Request for the setting up of a Committee of Inquiry to investigate alleged contraventions and maladministration in the application of Union law in relation to the placing of plant protection products on the market.

We, Members of the European Parliament, hereby request to set up a Committee of Inquiry to investigate alleged contraventions and maladministration in the application of Union law in relation to the placing of plant protection products on the market.

Subject of the Inquiry

The inquiry aims to investigate alleged contraventions of Union law and alleged maladministration in the application of Union law, which appear to be the act of the European Commission and public administrative bodies of Member States. In particular, the inquiry shall:

- investigate alleged failure of Member States authorities to implement Council Directive No 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, considering the criteria to submit applications by producers and the conditions of admissibility of these applications;
- investigate alleged failure of Member States authorities to implement Directive No 2008/99/EC of 19 November 2008 on the protection of the environment through criminal law, including the obligation to hold legal persons liable in case of offences committed;
- investigate alleged failure of Member States authorities to properly apply 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 , considering the criteria to submit applications by producers and the conditions of admissibility of these applications;
- investigate alleged failure of Member States authorities to properly apply Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions for the implementation of the renewal procedure for active substances, considering the obligations of checking applications and the conditions on the admissibility of the application;
- investigate alleged failure of Member States authorities to implement Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances and Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, considering the obligation for producers to submit all relevant data from the scientific peer reviewed open literature on the active substance and the plant protection product, and a full and unbiased report of the studies conducted as well as a full description of them;
- investigate alleged failure of the European Commission to grant approvals based on incomplete data;
- investigate alleged failure of the European Commission, as guardian of the Treaties, to act against Member States failing to properly apply the Regulations mentioned above to ensure the respect for Articles 114, 168 and 191 TFEU;
- make any recommendations that it deems necessary in this matter;

Detailed statement of the grounds

On 1st of June 2023, several European media outlets reported a new research, published in the Environmental Health Journal[1], by two professors of the Stockholm University, Sweden - Prof Christina Rudén and Dr Axel Mie - assessing the non-disclosure of developmental neurotoxicity (DNT) studies by plant protection products when submitting applications for market authorisations.

The researchers found 35 DNT studies submitted to the US Environmental Protection Agency as part of the pesticide approval process but found that nine of these had not been included in dossiers sent to the EU authorities for the same pesticides. These nine undisclosed DNT studies were produced between 2001 and 2007, up to 20 years before the submission of the most recent EU regulatory

[1] https://ehjournal.biomedcentral.com/articles/10.1186/s12940-023-00994-9

dossiers. The nine undisclosed DNT studies relate to the following substances: abamectin, buprofezine, ethoprophos, fenamidone, fenamiphos, fluazinam, glyphosate-trimesiom, pymetrozine and pyridaben.

Among the findings in the undisclosed studies were changes in brain size, delayed sexual maturation and reduced weight gain in the offspring of laboratory rats exposed to a pesticide when pregnant. The pesticides identified in the new study include the insecticides abamectin, ethoprophos and pyridaben and the fungicide fluazinam. These are, or have been, used on a range of crops including tomatoes, strawberries, potatoes and aubergines.

The EU authorities became aware of the studies between 2017 and 2022, so only between 14 and 21 years after they were conducted. According to the researchers, these undisclosed studies could have had an impact on the decision of market authorisation for at least four substances because of the potential effect on toxicological reference values or hazard classification.

Following the work of the two researchers, EFSA has requested additional information and missing data to pesticides producers in five out of the nine substances. Four products have to date not seen their market authorisation renewed, four other authorisations are currently being reviewed and one (abamectine) has been renewed in 2023 under stricter conditions.

The European Parliament, representing the Union's citizens, has to react and set up an inquiry committee to investigate the scale of the revelations and to provide any recommendation it deems necessary to verify whether the EU legislation at the time was properly implemented by Member States and enforced by the European Commission.

Council Directive No 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, and especially its Article 4 provided the conditions at the time for the authorization, placing on the market, use and control within the Community of plant protection products in commercial form and of active substances used to protect plants or plant products against harmful organisms. Article 4(5) and 4(6) detail that authorisations may be reviewed at any time if there are indications that any of the requirements for market authorisation are no longer satisfied on the basis of developments in scientific and technical knowledge. In such instances Member States may require the applicant to submit further information necessary for the review.

Directive No 2008/99/EC of 19 November 2008 on the protection of the environment through criminal law aims at improving how the EU defines criminal offences related to pollution, waste and threatening biodiversity and other natural resources. Article 3 requires Member States to ensure that a series of conducts constitute a criminal offence, when committed intentionally or with at least serious negligence, including the discharge, emission or introduction of a quantity of materials or ionising radiation into air, soil or water, which causes or is likely to cause death or serious injury to any person or substantial damage to the quality of air, the quality of soil or the quality of water, or to animals or plants. Article 7 instructs Member States to take the necessary measures to ensure that legal persons held liable in case of committing offences.

