in the elaboration of its application dossiers.

62. There are many concerns about glyphosate next to carcinogenicity, for example, concerns about the loss of farmland biodiversity, water contamination, soil health, dependence of farmers on few big corporations, superweeds etc. In your view, does the current legal framework for pesticides in the EU allow for the consideration of these broader societal issues in the authorization process? Should the legislation be improved so that these broader concerns can be taken into account? Is the current framework

focusing too narrow on safety issues (and right now even only on carcinogenicity), therefore placing too much responsibility on a scientific agency (EFSA)?

This is a very important question. On the one hand, the focus on safety is essential and, while public health and environmental protection objectives prevail over other objectives in the Regulation, this must constantly be defended against industry's lobbying and other commercial interests. For example, the lobbying in favour of keeping glyphosate on the market towards the Commission by major food commodities exporting countries was fierce. Similarly, farmers' groups representing large farms, for whom glyphosate enables economies of scale and lower production costs, lobbied strongly in favour of the relicensing of glyphosate. It appears that, eventually, trade considerations were given a higher priority over safety and other considerations by the Commission in its decision-making.

But it is also interesting that there was a marked split among farmers groups as groups representing small and organic farmers tended to oppose the relicensing of glyphosate. The concern of not putting farmers at a competitive disadvantage is a valid one: farmers should not be punished commercially for producing food in a way that does not endanger their own health and the environment. To take a decision that would have protected both public health, the environment and farmers' revenue, the Commission should have not only proposed a ban of glyphosate but also protective trade measures against unfair competition, by banning imports of food contaminated with glyphosate residues.

When it comes to the need to include other societal considerations, such as biodiversity, water and soil protection, yes, absolutely. Behind the glyphosate debate was a much larger and very much needed debate over the sort of agriculture EU citizens expect, and no longer want, today. How effective was the distinction between risk management and risk assessment at dealing with such expectations? Not very much I'm afraid. While safety aspects remain a non-negotiable starting point, we might have had a much more rich and meaningful debate on glyphosate if the question had been "Can glyphosate still be used for a more sustainable, healthy and fair food production in Europe, and if so how?" rather than simply "is glyphosate safe?".

Of course, sourcing reliable data on these other aspects (trade, biodiversity, soil health, market power of different players in food production etc.) raises the issue of independent expertise and the means that the EU is willing to invest in it. Today, a lot of the expertise feeding the policy process is brought by lobby groups, with deep inequalities among these in terms of access to decision-makers, capacity to build credibility for their arguments in the eyes of the Commission's officials, etc.

63. Would you agree that risk management should strictly be based on a scientific assessment? Would you agree that our European agencies are best qualified to present such assessments?

Risk management should be based on evidence, yes, but cannot be restricted to scientific evidence only. By its very nature, risk management has to take non-scientific considerations into account, such as political preferences, lobbying pressures from vested interests, cultural legacies, etc. In the case of glyphosate, for instance, the lobbying pressure from farmers was very significant and legitimate, in that it pointed to

the need to take into into account other dimensions of the problem than safety, such as trade policy.

That said, risk management would benefit from a risk assessment process that is more science-based than the current one (cf. Previous suggestions for improving the current regulatory framework for pesticides), which is primarily a regulatory process defined by law, not the usual features of scientific research. A very important point for instance would be to test formulated products used in the real world as rigorously as the so-called active substance, which is not the case today.

64. Would you agree that pesticides can have a positive impact on food safety, for instance by using fungicides to prevent mould infestations?

The problem of answering such a general question is that current grain and produce handling and storage methods, for instance, and therefore the very market conditions for these, reflect the fact that certain fungicides are available. So, while fungicides in grain for instance enable the storage of grain for much longer than was previously possible because it is clear that certain mould infestations produce mycotoxins that are very hazardous to humans and must be avoided, it is also a fact that several fungicides are also suspected of being endocrine disruptors too, which is not acceptable. Balancing the two risks of food safety and food security is an old problem, and the story of the past 50 years is one where short-term food security has been given absolute priority after a long, very history of hunger (the last famines triggered by natural conditions in Europe are not that old!). We now realise that we went too far in the opposite direction; a good compromise, where we would produce food today without endangering our health and future food production, must be built urgently.

65. On PPP's is indicated a recommended quantity to be used in order to be safe. Are these indications scientifically correct? If so, why are these indications questioned?

