European Parliament
2014-2019

Committee on the Environment, Public Health and Food Safety

2015/0000(RPS)

6.10.2015

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 106(2), (3) and (4)(c) of the Rules of Procedure

on the draft Commission Regulation (EU) …/… of XXX amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products (D0000/00 – 2015/0000(RPS))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Sylvie Goddyn

B8-0000/2015

European Parliament resolution on the draft Commission Regulation (EU) …/… of XXX amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products (D0000/00 – 2015/0000(RPS))

The European Parliament,

– having regard to the draft Commission Regulation (EU) …/… of XXX amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products,

– having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC[1] , and in particular Article 14(1)(a) thereof, and recitals 5), 12) and 27),

– having regard to the opinion delivered on 12 June 2015 by the committee referred to in Article 45 of Regulation (EC) No 396/2005,

– having regard to the Commission Implementing Regulation (EU) No 485/2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances[2],

– having regard to the Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor[3], published by the European Food Safety Agency on 11 March 2015, and replacing the earlier version published on 21 May 2014,

– having regard to the Commission Implementing Regulation (EU) 2015/1295 approving the active substance sulfoxaflor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011[4],

– having regard to the opinion delivered on 10 September 2015 by the United States

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1 OJ L 70, 16.3.2005, p. 1.
2 OJ L 139, 25.5.2013, p. 12–26
3 Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor. EFSA Journal 2014;12(5):3692[170 pp.].
4 OJ L 199, 29.7.2015, p. 8–11

Court of Appeals on Petition for Review of an Order of the Environment Protection Agency, requested by Pollinators Stewardship Council, American Honey Producers Association, National Honey Bee Advisory Board, and the American Beekeeping Federation, regarding the unconditional registration of sulfoxaflor[1],

– having regard to Article 5a(4)(e) of Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission[2],

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

– having regard to Rule 106(2), (3) and (4)(c) of its Rules of Procedure,

A. whereas the company Dow AgroSciences submitted an application to Ireland as Rapporteur Member State for the registration of sulfoxaflor on 1 September 2011;

B. whereas sulfoxaflor is a new insecticide that targets a range of insects; whereas it acts on the same receptor in insects as the class of insecticides referred to as neonicotinoids, although its mechanism is distinct from other neonicotinoids, and therefore it is currently the only member of a subclass of neonicotinoids called sulfoximines; whereas some insects that are resistant to other neonicotinoids are not resistant to sulfoxaflor because of the unique mechanism sulfoxaflor uses; whereas all neonicotinoids kill insects by interfering with their central nervous system, causing tremors, paralysis, and death; whereas neonicotinoids, including sulfoxaflor, are “systemic” insecticides, which means that they are sprayed onto plants, which then absorb the chemicals and distribute them throughout the plant, into the tissues, pollen, and nectar; whereas sulfoxaflor and other systemic insecticides therefore kill insects in two different ways: insects die when they come into contact with the pesticide, as when they are sprayed with it, and also when they ingest the plant which has absorbed the pesticide;

C. whereas the European Food Safety Agency (EFSA) never expresses in its conclusions that sulfoxaflor is a subclass of neonicotinoids, while explaining that sulfoxaflor is a novel insecticide that targets the insect nicotinic acetylcholine receptor; whereas EFSA even suggests that sulfoxaflor belongs to another class of insecticide by concluding "no cross resistance with other classes of insecticides, including neonicotinoids"; whereas neonicotinoids are known to be extremely toxic to honey bees due to their systemic translocation, which led the Commission to prohibit the use of three of them;

D. whereas the United States Environmental Protection Agency (EPA) and EFSA carried out an evaluation to determine the “acute median lethal dose”, or LD_{50}, of sulfoxaflor, meaning the dose at which half of the individual bees tested die; whereas EPA determined that the acute oral toxicity or oral LD_{50} was 0,052 micrograms of active substance per bee and that the acute contact toxicity or contact LD_{50} was 0,13 micrograms of active substance per bee; whereas based on the same studies submitted by the applicant, EFSA determined an oral LD_{50} of 0,146 micrograms of active substance per bee and a contact LD_{50} of 0,379 micrograms of active substance per bee; whereas these differing values show that EPA was more cautious than the EFSA, which

1 Opinion number 13-72346 of the United States Court of Appeals for the Ninth Circuit

2 OJ L 184, 17.7.1999, p.23.

did not prevent the United States Court of Appeals from vacating the EPA's registration of sulfoxaflor;

E. whereas Schmitzer studies[1,2], are used both by EPA and EFSA; whereas because the brood failed to emerge at high rates even in the control tunnels in the Schmitzer studies, the controls were not suitable for comparison with the brood termination rates of the tunnels treated with sulfoxaflor; thus, there was inconclusive data as to the effect of sulfoxaflor on brood termination rate; whereas accordingly, even these two studies reveal little about the effect of sulfoxaflor on brood development, due to problems with the control tunnels that caused high brood losses; whereas studies used by EFSA failed to demonstrate the absence of risk for animals, and in particular for bees;

F. whereas declarations of interest for the Schmitzer studies are not available;

G. whereas first-tier risk assessments of the active substance indicated high risk to honey bees; whereas a high risk to bees was concluded from data by the EFSA experts; whereas in order to manage the risk to bees, some risk mitigation measures were proposed by the Rapporteur Member State for field uses, however experts did not consider that the data and the assessments that were available were sufficient to demonstrate a low risk to bees for field uses even with the proposed measures (i.e. application only when bees are not present in the crop); whereas, therefore, a data gap was concluded for further information to address the risk to honey bees for field uses; whereas it is further noted that the available assessments for field uses refer to honey bees, and other pollinators such as wild bees are not covered; whereas EFSA concluded that with the available assessments, a high risk to bees was not excluded for field uses;

H. whereas sulfoxaflor is a new substance and thus its use cannot be considered as absolutely necessary for European agriculture;

I. whereas Commission Implementing Regulation (EU) 2015/1295 fails to provide specific provisions to protect honey bees and offers two complete years for the applicant to submit confirmatory information as regards the risk to honey bees, pollinators other than honey bees, and bee brood;

J. whereas Commission Implementing Regulation (EU) 485/2013, indicates that further restrictions may be necessary to exclude the high risk for bees, and that Member States may wish to impose further risk mitigation measures or restrictions to the placing on the market or use of the plant protection product containing dangerous substances for bees;

1. Opposes the adoption of the draft Commission Regulation;

2. Considers that the approval and definition of maximum residue levels of sulfoxaflor are not supported by substantial evidence to prevent unacceptable risks to animals, and in particular to bees;

3. Considers that the draft Commission Regulation is not compatible with the aim of

[1] Schmitzer S. (2011) Study on the effect of GF-2626 on honey bee brood (*Apis mellifera L.*) under semi-field conditions-tunnel test, Dow AgroSciences study no 80755

[2] Schmitzer S. (2011) Study on the effect of GF-2626 on honey bees and their brood (*Apis mellifera L.*) under semi-field conditions-tunnel test, Dow AgroSciences study no 101599

Regulation (EC) No 396/2005, which is to ensure that such residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals, and with the precautionary principle;

4. Calls on the Commission to withdraw the draft Regulation (EU) …/… of XXX amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products;

5. Calls on the Commission to submit a new legislative proposal on the basis of the Treaty on the Functioning of the European Union, banning the use of sulfoxaflor until complete studies about its effects on bees are available and reliable, and that EFSA concludes that sulfoxaflor is without danger to bees;

6. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.