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 repeals the above-mentioned directive. Its Article 7 (on application procedure) requires producers of the active substance applying for authorisation to submit a complete list of tests and studies related to the substance. Article 9 defines the condition for admissibility of the application and obliges, in case of missing elements in the application, the rapporteur Member State to inform the applicant, the other Member States and the European Commission that the application is inadmissible. Article 43 (on the renewal of an authorisation), Article 44 (on withdrawal or amendment of an authorisation) and Article 56 (on information on potentially harmful or unacceptable effects) are also of relevance here.

Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions for the implementation of the renewal procedure for active substances, complemented

Regulation 1107/2009. The proper implementation of Article 3 (on the checking of the application) and Article 8 (on the admissibility of the application) should be investigated.

Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances and Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products provide in annexes the data requirements to be submitted by pesticides producers. The annexes state that the information to be provided by applicants shall include all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species. In addition, the information shall include a full and unbiased report of the studies conducted as well as a full description of them.

In addition, as of 2019, the European Commission has published a **series of additional administrative guidance** on the submissions of applications and the list of documents to provide. These guidance documents are working documents of the Commission services, elaborated in co-operation with the Member States. They do not intend to produce legally binding effects and do not represent the opinion of the Commission, but are relevant to facilitate good application of the corresponding laws.

Finally, in its 2020 report on the evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, the Commission made the following remark in its findings to address delays and increasing transparency: "*In line with the views of the European Parliament to avoid procedural delays leading to inefficiencies, the Commission recommends that **Member States only accept complete dossiers of high quality as admissible** - both for applications for first or renewed approval of active substance and PPP authorisation applications.*"

Annex
Draft proposal to set up a Committee of Inquiry to investigate alleged contraventions and maladministration in the application of Union law in relation to the placing of plant protection products on the market, its powers, numerical strength and term of office.

The European Parliament,

– having regard to the request presented by XX Members for a committee of inquiry to be set up to investigate alleged contraventions and maladministration in the application of Union law in relation to the placing of plant protection products on the market,

– having regard to Articles 4, 114, 168, 169 and 191 TFEU,

– having regard to Council Directive No 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market,

- having regard to Directive No 2008/99/EC of 19 November 2008 on the protection of the environment through criminal law,

– 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 including basic substances,

– having regard to Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions for the implementation of the renewal procedure for active substances,

– 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 the European Commission guidance of 2 October 2009 on presenting and evaluating dossiers as per annex III, Directive 91/414/EEC January 2012,

– having regard to the European Commission administrative guidance of 8 April 2019 on submission of dossiers and assessment reports for the peer-review of pesticide active substances

– having regard to the European Commission administrative guidance of 22 March 2019 on preparing lists of test and study reports,

– having regard to the European Commission administrative guidance of 3 March 2021 for the processing of applications for regulated products,

– having regard to Decision of the European Parliament, the Council and the Commission of 19 April 1995 on the detailed provisions governing the exercise of the European Parliament's right of inquiry,

– having regard to Rule 208 of its Rules of Procedure,

– having regard to the proposal by the Conference of Presidents,

1. Decides to set up a Committee of Inquiry to investigate alleged contraventions and maladministration in the application of Union law in relation to the placing of plant protection products on the market.

2. Decides that the Committee of Inquiry shall:

- investigate alleged failure of Member States authorities to implement Council Directive No 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market;
- investigate alleged failure of Member States authorities to implement Directive No 2008/99/EC of 19 November 2008 on the protection of the environment through criminal law, including the obligation to hold legal persons liable in case of offences committed;
- investigate alleged failure of Member States authorities to apply 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 including basic substances, considering the criteria to submit applications by producers and the conditions of admissibility of these applications;
- investigate alleged failure of Member States authorities to apply Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions for the implementation of the renewal procedure for active substances;
- investigate alleged failure of Member States authorities to apply Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances and Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products, considering the obligation for producers to submit all relevant data from the scientific peer reviewed open literature on the active substance, and a full and unbiased report of the studies conducted as well as a full description of them;
- investigate alleged failure of the European Commission to grant approvals based on incomplete data;
- investigate alleged failure of the European Commission, as guardian of the Treaties, to act against Member States failing to properly apply the Regulations mentioned above to ensure the respect of Articles 114, 168 and 191 TFEU;

3. Decides that the Committee of Inquiry shall present its final report to Parliament within 9 months of the adoption of this decision.

4. Decides that the Committee of Inquiry should take account in its work any relevant evolutions within the remit of the Committee that emerge during its term.

5. Decides that any recommendations drawn up by this Committee should be dealt with by the relevant permanent committees.

6. Decides that the Committee of Inquiry will be composed of XX Members of the European Parliament.

7. Instructs its President to arrange for publication of this decision in the Official Journal of the European Union.