As far as I can tell, the setting up of an Acceptable Daily Intake, or of an occupational exposure threshold, is a regulatory process, not a scientific one, even though it is informed by the findings of scientific experiments. For instance, using a factor 100 between the NOAEL and the ADI is arbitrary.

66. In your opinion, does EFSA need more finances and personnel to do its job?

Absolutely. The current level of funding of EFSA is a scandal given the importance of its mission, and so is the poor coordination between EFSA's independent research needs and DG Research's funding programs (few relevant research budgets, and inadequate participation rules enabling interested industries to participate and influence EU funded research outcomes that are relevant for EFSA). At the very least, EFSA should be given the means to give the experts of its scientific panels decent working conditions, ideally by hiring them. Of course, EFSA's independence policy would also need to be reinforced to avoid the revolving door phenomenon for these experts.

67. In your opinion, who needs to pay for the scientific studies? Is it a problem if the industry does? Do scientists make their results dependent of who pays? Wat about studies for NGO's?

The funding bias has been abundantly showed in the scientific literature, first in pharma and today in food science: industry funded research overwhelmingly delivers research findings that favour industry's interest. The reasons are multiple, from control over the publication process, influence over the research questions to outright fraud and manipulation (ghostwriting or outright falsification of data). Regulatory studies on given products should therefore not be commissioned and/or published by the companies producing them.

At the same time, it is not justifiable to burden taxpayers with costs that will only benefit private companies' bottom line. I refer you to the above-mentioned suggestions for a reform of the regulatory system for pesticides today.

As to research sponsored by NGOs, I am not aware of much research going on regarding on, but it is likely that the funder's bias applies for them too. The difference, of course, is that NGOs do not fund research to obtain commercial authorisations for products they would be selling and, as far as I can tell, primarily use academic research that is relevant to their work.

68. What is your opinion on the current European system, in particular on the following points?

Beyond the short answers below, please see the answer to question 58.

a) The double level: the active substance is assessed at the European level and the PPP at the Member State level. At a strictly scientific level, is only assessing the active substance sufficient?

Certainly not. Just for glyphosate, there is a lot of research showing that PPPs are more toxic than the declared active substance alone, there are [patents filings](#) for glyphosate formulations explaining that these look for "synergistic" effects between glyphosate and other substances to increase the product's plant-killing ability... The formulations used in the real world should be assessed at a level matching that of the declared active substance, which is not the case today.

b) For the active substance, the assessment is performed by the Member State contacted by the asker. This assessment is then corrected by the EFSA in a peer review. However, capacities of the Member States are different; therefore, there are problems of disparity and workload. What could you propose to improve this situation? What do you think about assessments performed only by the EFSA in order to have only one conclusion and to improve the consistence of our system?

The problem is that EFSA in itself cannot perform its existing tasks today, because it does not have sufficient resources. On the other hand, some national agencies are indeed better equipped... as show a number of cases (BPA for instance) where the first alert came from national agencies, not EFSA. It makes more sense to start from the assets we already have, reinforce the independence and capacity of EFSA, and not try to artificially streamline everything: diversity is also an asset in science.

We can discuss then about the political question and decide to ratify the EFSA's conclusion at the EU's level or the Member State's level.

c) Currently, the asker provides information to agencies. How guarantying the rightness of information? Which improvements could you propose in your checking and audit system?

d) Public accountability of information is not total. Secret is justified by fair trade. How far economic viewpoint can be accepted in the scientific subject of pesticides?

The courts have repeatedly stated that commercial secrecy could not be opposed to public health imperatives and emissions into the environment, I support this position. For the rest, as I wrote above, international trade and commercial aspects should also be taken into account when discussing the regulation of pesticides, in a way that keeps safety as a first priority.

69. Do you consider that the residues of the active substance, its metabolites, a safener, synergist and the co-formulant contained in it, are studied and assessed sufficiently on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment in order to guarantee one of the purposes of the Regulation 1107/2009, which is the protection of both human and animal health and the environment? Do you see the results reflected in the authorisation assessment at MS level?

The assessment of formulations is performed by Member States, and the regulation is terribly weak in terms of the toxicological tests required. Formulations should at least be assessed at the current level of declared active ingredients.

70. The Implementation Assessment commissioned by the European Parliament (2018) revealed that "Several stakeholders (PPP producers and PPP users) stated that exposure is not sufficiently considered in the current framework" (p.164/588). Do you consider that the risk mitigation measures, take enough into consideration the non-dietary intake and the exposure of non-target organisms?

