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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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EUROPEAN
COMMISSION

Strasbourg, 12.12.2017
C(2017) 8414 final

COMMUNICATION FROM THE COMMISSION

on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides"

(Only the English text is authentic)

1. INTRODUCTION

Under Article 11(4) of the Treaty on the European Union, not less than one million citizens who are nationals of a significant number of EU Member States may take the initiative of inviting the European Commission, within the framework of its powers, to submit any appropriate proposal on matters where citizens consider that a legal act of the Union is required for the purpose of implementing the Treaties.

“Ban Glyphosate and Protect People and the Environment from Toxic Pesticides” is the fourth European Citizens' Initiative to have met the requirements set out in Regulation (EU) No 211/2011 of the European Parliament and of the Council on the Citizens' Initiative ("the ECI Regulation")[1].

It was officially submitted to the Commission by its organisers on 6 October 2017. By that date, a total of 1,070,865 statements of support from 22 Member States had been checked and validated by national authorities. The Initiative calls on the Commission to propose to EU Member States:

"1. To ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans, and has led to ecosystems degradation;

2. To ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry;

3. To set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future."

The Initiative must be considered in accordance with EU Treaty rules, including notably the principles of conferral, proportionality and subsidiarity.

The Commission received the organisers on 23 October 2017. On 20 November 2017, the organisers were given the opportunity to present their Initiative at a public hearing organised at the European Parliament. *Annex I* provides further information on the procedural aspects of the Citizens' Initiative.

The present Communication sets out the Commission's legal and political conclusions on the Initiative, the actions it intends to take and the reasons for taking these in line with Article 10(1)(c) of the ECI Regulation.

[1] O.J. L 65, 11.3.2011, p. 1.

2. STATE OF PLAY – RULES AND PROCEDURES ON PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET IN THE EU

2.1. Approval of active substances and authorisation of plant protection products in the EU

EU rules distinguish between active substances, such as glyphosate, and plant protection products.

Active substances are the components of plant protection products that actually control harmful organisms (the so-called pests, such as insects, fungi and weeds) or plant diseases.

Plant protection products - which are often referred to as pesticides (e.g. insecticides, fungicides, herbicides) - are mixtures containing one or several active substance(s) and other ingredients (so-called co-formulants).

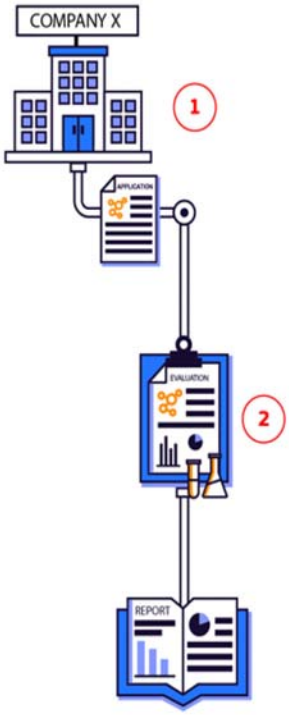
The legal framework for the placing of plant protection products on the EU Single Market is set by the Plant Protection Products Regulation[2].

Given that plant protection products are designed to have effects on (harmful or unwanted) living organisms, their placing on the market in the EU is strictly regulated so that all measures are taken to avoid potential adverse effects on human or animal health or the environment.

While active substances are approved at EU level, plant protection products are authorised by national authorities in each EU Member State taking into account their agricultural and environmental conditions.

[2] 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. OJ L 309, 24.11.2009, p. 1.

The approval process of **active substances** is as follows:



1. Company "X" submits an application for the approval of an active substance "Y" to any EU Member State (in case of renewals/reviews, the Member State is assigned by the Commission and cannot be chosen freely). That EU Member State – subsequently called "Rapporteur Member State" (RMS) – is then tasked with the initial scientific and technical evaluation of the active substance.

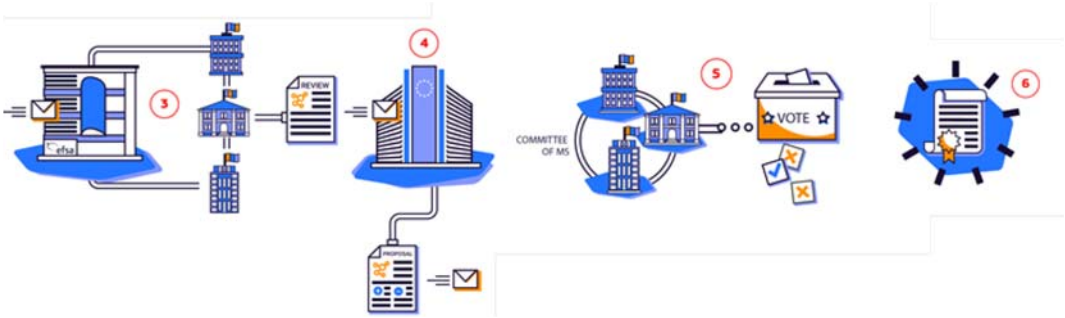
2. The RMS drafts an assessment report for the active substance "Y" and sends it to the European Food Safety Authority (EFSA), in charge of risk assessment.

