



Plenary sitting

B8-1228/2016

16.11.2016

MOTION FOR A RESOLUTION

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

on the draft Commission implementing regulation renewing approval of the active substance bentazone 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 (D047341/00 – 2016/2978(RSP))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Pavel Poc

European Parliament resolution on the draft Commission implementing regulation renewing approval of active substance bentazone 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 (D047341/00 – 2016/2978(RSP))

The European Parliament,

- having regard to the draft Commission implementing regulation renewing approval of the active substance bentazone 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 (D047341/00),
 - 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 and repealing Council Directives 79/117/EEC and 91/414/EEC¹, and in particular Article 20(1) thereof,
 - having regard to Articles 11 and 13 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers²,
 - having regard to the European Food Safety Authority Conclusion on the peer review of the pesticide risk assessment of the active substance bentazone³,
 - 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) and (3) of its Rules of Procedure,
- A. whereas the active substance bentazone acts as a selective post-emergent herbicide against broadleaved weeds in a broad range of crops and is commonly used in agriculture;
- B. whereas the active substance bentazone has a high potential for direct leaching to groundwater due to its inherent properties;
- C. whereas data from the UK Environment Agency shows that the active substance bentazone is the most frequently detected approved pesticide in UK groundwater and is also to be found in surface water; whereas a similar situation exists across Europe;

¹ OJ L 309, 24.11.2009, p. 1.

² OJ L 55, 28.2.2011, p. 13.

³ EFSA Journal 2015;13(4):4077.

- D. whereas Commission Implementing Regulation (EU) 2016/549 of 8 April 2016 amending Implementing Regulation (EU) No 540/201 extended the approval period for the active substance bentazone until 30 June 2017 because the assessment of the substance had been delayed;
- E. whereas the draft Commission implementing regulation renewing approval of the active substance bentazone 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 (hereinafter the ‘draft implementing regulation’) provides, on the basis of a scientific evaluation conducted by the European Food Safety Authority (EFSA), for the authorisation of bentazone until 31 January 2032, i.e. for the longest possible period;
- F. whereas, in accordance with Regulation (EC) No 1107/2009 and in the light of current scientific and technical knowledge, certain conditions and restrictions have been included in the draft implementing regulation, in particular a requirement to provide further confirmatory information;
- G. whereas, following consideration of the comments received on the Renewal Assessment Report (RAR), it was concluded that additional information should be requested from the applicants;
- H. whereas following consideration of the comments received on the RAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology and should adopt a conclusion on whether the active substance bentazone could be expected to meet the conditions laid down in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council;
- I. whereas applicants are required to submit confirmatory information as regards level 2/3 tests currently indicated in the OECD Conceptual Framework to address the potential for an endocrine-mediated mode of action regarding the developmental effects observed in a developmental toxicity study in rats (increased post implantation loss, reduced number of live foetuses and retarded foetal development in the absence of clear maternal toxicity suggesting that classification as reprotoxic category 2 may be appropriate);
- J. whereas the consumer risk assessment was not finalised because the proposed residue definitions for risk assessment in plants and for enforcement in livestock were considered as provisional owing to the identified data gaps;
- K. whereas the groundwater exposure assessment for the parent bentazone and metabolite N-methyl-bentazone was not finalised; whereas information is missing regarding the potential for groundwater exposure when annual application rates are above 960 g a.s./ha. (representative uses of up to 1440 g a.s./ha were applied for);
- L. whereas the Commission’s decision to approve an active substance while simultaneously requesting data confirming its safety (known as the confirmatory data procedure) would allow the active substance to be placed on the market before the

Commission obtained all the data necessary to support that decision;

- M. whereas the European Ombudsman's Decision of 18 February 2016 in case 12/2013/MDC on the practices of the Commission regarding the authorisation and placing on the market of plant protection products (pesticides) called on the Commission to stop using the confirmatory data procedure with respect to both approvals of active substances for plant protection products granted under Directive 91/414/EEC and future approvals granted under Regulation (EC) No 1107/2009;
 - N. whereas the Commission's draft implementing regulation fails to implement the European Ombudsman's proposals for a solution to improve the Commission's pesticide approval system;
 - O. whereas under Regulation (EC) No 1107/2009 the renewal of the approval of active substances should be for a period not exceeding 15 years; whereas the approval period should be proportionate to the possible risks inherent in the use of such substances; whereas the precautionary principle which, according to Regulation (EC) No 1107/2009, must be applied requires the Commission to ensure that it does not approve active substances in cases where public health or the environment could be endangered;
 - P. whereas the EFSA peer review proposes that the active substance bentazone be classified as toxic for reproduction category 2 in accordance with the provisions of Regulation (EC) No 1272/2008;
 - Q. whereas an issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not make it possible to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment;
 - R. whereas according to the EFSA conclusions, critical areas of concern have been identified, in particular the fact that the technical material specification proposed for both applicants was not comparable to the material used in the testing to derive the toxicological reference values and that it has not been demonstrated that the technical material used in the ecotoxicity studies is suitably representative of the technical specifications for both applicants;
1. Considers that the draft Commission implementing regulation exceeds the implementing powers provided for in Regulation (EC) No 1107/2009;
 2. Considers the assessment on the representative uses of active substance bentazone to be insufficient to conclude that, for at least one of the representative uses, a plant protection product containing the active substance bentazone may be expected not to have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment;
 3. Considers that, by applying the confirmatory data procedure for the approval of the

active substance bentazone, the Commission breached the provisions of Regulation (EC) No 1107/2009 and infringed the precautionary principle, as set out in Article 191 of the Treaty on the Functioning of the European Union;

4. Calls on the Commission to give priority to requesting and assessing any relevant missing information before taking a decision on approval;
5. Calls on the Commission to withdraw its draft implementing regulation and to submit a new draft to the committee;
6. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.