European Parliament
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Committee on the Environment, Public Health and Food Safety

2015/0000(RSP)

15.3.2016

DRAFT MOTION FOR A RESOLUTION

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

on the draft Commission implementing regulation renewing the approval of the active substance glyphosate 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 Implementing Regulation (EU) No 540/2011
(DD044281-01 – 2015/0000(RSP))

Committee on the Environment, Public Health and Food Safety

Rapporteurs: Pavel Poc on behalf of the S&D group, Kateřina Konečná on behalf of the GUE/NGL group, Bas Eickhout on behalf of the Greens/EFA group, Piernicola Pedicini on behalf of the EFDD group, Mark Demesmaeker, Sirpa Pietikäinen, Frédérique Ries

B8-0000/2016

European Parliament resolution on the draft Commission implementing renewing the approval of the active substance glyphosate 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 Implementing Regulation (EU) No 540/2011
(DD044281-01 – 2015/0000(RSP))

The European Parliament,

– having regard to the draft Commission implementing regulation renewing the approval of the active substance glyphosate 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 Implementing Regulation (EU) No 540/2011 (D044281-01),

– having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 20 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[1], 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 powers[2],

– having regard to Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[3],

– 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 systemic herbicide glyphosate currently has the highest global production volume of all herbicides; whereas its global use has increased dramatically, by a factor of 260, in the last 40 years (from 3 200 tons in 1974 to 825 000 tonnes in 2014)[4];

B. whereas glyphosate is a non-selective herbicide, killing all herbage; whereas glyphosate acts by interfering with the so-called shikimate pathway, a pathway that is also present in algae, bacteria and fungi; whereas sub-lethal exposures of *Escherichia coli* and *Salmonella enterica* serovar Typhimurium to commercial formulations of glyphosate

[1] OJ L 309, 24.11.2014, p. 1.
[2] OJ L 55, 28.2.2011, p. 13.
[3] OJ L 031, 1.2.2002, p. 1
[4] http://enveurope.springeropen.com/articles/10.1186/s12302-016-0070-0

were found to induce a changed response to antibiotics;

C. whereas 76% of the use of glyphosate worldwide is in agriculture; whereas glyphosate is also widely used in forestry, urban and garden applications;

D. whereas glyphosate and/or its residues have been detected in water, in soil, in food and drinks, in non-comestible goods, as well as in the human body (e.g. urine and mother milk);

E. whereas the general population is exposed primarily through residence near sprayed areas, through home use, and through diet; whereas the exposure to glyphosate is rising due to the dramatic increase in the total volume of glyphosate used; whereas the impact of glyphosate to human health must not be underestimated;

F. whereas according to Regulation (EC) No 1107/2009, an active substance shall only be approved if it is not to or has not to be classified as a carcinogen category 1A or 1B in accordance with the provisions of Regulation (EC) No 1272/2008, unless the exposure of humans to that active substances is negligible or that there is a serious danger to plant health that cannot be contained by other available means,

G. whereas in March 2015, the International Agency for Research on Cancer (IARC) classified glyphosate as "probably carcinogenic to humans" (Group 2A) based on "limited evidence" of cancer in humans (from real-world exposures that actually occurred), "sufficient evidence" of cancer in experimental animals (from studies of "pure" glyphosate) as well as "strong evidence" of mechanistic information related to carcinogenicity (for genotoxicity and oxidative stress) both for "pure" glyphosate and for glyphosate formulations;

H. whereas the criteria used by IARC for Group 2A are comparable to those of Category 1B in Regulation (EC) No 1272/2008;

I. whereas, nevertheless, in November 2015, the European Food Safety Authority (EFSA) finalised the peer review of glyphosate and concluded that "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008";

J. whereas Commission Implementing Regulation (EU) …/... of XXX renewing the approval of the active substance glyphosate 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 Implementing Regulation (EU) No 540/2011 (the "draft implementing Regulation") proposes to authorise glyphosate until 30 June 2031, the maximum period possible, for any use, without any restrictions (except for one out of more than 500 co-formulants), without any legally binding conditions on the use, and subject to confirmatory information on endocrine disrupting properties;

K. whereas the purpose of Regulation (EC) No 1107/2009 is "to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market thought the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production";

L. whereas the provisions of Regulation (EC) No 1107/2009 are “underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment”; whereas “in particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory”;

M. whereas pursuant to Article 13(2) of Regulation (EC) No 1107/2009, the decision about the approval/non-approval/conditional approval of an active substance shall be based on the Commission's review report and on “other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant”;

N. whereas Article 7(1) of Regulation (EC) No 178/2002 stipulates that “in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment”,

O. whereas the conditions of recourse to the precautionary principle as laid down in Regulation (EC) No 178/2002 are clearly fulfilled in light of the ongoing controversy about the carcinogenic properties of glyphosate;