3. In consultation with other EU Member States, EFSA carries out a peer review of the assessment report and sends its conclusions to the European Commission.

4. Based on EFSA's review, the European Commission, in charge of risk management, makes a proposal on whether or not to approve substance "Y".

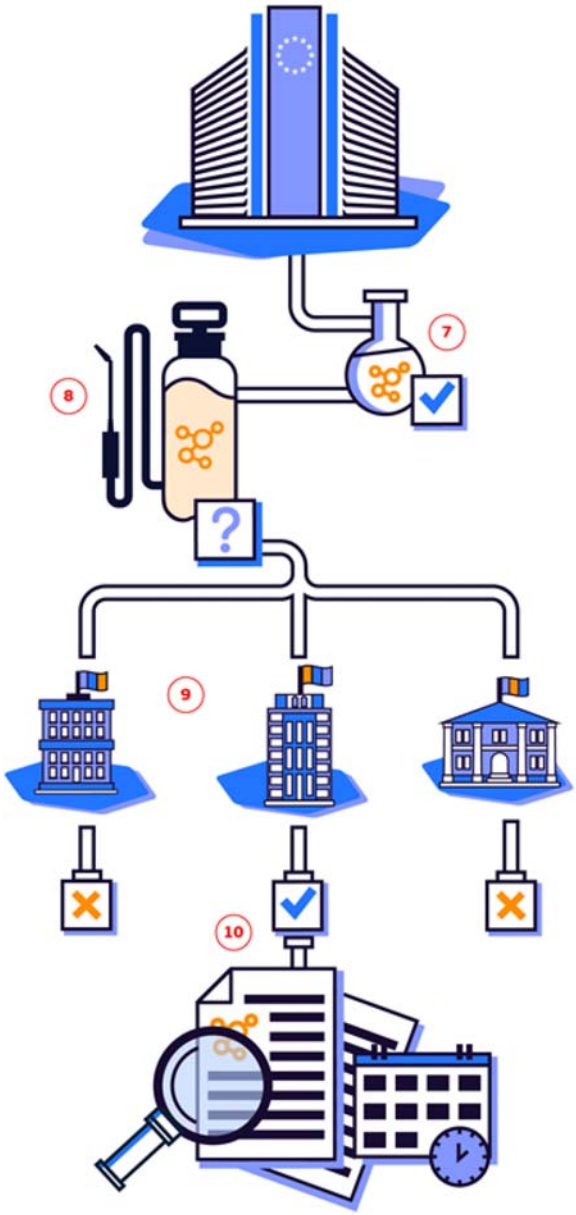
5. A regulatory committee composed of representatives of all EU countries votes on the Commission proposal for active substance "Y" (more information on Comitology procedure http://ec.europa.eu/transparency/regcomitology/index.cfm?do=FAQ.FAQ).

6. After the Committee has delivered an opinion, the Commission adopts and publishes a Regulation approving or refusing the approval of the active substance "Y".



As a result of the development and application of these EU rules, as well as business considerations, in the past 25 years the number of approved active substances in plant protection products has been cut down by approximately 50%.

The authorisation process of **plant protection products** is as follows:



7. After approval of an active substance at EU level…

8. …plant protection products containing it may be authorised by national authorities in each EU Member State.

9. EU rules allow Member States to refuse or restrict the use of plant protection products, based on the agricultural and environmental circumstances in their territory. For example, some Member States have not allowed the use of such products close to the harvest of cereals or by private consumers.

10. For authorised plant protection products Member States have to enforce their correct use according to their label.

The Commission checks the implementation of the legislation in the Member States by conducting audits, following up on any shortcomings and publishing all reports of these audits

The Commission regularly assesses whether the applicable regulatory framework is still fit for purpose under its REFIT programme[3]. It is currently conducting an evaluation of the Plant Protection Products Regulation and, in that context, a consultation of stakeholders and the public is ongoing[4]. The outcome of this REFIT evaluation will be presented in a report to the European Parliament and to the Council and is expected early in 2019. Furthermore, to ensure decision making based on the best available scientific advice, the Commission's Scientific Advice Mechanism is preparing an opinion on the authorisation processes of plant protection products. The opinion is expected before summer 2018.