No. First of all, there is no reliable data on the uses of pesticides. Even in rich and densely populated countries like the Netherlands, there is no reliable data on which and how much pesticides are applied. Passers-by and neighbours are largely ignored, and the risk mitigation measures are usually insufficient for what I know.

Questions to Ms Franziska ACHTERBERG / Greenpeace Europe:
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71. You are always advocating for less pesticides. Could you please elaborate a bit on the risks for non-use? Especially with regards to the loss of fungicides and its negative impacts on human health?

72. What kind of pesticides would you accept?

73. That do you think should be improved/changed in the risk communication of the PPP regulation?

74. We see the lack of low risk pesticides as well as alternatives to copper-based-fungicides, also in ecological agriculture. What would be your solutions?
75. How many meetings have you had with the European Commission, the European Parliament, European agencies and representatives of Member States in the past two years?
76. What is your budget? What are your sources of funding?
77. Your organisation is constantly criticising industry for not being transparent enough, and for exertion undue influence. Can you please explain to us the funding of your organisation, and in particular the links your organisation has with the Isvara Foundation as reported in Politico? (see reference <https://www.politico.eu/article/ayman-jallad-ayman-jallad-mystic-money-man-behind-brussels-activists-ngo-funding/>).
78. A document from 2005 (see Appendix I, text highlighted in yellow) suggests that the Commission considered environmental issues as a "minor issue" only, and was proposing to stop banning pesticides for environmental reasons only. What is your view of this position, also in light of art.4 of Regulation 1107/2009? Has this consideration of environmental issues changed in recent years and what policy statements would you refer to highlight your answer?
79. In relation to the evaluation of the inspection unit of SANTE, according to the Commission's report to the Ombudsman in 2018 following the complaint 12/2013/MDC (see Appendix II, page 12)
- "In 2015, the Commission undertook a survey of all Member States on the authorisation of PPPs. The responses to the survey showed that the majority of the Member States did not comply with the legal requirements laid down in the Regulation (EC) No 1107/2009 regarding deadlines for the authorisations of PPPs.*
- In 2016 and 2017, audits on the authorisation of PPPs were conducted in 7 Member States: Germany, the United Kingdom, Luxembourg, Portugal, France, Lithuania, and Spain. Audit reports can be found on the Commission website. The audits confirmed that the national re-evaluations of PPPs on the market, which must take account of the EU approval Regulations and their related conditions, are significantly delayed. In three Member States there were significant numbers of PPPs still authorised which had not been evaluated in accordance with EU agreed uniform principles^{19,20}. In these Member States the percentage of authorised PPPs that had not been evaluated in accordance with the uniform principles ranged from 9% to 33%."*
- What is your evaluation on how this situation may affect the environment?
80. One of the purposes of Regulation 1107/2009 is "to ensure a high level of protection of both human and animal health and the environment... The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment." (recital 8, addressed in article 4)
81. Based on your work and research, do you consider that this aim of the regulation is fulfilled, and therefore the authorisation and use of pesticides in the EU do not cause any harmful effects on animals or any unacceptable effects on the environment? In your opinion, do you consider that the current authorisation and use of pesticides allows a high level of protection of the environment and its ecosystems?
82. On Residues: According to Regulation 1107/2009, pesticide residues, or mixtures of pesticide residues should have no harmful effects on humans and animals and no

unacceptable effects on the environment and each active substance (or its metabolites) has to fulfil the following conditions (Annex II, 3.7 and 3.8): it should not be considered a POP, a Persistent Bioaccumulative and Toxic (PBT), very persistent, very biocumulative, an endocrine disruptor to non-target organisms, to have unacceptable acute or chronic effects on bees or to have unacceptable impacts following ecotoxicity testing among others.

In your opinion do you consider that the current system ensures that all the above criteria are fulfilled? Do you know of any cases where these criteria are not fulfilled?

