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Renewal of the approval of the active substance glyphosate

European Parliament resolution of 13 April 2016 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 (D044281/01 — 2016/2624(RSP))

(2018/C 058/11)

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 21 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 European Food Safety Authority (EFSA) Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate ([4]),

— 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 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 tonnes in 1974 to 825 000 tonnes in 2014) ([5]);

B. whereas glyphosate is a non-selective herbicide which kills all herbage; whereas it 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 have been found to induce a changed response to antibiotics;

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) OJ L 55, 28.2.2011, p. 13.
([3]) OJ L 31, 1.2.2002, p. 1.
([4]) http://www.efsa.europa.eu/en/efsajournal/pub/4302
([5]) http://enveurope.springeropen.com/articles/10.1186/s12302-016-0070-0

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

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

E. whereas the general population is exposed primarily through residence near sprayed areas, through home use, and through diet; whereas exposure to glyphosate is on the rise owing to the increase in the total volume of glyphosate used; whereas the impact of glyphosate and its most common co-formulants on human health must be regularly monitored;

F. whereas according to Regulation (EC) No 1107/2009, an active substance may only be approved if it is not or is 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 the active substance concerned is negligible or 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), on the basis of 'limited evidence' of cancer in humans (from cases of real-world exposure that actually occurred), 'sufficient evidence' of cancer in laboratory animals (from studies of 'pure' glyphosate), and 'strong evidence' of mechanistic information related to carcinogenicity (for genotoxicity and oxidative stress) for both 'pure' glyphosate and glyphosate formulations;

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

I. whereas, nevertheless, in November 2015 the European Food Safety Authority (EFSA) finalised a 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 (hereinafter the 'draft implementing regulation'), based on scientific evaluation conducted both by the BfR and EFSA, proposes to authorise glyphosate until 30 June 2031, i.e. for the maximum period possible, for any use, with a restriction for one of the co-formulants and the establishment by Member States of a list of co-formulants not accepted for inclusion in plant protection products, without any legally binding conditions on its use, and subject only to confirmatory information on endocrine-disrupting properties;

K. whereas the stated 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 through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production';

L. whereas it is stated in the text of Regulation (EC) No 1107/2009 that its provisions 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 the text further states that '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';

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M. whereas pursuant to Article 13(2) of Regulation (EC) No 1107/2009, any decision regarding 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 renewal of approval for active substances is 15 years; whereas in the interests of safety, the approval period should be proportionate to the possible risks inherent in the use of such substances, while 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), so as to include further requirements aimed at ensuring that the Commission does not evade its responsibility to ensure the 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 it can be doubted whether they can 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 use of the non-selective herbicide glyphosate kills not only unwanted weeds, but all plants, as well as algae, bacteria and fungi, thereby having an unacceptable impact on biodiversity and the ecosystem; whereas as such, glyphosate fails to comply with point (e)(iii) of Article 4(3) of Regulation (EC) No 1107/2009;

S. whereas several Member States have already taken precautionary measures to protect public health and the 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 EFSA's evaluation was based on a large body of evidence, including a number of studies not assessed by the IARC, and according to EFSA this is one of the reasons why it reached different conclusions;

U. whereas the head of EFSA's Pesticides Unit, which was in charge of the assessment, described certain studies not assessed by the 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 makes independent scientific scrutiny impossible; whereas EFSA did not provide verifiable proof that disclosure would harm the industry in accordance with its 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 regarding 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 a 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, an endocrine-mediated mode of action cannot be ruled out; whereas the Commission will provide standards for defining endocrine disruptors by August 2016;

X. whereas the EFSA stated as a 'concern' that 'an endocrine-mediated mode of action could not be ruled out', as the assessment could not be finalised on account of data gaps; whereas, however, point 2.2 of Annex II to Regulation (EC) No 1107/2009 provides that an active substance shall only be approved where a complete dossier is submitted; whereas this is all the more important given that Regulation (EC) No 1107/2009 provides that an active substance shall only be approved if it is not considered to have endocrine-disrupting properties that may cause adverse effects in humans, unless the exposure of humans to that active substance is negligible or there is a serious danger to plant health that cannot be contained by other available means;

Y. whereas it is inappropriate for the Commission to deal with this significant deficiency via confirmatory data to be submitted after the decision on reapproval, as the confirmatory data procedure should apply only in certain exceptional cases as laid down in point 2 of Annex II to Regulation (EC) No 1107/2009, and should not concern data requirements which existed at the time the application was submitted;

Z. whereas over the past two decades further evidence has accumulated of adverse effects, especially the fact that several vertebrate pathways are likely targets of action of glyphosate, including hepatorenal damage and effects on nutrient balance through glyphosate chelating action ([2]);

AA. 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 was expected for the end of March 2016; whereas the decision-making process is expected to last 18 months;

([1]) OJ L 145, 31.5.2001, p. 43.
([2]) http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0

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AB. whereas a significant use of glyphosate is for 'desiccation', the killing of the actual crop plant prior to harvest in order to accelerate its ripening and facilitate its harvesting (also known as 'green burndown'); whereas this practice not only has significant adverse effects on biodiversity, but also typically results in much higher residue levels in the final harvested products, and thus leads to increased human dietary exposure ([1]); whereas this practice also contaminates the straw from the treated crop and thus makes it unsuitable for animal feed; whereas it is unacceptable, both for the protection of human health and for the environment, to use a non-selective herbicide for such purposes;