[3] https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-and-less-costly_en.

[4] Further information can be found at: https://ec.europa.eu/food/plant/pesticides/refit_en.

2.2. Sustainable use of plant protection products

The current EU rules for pesticides ensure that only safe active substances and plant protection products which can be used safely are approved in the EU. They also promote low-risk active substances and non-chemical alternatives, and require measures to be taken that ensure a sustainable use of pesticides.

The EU Directive on the sustainable use of pesticides (SUD)[5] provides a framework for the reduction of risks and impacts of pesticide use on human health and the environment and for promoting the use of Integrated Pest Management (IPM) and alternative approaches or techniques, such as non-chemical alternatives to pesticides.

IPM is an integrated approach that combines different techniques aiming at keeping the use of pesticides and other forms of intervention only to levels that are economically and ecologically justified. Based on thorough monitoring of pest pressure, sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.

Member States describe how they implement the Directive in their National Action Plans (NAPs). These plans should contain quantitative objectives, targets, measurements and timetables to reduce the risks and impacts of pesticide use. The Directive identifies specific measures that Member States are required to include in their plans for proper implementation.

The main actions relate to:

- training of users, advisors and distributors,
- inspection of pesticide application equipment,
- prohibition of aerial spraying,
- limitation of pesticide use in sensitive areas, and
- information and awareness-raising about pesticide risks.

Today, the Common Agriculture Policy supports implementation of the SUD through measures such as the Farm Advisory Systems (aimed at supporting farmers in the implementation of IPM), Rural Development policy and the promotion of organic farming.

In addition, research and innovation under various Union programmes, such as EIP-AGRI[6] and the EU's Horizon 2020 programme[7] boost the development and uptake of plant protection innovations in sustainable plant protection on farms.

In October 2017, the European Commission adopted a report to the European Parliament and the Council[8] and published an overview report[9] on progress in the implementation of

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5 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, OJ L 309, 24.11.2009, p. 71.

6 https://ec.europa.eu/eip/agriculture/en/european-innovation-partnership-agricultural.

7 https://ec.europa.eu/programmes/horizon2020.

8 https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_sup_report-overview_en.pdf.

the Directive, which shows that implementation of measures remains patchy, as some Member States have been more active than others. Improvement is needed in particular as regards the use of all tools available under Integrated Pest Management. National plans are still very diverse in their completeness and coverage, and are currently being reviewed by most Member States.

While acknowledging the extensive measures put in place by EU Member States, the Commission encouraged them to improve their plans significantly to cover all elements of the Directive and to establish more precise and measurable targets. This was done through discussion in the Working Group, and by means of writing to all Member States to highlight the weaknesses identified in that country. EU Member States should have converted the IPM principles into prescriptive and assessable criteria. While a range of measures is taken to promote the use of IPM, this does not necessarily ensure that the relevant IPM techniques are actually implemented by professional users.

3. ASSESSMENT OF THE EUROPEAN CITIZENS' INITIATIVE REQUESTS

The European Commission has carefully analysed the requests of the European Citizen's Initiative and would like to offer the following assessment.

3.1. Aim 1 of the Initiative: "To ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans, and has led to ecosystems degradation"

Glyphosate[10]-containing plant protection products are used as herbicides, primarily to combat undesired plants (i.e. "weeds") that compete with cultivated crops in agricultural production or to control plants that may be a problem for other reasons (e.g. on railway tracks where removing weeds is essential for track safety) or by amateur users. In agriculture, they are typically applied before crops are sown to facilitate better growth of crops by eliminating competing plants. This eliminates or minimises the need for mechanical weeding and, in so-called "low tillage" farming, for ploughing[11] thereby reducing soil erosion and carbon emissions. Glyphosate is also used to a lesser extent as a pre-harvest treatment to control certain types of weeds or to facilitate better harvesting by regulating plant growth and ripening.

Following the introduction of the relevant EU legislation, glyphosate has been approved for use since 1 July 2002 after its first scientific review under Directive 91/414/EEC[12] (which has been repealed and replaced by the current Plant Protection Products Regulation). Previously it was on the market in Member States in accordance with national rules. From 2012 to 2017, glyphosate has been through an updated scientific evaluation to consider whether it still meets the safety criteria in the EU rules.