83. A recent study found a 75% decline of insect biomass in proximity to agricultural sites (Hallmann et al, 2017), another found that more than 400 million of birds have disappeared in Europe (Inger et al. 2014), whereas an average of 33% of all birds have disappeared in France (French National Museum of Natural History, CNRS, 2017). All these studies attributed the observed decline in populations of species, at least in part, to intensive agriculture and the use of pesticides. In your perspective, what is the significance of these observations in relation to biodiversity and ecosystem services? Do you consider these changes alarming? And if yes, what political action would you propose as necessary?
84. A meta-analysis study in 2014 (Malaj et al. 2014) studied more than 2000 European freshwater sites and found that in 42% of the sites, aquatic ecosystems (using as reference invertebrate, fish and algae) were under chronic chemical risk, and pesticides were the major contributors. Is it true that the use of pesticides in agricultural areas are putting our freshwater ecosystems at risk? What are the long term consequences of such impacts?
85. What recommendations do you have on how to improve the current functioning or design of the EU pesticides approval process in order to ensure the highest possible level of protection of the environment and health as well as a high level of public trust in the process? Please feel free to also include areas which may not have already been covered in PEST hearings to date.
86. What is your evaluation of the Commission's proposal on the revision of the General Food Law?
87. Greenpeace is sometimes famous for its polemical actions, which harm fair goals despite initial good intentions. How NGOs, which militate on scientific topics, can avoid an inverted lobbying to protect the objectivity of science and not to harm some fair goals?
88. In comparison with the strict scientific ecology, Greenpeace sometimes practices a political ecology and deals with purely political topics such as economy, migration or culture. Is the intrusion of politics into purely scientific topics with no danger? Would your action be more efficient and better welcomed by the public opinion if you separate scientific question and ideological debate?

Questions to Mr Martin PIGEON / Corporate Europe Observatory (CEO):

89. You are always advocating for less pesticides. Could you please elaborate a bit on the risks for non-use? Especially with regards to the loss of fungicides and its negative impacts on human health?

I do not agree with this description of my work. The main point of my work is to describe and try to mitigate the excessive influence of agribusiness corporations in related EU

decision-making processes, from risk assessment to the final stages of political decision-making. I therefore focus much more on EFSA's independence and transparency policies, as well as DG SANTE's interactions with the agribusiness industry, than pesticides per se.

From what I know, the main risk of not using pesticides mainly relates to the possibility of crop losses in agricultural systems that are not designed to withstand the pressure of pests without them. This is particularly the case for the monocropping of very productive but very fragile plant varieties. But even then, insurance schemes developed in Northern Italy show that there are other methods than pesticides to enable farmers to insure themselves against crop losses.

I have answered the question on fungicides and mycotoxins earlier, under question 68, a response which I re-paste below.

The problem of answering such a general question is that current grain and produce handling and storage methods, for instance, and therefore the very market conditions for these, reflect the fact that certain fungicides are available. Fungicides in grain for instance enable the storage of grain for much longer and in larger quantities than was previously possible, which in turn can improve food safety and security for consumers: certain mould infestations produce mycotoxins whose consumption is very hazardous to humans and must absolutely be avoided.

That said, several fungicides are also suspected of being endocrine disruptors too, whose consumption is not acceptable either. Balancing the two risks of food safety and food security is an old problem, and the story of the past 50 years is one where short-term food security has been given absolute priority after a long, very long history of hunger in agricultural human societies (the last famines triggered by natural conditions in Europe are not that old!). We now realise that we went too far in the opposite direction, as while food security has stopped being an issue in Western Europe for decades, we're now realising that the very destructive way we grow food today endangers future food production capacity. A better compromise, one where we would grow food without endangering our health and future food production, remains to be built.

90. What kind of pesticides would you accept?

As a measure of last resort when other approaches are not sufficient, I would accept any pesticide used in a way that is shown not to be detrimental to human and environmental health.

91. That do you think should be improved/changed in the risk communication of the PPP regulation?

See my answer to question 58.

92. We see the lack of low risk pesticides as well as alternatives to copper-based-fungicides, also in ecological agriculture. What would be your solutions?

I'm not a specialist but don't think the description of a lack of low-risk pesticides is correct. On the opposite, several low concern traditional preparations were forbidden on the market for a long time because they would not comply with the requirements developed for very toxic synthetic pesticides. This is now changing.

From what I know, the point on copper-based fungicides is a very valid one, especially in vineyards, as copper is very harmful to soil and fauna's health but grape is very susceptible to fungal infections. As far as I know, there is no alternative to copper-based fungicides that would be as efficient to protect grape from mildew, and that is a huge problem: in some old vineyards, the accumulation of copper in soil has reached such proportions that even grasses no longer can grow...