P. whereas according to Article 14(2) of Regulation (EC) No 1107/2009 the maximum possible period for the renewal of the approval for active substances is 15 years; whereas in the interest of safety, the approval period should be proportionate to the possible risks inherent in the use of such substances and experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken;

Q. whereas the European Ombudsman in her Decision in case 12/2013/MDC of 18 February 2016 on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides) called on the Commission to review its approach to the definition and implementation of mitigation measures (conditions and restrictions), including further requirements so as not to discharge its responsibility for ensuring effective protection of human health, animal health and the environment by allowing Member States almost absolute discretion as regards the definition of mitigation measures for potentially unsafe substances, given that standard formulations are very open-ended and can be doubted to be legally described as requiring mitigation measures at all;

R. whereas the draft implementing Regulation does not however contain any legally binding risk mitigation measures, despite a high long-term risk found for almost all uses of glyphosate for non-target terrestrial vertebrates, including mammals and birds; whereas the use of the non-selective herbicide glyphosate does not only kill unwanted weeds, but all plants, as well as algae, bacteria and fungi, hereby having an unacceptable impact on biodiversity and the eco-system; as such, glyphosate fails to

comply with point (e)(iii) of Article 4(3) of Regulation (EC) No 1107/2009;

S. whereas several Members States have already taken precautionary measures to protect public health and environment; whereas in order to achieve the same level of protection in all Member States, in case of approval of an active substance, clear and legally binding conditions for its use should be set at Union level;

T. whereas EFSA, at the request of the Commission, considered in its assessment, the report published by the International Agency for Research on Cancer (IARC), which classified glyphosate as probably carcinogenic to humans; whereas the evaluation was based on a large body of evidence, including a number of studies not assessed by the IARC which, according to EFSA, is one of the reasons for reaching different conclusions;

U. whereas the Head of EFSA's Pesticides Unit in charge of the assessment, called certain studies not assessed by IARC as “key” and “pivotal”; whereas EFSA has so far refused to make these studies publicly available, as the applicants have claimed that disclosure would harm their commercial interests; whereas non-publication of studies does not allow independent scientific scrutiny; whereas EFSA did not provide a verifiable proof that the disclosure would harm the industry, pursuant to the legal obligation under Article 63 of Regulation (EC) No 1107/2009;

V. whereas according to Article 4(2) of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[1] , the institutions shall refuse access to a document where disclosure would undermine the protection of commercial interests unless there is an overriding public interest in disclosure; whereas in light of the ongoing controversy between IARC and EFSA on an issue as publicly relevant as cancer and the global relevance of the decision about the reapproval/conditional reapproval or non-reapproval of glyphosate, there is clearly an overriding interest in disclosing these studies;

W. whereas there are not only serious concerns about the carcinogenicity of glyphosate but also doubts as regards possible mode of action in relation to its endocrine disruptive properties; whereas glyphosate-based formulations have been found to be endocrine disruptors in human cell lines and, in the absence of the proper scientific horizontal criteria, endocrine-mediated mode of action cannot be ruled out;

X. whereas in July 2015 the rapporteur Member State indicated its intention to submit a dossier concerning the harmonised classification of glyphosate under Regulation (EC) No 1272/2008 to the European Chemicals Agency, which is the relevant scientific authority with regard to the harmonised classification of chemical substances; whereas the application is expected for end of March 2016; whereas the decision-making process is expected to last 18 months;

Y. whereas in March 2016 the vote on the draft implementing Regulation renewing the approval of the active substance glyphosate in the Standing Committee on Phytopharmaceuticals was postponed;

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[1] OJ L 145, 31.5.2001, p. 43

Z. whereas the US Government Accountability Office (GAO) recently issued a recommendation to the United States Food and Drug Administration to assess risk and disclose information on glyphosate residues in relation to public health;

1. Considers that the draft Commission implementing regulation fails to ensure a high level of protection of both human and animal health and the environment, fails to apply the precautionary principle, and exceeds the implementing powers provided for in Regulation (EC) No 1107/2009;

2. Calls on the Commission to withdraw its draft implementing regulation and to submit a new draft to the committee;

3. Calls on the Commission not to renew the approval of glyphosate and to set up a clear time frame for establishing a list of co-formulants not accepted for inclusion in plant protection products;

4. Calls on the Commission to rapidly ensure an independent review of the classification of glyphosate based on all available scientific evidence relating to carcinogenicity of glyphosate as well as possible endocrine disruptive properties under the expected scientific horizontal criteria for endocrine disruptors;

5. Calls on the Commission and on EFSA to immediately disclose all the scientific evidence that has been a basis for the positive classification of glyphosate and the proposed re-authorisation, given the overriding public interest in disclosure;

6. Calls on the Commission to mandate its Food and Veterinary Office to test and monitor glyphosate residues in foods and drinks produced in the Union, as well as in imported produce;

7. Is of the opinion that an appropriate follow up of this resolution and thus the submission of a thoroughly amended new draft by the Commission will be crucial for the trust in and between the institutions of the European Union;

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