Basic information

2018/2153(INI) INI - Own-initiative procedure	Procedure completed
Union's authorisation procedure for pesticides **Subject** 3.10.09.02 Plant health legislation 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
PEST Special committee on the Union's authorisation procedure for pesticides	LINS Norbert (PPE) STAES Bart (Verts/ALE)	12/03/2018 12/03/2018
	Shadow rapporteur BONAFÈ Simona (S&D) MCINTYRE Anthea (ECR) RIES Frédérique (ALDE) HAZEKAMP Anja (GUE/NGL) PEDICINI Piernicola (EFDD) MAYER Georg (ENF)	

European Commission

Commission DG	Commissioner
Health and Food Safety	ANDRIUKAITIS Vytenis Povilas

Key events

Date	Event	Reference	Summary
05/07/2018	Committee referral announced in Parliament		
06/12/2018	Vote in committee		
18/12/2018	Committee report tabled for plenary	A8-0475/2018	Summary
14/01/2019	Debate in Parliament	CRE link	
16/01/2019	Decision by Parliament	T8-0023/2019	Summary
16/01/2019	Results of vote in Parliament		
16/01/2019	End of procedure in Parliament		

Technical information	
Procedure reference	2018/2153(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Special committee/Committee of inquiry
Legal basis	Rules of Procedure EP 213
Stage reached in procedure	Procedure completed
Committee dossier	PEST/8/13887

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE627.625	17/09/2018	
Amendments tabled in committee		PE628.665	15/10/2018	
Amendments tabled in committee		PE628.666	15/10/2018	
Amendments tabled in committee		PE628.667	15/10/2018	
Amendments tabled in committee		PE628.668	15/10/2018	
Amendments tabled in committee		PE628.669	15/10/2018	
Committee report tabled for plenary, single reading		A8-0475/2018	18/12/2018	Summary
Text adopted by Parliament, single reading		T8-0023/2019	16/01/2019	Summary

European Commission

Document type	Reference	Date	Summary
Commission response to text adopted in plenary	SP(2019)355	28/05/2019	

Additional information

Source	Document	Date
EP Research Service	Briefing	

Union’s authorisation procedure for pesticides

2018/2153(INI) - 16/01/2019 - Text adopted by Parliament, single reading

The European Parliament adopted by 526 votes to 66, with 72 abstentions, a resolution on the Union’s authorisation procedure for pesticides.

Following the Special Committee’s report on the EU authorisation procedure for pesticides, Parliament considered that, although the EU has one of the strictest systems in the world, Regulation (EC) No 1107/2009 of the European Parliament and of the Council and its implementation should be improved if its objective is to be achieved.

General remarks

Members stressed the importance of ensuring independent, objective and transparent scientific assessment of active substances and plant protection products.

They called on the Commission and the Member States to:

- allocate sufficient resources and appropriate expertise to the assessment of active substances and plant protection products and to ensure independent, objective and transparent assessment in light of current scientific and technical knowledge;

- ensure full and uniform application of the hazard-based cut-off criteria for active substances that are mutagenic, carcinogenic or toxic for reproduction, or that have endocrine-disrupting properties;

- duly apply the precautionary principle when the possibility of harmful effects on health is identified but scientific uncertainty persists, by adopting provisional risk management measures necessary to ensure a high level of protection of human health;

- no longer allow the use of plant protection products in areas used by the general public or by vulnerable groups and to adopt measures to stop, without delay or derogation possible, the long-distance application of pesticides near schools, nurseries, playgrounds, maternity hospitals or care facilities;

- fully implement the principles of the 3Rs (replacement, reduction and refinement);

- ensure effective controls on agricultural products imported from third countries and step up efforts to stop trade in illegal plant protection products.

The resolution also called for the creation of an effective **post-market vigilance system** to systematically monitor the real-life impacts of the use of plant protection products on human and animal health and on the environment as a whole, including in the long term.

The Commission was called urged to:

to improve its risk communication in order to inform the public in an appropriate, understandable and easily accessible way and to conduct an epidemiological study on the real-life impacts of plant protection products on human health;

- ensure that sales statistics concerning pesticides are publicly available per active substance and per Member State, and that pesticide use statistics are further improved so as to provide full information for the environmental risk assessment as well as the comparative assessment under the Regulation;

- develop a standardised EU-wide IT platform or database to support the sharing of post-market monitoring data, and considers that post-market monitoring data and other available monitoring data should be used in the authorisation process.

Application for approval of active substances

Parliament called on the Commission to propose amending the Regulation so as to empower it to adopt a work programme with regard to the designation of the rapporteur Member State (RMS) for applications for approvals, on the basis of criteria for an independent, objective and transparent assessment: expertise, resources, absence of conflict of interest, relevance for the product, technical capacity and ability to achieve scientifically robust and reliable outcomes within the given timeframe, together with a comprehensive peer review process and a stakeholder consultation, on lines similar to the system for re-approval of active substances.

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

They considered it important that applicants should be required to register all regulatory studies that will be performed in a public register, and allow a comment period during which stakeholders are able to provide existing data to ensure all relevant information is taken into account.

Draft assessment by the RMS

The RMS should clearly demonstrate in the draft assessment report that all studies have been properly checked for their relevance, scientific quality and validity.