In terms of solutions, I am not following the latest developments of research on this but I suppose there is a lot of research going on in breeding plant varieties that could better withstand this fungus, agronomical approaches which could help grapes better resist to this infection, and new substances that could control mildew efficiently but would be less toxic than copper.

93. Can you tell the committee how many meetings you have had with the European Commission and the relevant EU regulatory agencies over the last two years?

See my answer to question 98.

94. Can you also inform the committee about your organisation's annual budget, and its respective sources of funding?

Corporate Europe Observatory receives donations from individual supporters as well as grants from a number of trusts and grant-making foundations. Our strict funding policy rejects funding from the EU, governments, political parties and corporations in order to maintain the independence of our research. You can access our [CEO accounts 2008-2017](#) and can also consult the list of trusts and foundations currently supporting us below. Our 2018 budget is expected to be about 850,000€ for a team of 14-15 persons.

[Adessium Foundation](#)

"Adessium Foundation was established in 2005 by the Van Vliet family, which is characterized by integrity, a balance between people and nature, and a respect for the environment."

[Fondation Charles Léopold Mayer pour le Progrès de l'Homme \(fph\)](#)

"The Charles Léopold Mayer Foundation for the Progress of Humanity focuses on governance, ethics and sustainable living modes."

[Funders for Fair Trade Foundation](#)

Funders for Fair Trade Foundation (established in 2014 by the Jenif Foundation) focuses on fair trade from the perspective of public health, environmental protection and human rights.

[JMG Foundation](#)

The JMG Foundation is a U.K.-based organization (founded by Ben JMG) that provides a hyperlink to the organisation's entry on SourceWatch.

[Guerrilla Foundation](#)

The Guerrilla Foundation was founded in 2016 by Antonis Schwarz. It aims to catalyze systems change, generate bottom-up pressure on political elites and support grassroots movements.

[Joseph Rowntree Charitable Trust](#)

"The Joseph Rowntree Charitable Trust is a Quaker trust which supports social justice and challenges the existing power imbalances in society to effect real change."

[Isvara Foundation](#)

"The Isvara Foundation is a progressive trust that awards grants to organizations that challenge and characterize the currently dominant process of corporate-led globalisation."

from a personal donation made by Mr. Jallad.”

[Marisla Foundation](#)

The Marisla Foundation was established in 1986 by Anne Getty Earle (as part of the Marisla Program) and one special interests category.”

[Misereor](#)

Misereor is one of the biggest aid organisations linked to the Roman Catholic Church. Its grant-making and project activity is entirely independent of the faith.

[Olin Foundation GmbH](#)

The Olin Foundation “is committed to the protection of natural habitats and biodiversity. It was established in May 2012 by Alexander Szlovák. It receives its financial resources from the Olin Foundation.”

[Open Society Initiative for Europe](#)

The Open Society Foundations were set up in 1979 by George Soros. They support civil society organisations in the European Union by supporting the activists and civil society organizations.

[Schöpflin Stiftung](#)

The Schöpflin Foundation, established by Hans Schöpflin in 2001, “is committed to the protection of the environment for future generations.”

[Un Monde par Tous](#)

Un Monde par Tous supports initiatives promoting alternative modes of production and consumption that are leading to severe environmental degradation. The foundation works to reduce the impact of these activities.

95. At an earlier hearing with the Commission and EFSA, the PEST committee raised the issue of industry funding for research used in the approval process. It was put to EFSA that this model should be revised and instead all studies should be financed through public money, e.g. by EFSA themselves. The representatives from EFSA expressed the view that this would support increased industry profits, as the burden of scientific proof would shift from the economic operator who benefits from the approval to the regulatory authority. Do you concur with this view?

Yes and no. I think the costs of regulatory data production and evaluation should be paid by a public fund which would be fed by a sectoral tax on industry's sales: the burden of the proof and the financing need to stay with industry, but industry should no longer exert any control over the design, production and reporting of regulatory data.

96. As representatives of the European citizens' initiative against glyphosate, you have raised a number of criticisms of the regulatory process for pesticides in general, particularly with regard to last year's glyphosate re-approval. What practical alternatives do you suggest?

See my answer to question 58.

97. What is your budget? Can you describe your role? What are your sources of funding?

See my answer to question 94 for CEO's budget and funding. My role is that of a researcher (I produce information on corporate lobbying in the agribusiness sector, mainly) and of a campaigner (I campaign for stricter regulation of lobbying, and improved independence and transparency policies at EFSA and, more generally, among the EU institutions – my current campaigning on the issue of pesticides homologation comes from this angle).

