Basic information

2021/2706(RSP) RSP - Resolutions on topical subjects	Procedure completed
Resolution on Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea **Subject** 3.10.09 Plant health legislation, organic farming, agro-genetics in general	

Key events

Date	Event	Reference	Summary
09/06/2021	Decision by Parliament	T9-0285/2021	Summary
09/06/2021	Results of vote in Parliament		
10/06/2021	End of procedure in Parliament		

Technical information

Procedure reference	2021/2706(RSP)
Procedure type	RSP - Resolutions on topical subjects
Procedure subtype	Resolution on implementing act or powers
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/06031

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Motion for a resolution		B9-0312/2021	08/06/2021	
Text adopted by Parliament, single reading		T9-0285/2021	09/06/2021	Summary

European Commission

Document type	Reference	Date	Summary
Commission response to text adopted in plenary	SP(2021)531	23/09/2021	

Resolution on Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea

2021/2706(RSP) - 09/06/2021 - Text adopted by Parliament, single reading

The European Parliament adopted by 434 votes to 230, with 27 abstentions, a resolution **objecting** to Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances.

Flumioxazine was included in Annex I to Council Directive 91/414/EEC on 1 January 2003 by Commission Directive 2002/81/EC and was deemed to be approved by Regulation (EC) No 1107/2009.

A procedure to renew the approval of flumioxazine under Commission Implementing Regulation (EU) No 844/2012(8) has been ongoing since 2010. The approval period for the active substance flumioxazine has already been extended by five years and subsequently by one year every year since 2015 and now again by one year by Implementing Regulation (EU) 2021/745 which extends the approval period until 30 June 2022.

Members recalled that in the 18 years since its approval as an active substance, flumioxazine has been identified and classified as **toxic for reproduction category 1B and as a probable endocrine disruptor**. The European Food Safety Authority (EFSA) concluded already in 2014, and subsequently in 2017 and 2018, that there were critical areas of concern as flumioxazine is classified under reproductive toxicity category 1B and also that the potential endocrine disruption of flumioxazine was an issue that could not be finalised and a critical area of concern.

EFSA published in September 2020 its updated peer review of the pesticide risk assessment of the active substance flumioxazine, in which it was not able to rule out endocrine-disrupting properties as several data gaps were identified, also on other safety aspects, leading to critical areas of concern.

More specifically, EFSA also identified data gaps in the area of residues and consumer safety, EFSA was not able to finalise the ground water exposure assessment due to data gaps, and the assessment of the endocrine-disrupting properties of flumioxazine for humans and non-target organisms could not be finalised due to the incomplete data sets.

Parliament has already opposed two previous extensions of the approval period for flumioxazine in its resolutions of 10 October 2019 and 10 July 2020. The Commission has not responded convincingly to these resolutions and has not satisfactorily demonstrated that it would not exceed its implementing powers by granting a further extension.

In the light of these considerations, Parliament considered that the **implementing regulation (EU) 2021/745 is not in line with EU law** in that it does not respect the precautionary principle, strongly criticising the considerable delay in the process of renewing the authorisation and identifying endocrine disruptors.

Members considered to extend the approval period for flumioxazine again is not in line with the safety criteria laid down in Regulation (EC) No 1107 /2009 and is based neither on evidence that that substance can be used safely, nor on a proven urgent need for that substance in food production in the Union.

The Commission is invited to:

- **repeal its Implementing Regulation** (EU) 2021/745 and submit a new draft to the Commission that takes into account the scientific evidence on the harmful properties of all substances concerned, in particular flumioxazine;

- present a proposal for the non-renewal of the approval of flumioxazine at the next meeting of the Standing Committee on Plants, Animals, Food and Feed;

- communicate to Parliament the specific circumstances and reasons why the assessments are being delayed;

- submit draft implementing regulations to extend the approval periods only of substances for which the current state of science is not expected to lead to a Commission proposal for non-renewal of the approval of the active substance concerned;

- withdraw the approvals for substances, if proof or reasonable doubt exists that they will not meet the safety criteria laid down in Regulation (EC) No 1107/2009.