AC. whereas the great majority of genetically modified crops are resistant to glyphosate ([2]); whereas 56 % of global glyphosate use in 2012 was for glyphosate-resistant genetically modified crops ([3]);

AD. whereas in 2015 and 2016 the European Parliament objected to four different draft Commission implementing acts concerning the placing on the market of products containing, consisting of, or produced from, genetically modified crops ([4]) ([5]) ([6]) ([7]); whereas all of these crops were genetically modified to be resistant to glyphosate; whereas three of these crops were also genetically modified to be resistant to a second herbicide, thus combining multiple resistances;

AE. whereas the widespread use of glyphosate on glyphosate-resistant crops over the last 20 years is known to have led to the development of resistant weeds, as the repeated use of glyphosate without sufficient alternation of weed killers or weeding practices has been found to highly favour the evolution of resistant weeds; whereas, in response, agro-biotech companies are adding further herbicide-tolerant traits to crops, as evidenced by three of the four genetically modified crops opposed by the European Parliament, a treadmill that may lead to an increase in the multi-resistance of weeds ([8]); whereas such a toxic spiral is not sustainable;

AF. whereas studies have shown that integrated pest management based on crop diversification, soil tillage regimes, sowing dates and mechanical weeding can reduce herbicide use while preserving crop yields and being more sustainable and environmentally friendly, with important biodiversity benefits ([9]);

([1]) http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0
([2]) http://www.ncbi.nlm.nih.gov/pubmed/26296738
([3]) http://enveurope.springeropen.com/articles/10.1186/s12302-016-0070-0
([4]) European Parliament resolution of 16 December 2015 on Commission Implementing Decision (EU) 2015/2279 of 4 December 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (MON-ØØ6Ø3-6 × ACS-ZMØØ3-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2015)0456).
([5]) European Parliament resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788 (MON-877Ø5-6 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2016)0040).
([6]) European Parliament resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2016)0038).
([7]) European Parliament resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87708 × MON 89788 (MON-877Ø8-9 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2016)0039).
([8]) http://www.ncbi.nlm.nih.gov/pubmed/26296738
([9]) http://ec.europa.eu/environment/integration/research/newsalert/pdf/ herbicide_reduction_can_preserve_crop_yields_as_well_as_-biodiversity_benefits_of_weeds_445na2_en.pdf

AG. whereas EFSA found in 2015 that for certain pesticides, including glyphosate, the number of determinations of maximum residue limits (MRLs) reported was significantly below the number needed to derive statistically sound conclusions; whereas, according to EFSA, reporting countries should extend the scope of the analytical methods used for enforcement of MRLs to make sure that the detection rate and the MRL exceedance rate are not biased by the low number of determinations or lack of data from certain countries ([1]);

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

AI. 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 with regard to glyphosate residues in relation to public health;

1. Considers that the Commission's draft 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 submit a new draft implementing regulation in order to better address the sustainable use of herbicides containing glyphosate; calls on the Commission to recommend that Member States in particular limit or prohibit the sale of glyphosate for non-professional users and ask for an assessment by the Commission, together with experts from Member States, to evaluate the use of plant protection products for non-professionals and make proposals, to develop training and user authorisation for professionals, to provide better information on the use of glyphosate, and to place strict limits on the pre-harvest use of products containing the active substance glyphosate;

3. Calls on the Commission to renew the approval of glyphosate for 7 years; recalls that under Regulation (EC) No 1107/2009 the Commission can withdraw the approval of an active substance during the period of its authorisation on the basis that new scientific evidence can demonstrate that it no longer satisfies the criteria for its approval; calls on the Commission and Member States to accelerate their work on the list of co-formulants not accepted for inclusion in plant protection products; welcomes the exclusion of POE-tallowamine from use in plant protection products containing glyphosate;

4. Calls on the Commission in particular not to approve any non-professional uses of glyphosate;

5. Calls on the Commission in particular not to approve any uses of glyphosate in or close to public parks, public playgrounds and public gardens;

6. Calls on the Commission in particular not to approve any agricultural uses of glyphosate where integrated pest management systems are sufficient for the necessary weed control;

7. Calls on the Commission to re-evaluate its approval in light of the pending submission of a dossier concerning the harmonised classification of glyphosate under Regulation (EC) No 1272/2008 to the European Chemicals Agency (ECHA);

8. Calls on the Commission to rapidly ensure an independent review of the overall toxicity and classification of glyphosate based on all available scientific evidence, including that relating to carcinogenicity of glyphosate, as well as possible endocrine-disruptive properties under the expected scientific horizontal criteria for endocrine disruptors;

([1]) http://www.efsa.europa.eu/sites/default/files/scientific_output/ files/main_documents/4038.pdf

9. Calls on the Commission and on EFSA to disclose immediately all the scientific evidence that has been the basis for the positive classification of glyphosate and the proposed re-authorisation, given the overriding public interest in disclosure; calls on the Commission furthermore to make all necessary efforts to facilitate full disclosure of the scientific evidence used in the context of the EU evaluation process;

10. 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;

11. Calls on the Commission and Member States to finance research and innovation with regard to alternative sustainable and cost-efficient solutions for pest-management products to ensure a high level of protection of human and animal health and the environment;

12. Is of the opinion that an appropriate follow-up of this resolution by the Commission is important for trust in and between the institutions of the European Union;

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