98. How many meetings did you have with the European Commission, Members of the European Parliament and representatives of the Council and Member States permanent representations in the last two years?

Since September 2016, I had :

- 6 meetings with the political levels of the European Commission (these are normally publicly declared by the Commission), with the Health and Research Commissioners and their cabinets.*
- 3 meetings with the technical levels of the European Commission (SANTÉ) so far this year, 2 between June and December 2017, and about 6 (I could not retrieve the exact information in time for the hearing) between September 2016 and June 2017, so about 11 in total. These meetings are unfortunately not publicly registered by the European Commission.*
- EFSA: I meet with EFSA staff regularly (on average 3-4 times a year I would say) in various events (for instance I shared a panel in the European Science Journalism conference, in Toulouse, with EFSA's director last July 8), but my main interaction with the agency is in writing or over the phone. In terms of actual meetings, I did not have any with EFSA's staff since June 2017, and before that I had two meetings with EFSA staff, both at their request (one with EFSA's director and another with one of their communications persons). These meetings are unfortunately not publicly registered by EFSA.*
- EP: I think I've had about 2 or 3 meetings with CONT Members and/or their staff since September 2016 on the issue of EFSA's independence and transparency policies. I have also had three meetings with members of the PEST Committee and/or their staff, 2 meetings with ENVI members, I participated to a previous EP hearing on the Monsanto papers as well as to one panel discussion in the EP on the issue of data transparency in research (in particular in the pharmaceutical sector). With a few exceptions (some political groups do declare their meetings with campaigners and corporate lobbyists), these meetings are not publicly registered by the European Parliament.*
- Permanent representations of Member States: none, but I had 3 meetings with members of the French Parliament (National Assembly and Senate) over that period of time.*

As an aside, as a researcher in corporate lobbying I find it regrettable that Mr. Chinn has not been asked the same question!

99. What measures do you think are necessary to ensure the highest level of transparency at EFSA and in relation to the other stakeholders and documents involved in the authorisation process? What recommendations do you have on conflicts of interest for all stakeholders/organisations involved in the process?

On data transparency at EFSA, see my answer to question 58.

In terms of preventing conflicts of interests at EFSA, the obvious emergency is closing the remaining loopholes in the agency's independence policy, which, sadly, was not done by EFSA during its latest reform of the policy. See our [analysis](#) of the new policy: the scope for evaluating interests is narrowed to the specific themes the panel is working on while risk assessment methodologies are common to many sectors (several previously conflicted EFSA experts have been re-appointed to different panels this year), and research funding by industry remains excluded from the two-years cooling-off period as long as the amounts at stake do not rise above 25% of the total research budget managed by the expert and/or his research team. With such a high ceiling, hardly any expert would not be appointed.

100. There have been many improvements to EFSA transparency policy over recent years, partly due to pressure exerted by the Parliament's discharge procedure. Is the independence of EFSA from industry now guaranteed? If not, what further improvements can be made?

While EFSA has improved its process transparency, which is very convenient for lobbyists monitoring its work, it has not improved data transparency, which would enable independent scientific scrutiny on its work. Worse, it seems to be actively fighting data transparency in the European Court of Justice. We hope the Commission's proposal once amended to correct some of its flaws and adopted will enable (or force!) EFSA to improve on this point.

In terms of EFSA's independence from industry, we're not there yet. Not at all, actually. A corporate lobbyist was just appointed to EFSA's Board, the director of a lobby group representing the farming and food industries of Denmark. Two years ago, EFSA's director recruited as EFSA's new Director for Communications and without any cooling-off period a lobbyist working for the largest lobby group for the food and drink industry in the UK, the Food and Drink Federation (FDF). And among the members of EFSA's scientific panels that have just been renewed, I have seen some names of experts that we have shown to be in a conflict of interest situation repeatedly since we started working on this issue 10 years ago!

101. It has been argued that independence from industry can never be achieved, since so many experts do receive funding from industry or have ties to industry. What do you think about this? What in your view are some of the solutions to help build and support independent science and researchers?

First, one needs to understand that the working conditions for external experts at EFSA are not attractive today, in particular for young researchers. For an average workload of 60-70 full days a year, they are only compensated for the days they actually attend meetings, and they cannot really publish their work in the scientific literature as the data they're using, coming from industry, cannot be disclosed. This is already a first source of discouragement for external experts to apply to EFSA panels.