Member States should ensure that they are properly represented in the European Food Safety Authority (EFSA) by independent national experts. EFSA and the European Chemicals Agency (ECHA) should also be allocated sufficient funds in order to carry out their tasks in an independent, objective and transparent manner, so as to ensure a high level of protection of human and animal health and the environment, and also in view of the additional workload anticipated for those agencies.

Authorisation of plant protection products by Member States

Members called on the Commission to undertake an in-depth assessment of the zonal system, with a view to assessing how best to ensure the proper harmonised scientific assessment of plant protection products while safeguarding the responsibilities of Member States for the authorisation, restriction or refusal thereof, and to revise the limitations for refusal of authorisation.

Harmonised guidelines for the assessment of plant protection products should be established by EFSA.

Members proposed that the Commission submit a detailed report to Parliament within 2 years on the national practices of risk assessment and risk management of plant protection products.

Encouraging research and innovation

Parliament has called for the Horizon Europe programme, other EU financial instruments and Member States to provide sufficient funding to promote independent research on the impact of plant protection products on human and animal health, the environment and agricultural production.

The Commission and the Member States are called on to promote the development and use of sustainable and ecological alternatives to plant protection products, integrated pest management measures and low-risk pesticides, as an important measure for reducing the adverse impacts of pest management.

Union’s authorisation procedure for pesticides

2018/2153(INI) - 18/12/2018 - Committee report tabled for plenary, single reading

The Special Committee on the Union’s authorisation procedure for pesticides adopted the joint report by Norbert LINS (EPP, DE) and Bart STAES (Greens/EFA, BE) on the Union’s authorisation procedure for pesticides.

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

General remarks

Members stressed the importance of ensuring independent, objective and transparent scientific assessment of active substances and plant protection products.

They called on the Commission and the Member States to:

- allocate sufficient resources and appropriate expertise to the assessment of active substances and plant protection products and to ensure independent, objective and transparent assessment in light of current scientific and technical knowledge;

- ensure full and uniform application of the hazard-based cut-off criteria for active substances that are mutagenic, carcinogenic or toxic for reproduction, or that have endocrine-disrupting properties;

- duly apply the precautionary principle when the possibility of harmful effects on health is identified but scientific uncertainty persists, by adopting provisional risk management measures necessary to ensure a high level of protection of human health;

- no longer allow the use of plant protection products in areas used by the general public or by vulnerable groups.

- ensure effective controls of the agricultural products imported from third countries with a view to ensuring a high level of protection and a level playing field for European food production;

- engage in increased efforts to stop the trade of illegal plant protection products, as these products undermine the objectives of Union legislation in this area.

The report also called for the creation of an effective ***post-market vigilance system*** to systematically monitor the real-life impacts of the use of plant protection products on human and animal health and on the environment as a whole, including in the long term.

The Commission was called urged to:

- ensure that sales statistics concerning pesticides are publicly available per active substance and per Member State, and that pesticide use statistics are further improved so as to provide full information for the environmental risk assessment as well as the comparative assessment under the Regulation;

- develop a standardised EU-wide IT platform or database to support the sharing of post-market monitoring data, and considers that post-market monitoring data and other available monitoring data should be used in the authorisation process;

- accelerate the implementation of the pilot project 'Environmental monitoring of pesticide use through honey bees', which will, *inter alia*, allow the implementation of EU legislation in terms of pesticide application and authorisation to be evaluated.

Application for approval of active substances

The committee called on the Commission to propose amending the Regulation so as to empower it to adopt a work programme with regard to the designation of the rapporteur Member State (RMS) for applications for approvals, on the basis of criteria for an independent, objective and transparent assessment: expertise, resources, absence of conflict of interest, relevance for the product, technical capacity and ability to achieve scientifically robust and reliable outcomes within the given timeframe, together with a comprehensive peer review process and a stakeholder consultation, on lines similar to the system for re-approval of active substances.

Members considered it important that applicants should be required to ***register*** all regulatory studies that will be performed in a public register, and allow a comment period during which stakeholders are able to provide existing data to ensure all relevant information is taken into account.

Draft assessment by the RMS

The committee stressed that the assessment should include a thorough evaluation of the raw data, as well as data related to final product formulations as available at that stage of the evaluation.

Member States should ensure that they are properly represented in the European Food Safety Authority (EFSA) by independent national experts. EFSA and the European Chemicals Agency (ECHA) should also be allocated sufficient funds in order to carry out their tasks in an independent, objective and transparent manner, so as to ensure a high level of protection of human and animal health and the environment, and also in view of the additional workload anticipated for those agencies.

Authorisation of plant protection products by Member States

Members called on the Commission to undertake an in-depth assessment of the zonal system, with a view to assessing how best to ensure the proper harmonised scientific assessment of plant protection products while safeguarding the responsibilities of Member States for the authorisation, restriction or refusal thereof, and to revise the limitations for refusal of authorisation.

Harmonised guidelines for the assessment of plant protection products should be established by EFSA.

Members proposed that the Commission submit a detailed report to Parliament within 2 years on the national practices of risk assessment and risk management of plant protection products.

Alternative methods

The Commission and the Member States are called on to promote the development and use of sustainable and ecological alternatives to plant protection products, integrated pest management measures and low-risk pesticides, as an important measure for reducing the adverse impacts of pest management.