Second, it is a major victory of corporate lobbying to have obtained that EU and national research policies often force academia to establish public private partnerships with businesses to access public research funds in the name of "innovation". This, indeed, sadly and increasingly narrows the pool of available independent experts.

This reality must be taken into account into the next EU's research framework programme, "Horizon Europe": while PPPs can have their merits for products development, they

are deadly when it comes to risk assessment. The EU must allocate significant research funding to research into food safety and public and environmental health that is independent from industry. I cannot insist enough on the importance of this.

Otherwise, there is a simple way for EFSA to deal with the problem: use its “hearing experts” system, which enables scientific panels to organise hearings of conflicted experts to collect their expertise without undermining their independence. The existence of this system makes EFSA’s decision to appoint conflicted experts on its panels all the more incomprehensible.

102. What is your view on the use of GLP standards in the pesticide authorisation procedure?

GLP are a transparency standard developed to increase transparency after huge cases of scientific fraud by industry in the 1970s. It is important that industry complies with GLP for its studies as long as it needs to commission regulatory studies (even though GLP does not protect against the falsification of raw data), but GLP should not be equalled with scientific quality; in particular, EFSA must stop discarding academic research simply because it would not match this standard.

The Commission’s proposal to increase the means of GLP inspections is good.

103. At the PEST mission to EFSA, Mr Url spoke in favour of laying down a harmonised independence policy amongst all EU agencies and invited the PEST committee to come up with a proposal. What is your view on this suggestion? Would this be desirable/achievable in practice? What measures would need to be put in place to ensure that this would ensure the highest levels of independence possible (rather than resulting in a policy of the lowest common denominator)?

As the agency possibly the most exposed to public criticism over its independence, it is understandable that EFSA wants to transfer the responsibility to defend its independence to a higher level. I think this idea will have some merits once EFSA adopts an independence policy that is meaningful and properly protects it against the influence of the companies whose products it is evaluating, which is not the case today. When this is achieved, EFSA’s policy can then be used as a reference for other regulatory agencies such as EMA or ECHA.

104. From July 2018, under its new independence policy, EFSA will be able to request declarations of interests from Member State experts which will be checked by EFSA. What is your view on this? Will this help reduce conflicts of interest?

In principle this is very welcome, but as far as I’m aware EFSA does not have the legal means to force these national public officials to comply with the measure...

105. What overall recommendations do you have on how to improve the current functioning or design of the EU pesticides approval process in order to ensure the highest possible level of protection of the environment and health as well as a high level of transparency and public trust in the process? Please also feel free to include areas/ideas/proposals which may not have already been covered in PEST hearings to date.

Please see my response to question 58.

106. Which influence do lobbies pro and anti-pesticides currently have on both scientific and political European system?

I would say that pro-pesticides lobby groups have a significant influence on the technical levels of the decision-making system (regulatory agencies, public officials), while anti-pesticides group, who cannot match industry's resources, can only use public opinion and the political pressure to try to control the damage (when they're aware of it, which is not always the case!). Let's remember that while public opinion has rarely been so aware of the risks posed by the way pesticides are used in Europe, the general trend (with huge differences among countries) is that the volume of pesticides being used appears overall quite stable whereas the killing power of recent molecules is stronger.

107. Does lobbying have an impact on the assessments performed by the EFSA and the ECHA? Did it have an impact on Glyphosate's assessment, given that the EFSA had partly used studies from industry?

It depends how one defines lobbying as, in the case of glyphosate and pesticides more generally, 'the scandal is what's legal' to a large extent... I mostly know EFSA, so I will only focus on this agency. But given that EFSA/BFR worked on the basis of a dossier written by glyphosate producers, that this dossier eventually became the basis for EFSA's final report, that later research on the raw data showed that EFSA/BFR had probably failed to double-check it because they had missed several tumor findings unreported by the companies' scientists in the studies' summaries, that EFSA's peer review was performed by largely anonymous officials with no guarantee of political independence from their governments, that industry had access to EFSA's final conclusions 15 days before their publications, yes, I think one can reasonably say that that industry interests had quite an influence on EFSA's work.

108. The EU's action is based on stakeholders' consultation. Consequently, the EU has to deal with lobbies from companies. Do scientific organizations work in a perfect independence within the EU?

In Brussels, lobby groups are indeed a kind of auxiliary bureaucracy. I don't think this is anywhere satisfactory: lobby groups are not elected by anyone.

I am not sure what the next question means. Independence from what, from whom? Perhaps my answer to question 101 is relevant to this question.

109. Lobbying does not come only from companies. It also comes from some NGOs. Is NGO's action sometimes questionable?

NGOs usually represent broader interests than companies, but NGOs are also concerned by what I write above: not elected by anyone. So, yes, the action of NGOs is sometimes questionable, all the more when they are used for corporate lobbying purposes!

110. How guarantying the independence of scientific and political organizations against lobbies in the EU?

This is a very broad question which would need to be defined further: independence from whom?

If the question is about independence from corporate interests, to try to answer briefly, I would say that research policies should absolutely be improved so as to stop the ongoing corporatisation of science in the name of “innovation”, which often forces universities to establish research partnerships with businesses to access public research funding and to work on issues that are mainly relevant from a commercial perspective. This would restore more freedom in academia and, also, enable better working conditions in research, particularly for young researchers.

Similarly, the delivery of reliable independent expertise is not compatible with the ongoing drive to cut the budget of, or/and privatise, public research agencies (for example the UK Conservative government went as far as privatising entirely the UKs food safety agency, FERA).

As far as the independence of political organisations is concerned, strict regulation of campaign funding and media ownership should be introduced (this would deserve a much broader discussion).

111. Do you observe similarities in the corporate lobbying done in the past for some nowadays banned pesticides, such as PCBs and Agent orange, to the lobbying done nowadays from the big corporations? What could be improved in the legislation in order that the civil society and other stakeholders have the same access and influence the decision-making as the applicant?

Yes. The discourse and tactics of corporate lobbyists facing a possible ban of their product has remained remarkably similar over the past decades, especially insisting on the difference between hazard and risk, casting doubt on critical science, blaming users for mishandling the product, and crying for job and economic losses.

For instance, Monsanto released in 1970 the following statement on PCBs:

“It has also been implied that polychlorinated biphenyls are “highly toxic” chemicals. This is not true. Just like other industrial chemicals and home products now in widespread use, PCBs are not hazardous when properly handled and used. During more than 40 years of U.S. production and use, cases of any toxic effect have been extremely rare – and then only where the simple precautions recommended for use were not followed.

Monsanto has research programs under way to identify the compounds, reported to be PCB, and locate their source. The program involve precise analysis of environmental samples of water and soil

[...]

Very early results of chronic toxicity studies confirm that PCBs are not highly toxic. [...]”

Another quote by a corporate executive:

“the whole proceeding against an industry that has made invaluable contributions to the American economy for more than fifty years is the worst example of fanaticism since the New England witch hunts in the Seventeenth Century”.

This was Lawrence Blanchard in 1976. Mr. Blanchard was at the time the vice-chairman of the Ethyl Corporation and complained about the US Environmental Protection Agency’s first attempts to remove lead from gasoline. Ethyl Corporation was the main manufacturer of lead tetraethyl (TEL), an antiknock additive to gasoline responsible for massive worldwide lead pollution in the XXth century. Lead is a substance whose very toxic properties, particularly on the central nervous system, have been known since the Antiquity. TEL was phased out in the US in the 1980s and in Europe in the late 1990s and its removal caused a sharp and immediate reduction in atmospheric lead pollution. It is however still being produced and sold in some developing countries.

Questions to Mr John CHINN / Crop Health and Protection (CHAP):

112. What are the biggest threats to crop production in Europe? How do you see the role of pesticides in that system?
113. Regulation (EC) 1107/2009 states its purpose is: *“to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture”*. How do you think that each of these objectives are met and what could be done to further their attainment?
114. In your view, what are the key hurdles to the uptake of new technologies in the agricultural sector?
115. What role do you see for pesticides in modern and sustainable farming? How would you assess the role of technologies such as precision farming for the development of farming in general and the use of pesticides? Looking into the technological developments that can be expected for the near future, would you say that a sustainable use of pesticides is possible?
116. In the next decades, humanity has to increase yields to assure the food needs. Can the food-processing industry be sustainable, given that your innovations already obtained?
117. If the food-processing industry can become sustainable, which strategy can you propose to replace the current food-processing industry, implying to face big companies such as Bayer-Monsanto?