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9 http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=114.

10 *N*-(phosphonomethyl)glycine ($C_3H_8NO_5P$).

11 Low-till agriculture is a practice in which soil disturbance is kept to a minimum to preserve the topsoil. This increases the water holding capacity of the soil as well as the content of organic matter and nutrients. This practice allows new plants to grow more effectively and helps to reduce soil erosion.

12 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L 230, 19.8.1991, p. 1.

3.1.1. Impacts on human health

The active substance glyphosate has been evaluated in line with the process described in section 2.1. A comprehensive and transparent assessment of all available data and information was carried out by the Rapporteur Member State, Germany, and peer reviewed by all other EU Member States and EFSA. A public consultation[13] was carried out on the assessment by the Rapporteur Member State which provided a platform for citizens and other stakeholders to voice their concerns and submit views and further information.

In March 2015 the International Agency for Research on Cancer (IARC, the specialised cancer agency of the World Health Organisation) published its monograph[14] on glyphosate, concluding that glyphosate should be classified as 'probably carcinogenic to humans'. Consequently, during the EU peer review the Commission requested EFSA to take into account the IARC monograph to ensure that all relevant information was available for its Conclusion[15]. The peer review process also included detailed expert discussion on the genotoxic and carcinogenic potential of glyphosate, as well as other issues, and took epidemiological data into account. All of the assessments and peer review documentation, including background documents, have been made available on the EFSA website[16].

With regards to the assessment of carcinogenicity, EFSA concluded that 'glyphosate is unlikely to pose a carcinogenic hazard to humans'. In light of the diverging view between EFSA and IARC, the Commission decided[17] to extend the approval period of glyphosate until 6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the European Chemicals Agency (ECHA) on the harmonised classification as regards carcinogenicity of this active substance. In accordance with EU legislation[18], it is the role of the Committee for Risk Assessment of ECHA to carry out scientific assessment of proposals for harmonised classification of substances. The ECHA Committee concluded by consensus on 15 March 2017 that a classification of glyphosate as carcinogenic is not justified and forwarded its opinion to the Commission on 15 June 2017. ECHA also concluded that glyphosate should not be classified as mutagenic or toxic for reproduction. The same conclusion was reached by EFSA, supported by experts from all EU Member State competent authorities. That conclusion is shared by other national and international bodies (from Canada, Japan, Australia and New Zealand, and also the Joint UN Food and Agriculture Organisation/World Health Organisation Meeting on Pesticide Residues (JMPR)).

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13 http://dar.efsa.europa.eu/dar-web/provision.

14 http://monographs.iarc.fr/ENG/Monographs/vol112/mono112.pdf.

15 EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, 107 pp. doi:10.2903/j.efsa.2015.4302. See also http://www.efsa.europa.eu/en/corporate/pub/glyphosate151112.

16 https://www.efsa.europa.eu/en/press/news/151119-1.

17 **Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate** OJ L173, 30.06.2016, p. 52-54.

18 Regulation of the European Parliament and of the Council (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, OJ L353, 31.12.2008, p. 1.

IARC's is therefore the sole assessment which concluded that glyphosate is 'probably carcinogenic to humans'. Among the reasons for this different view of IARC, as also highlighted in the explanatory note of the Commission's Scientific Advice Mechanism[19], are the following: the IARC looked at both glyphosate – the active substance – and glyphosate-based plant protection products. The EU assessment, on the other hand, considered only glyphosate, as Member States are responsible for evaluating each plant protection product that is marketed in their territories[20]. Furthermore, IARC only considers published studies, whereas the EU assessment also considers studies submitted by applicants as part of their dossiers that are not in the public domain as explained under 3.2.1 below. In total, the EU assessment considered more evidence including additional key studies that were not considered by IARC[21]. These distinctions mainly explain the differences in how EFSA and IARC weighed the available data.

Concerns and allegations publicly raised about the quality and robustness of the EU assessment were checked on each occasion at the request of the Commission by ECHA, EFSA and the German Federal Institute for Risk Assessment (BfR), in charge of the assessment of glyphosate in the Rapporteur Member State. In all cases, these bodies concluded that the concerns and allegations were unfounded[22, 23].

3.1.2. Impact on ecosystems

The EU review took into account the estimated levels of glyphosate in soil, water and air and a full risk assessment was undertaken for non-target organisms (for example: birds, mammals, insects). The EU assessment did not provide any evidence that indicates ecosystem degradation caused by glyphosate when it is used in accordance with the conditions of authorisation and in line with good agricultural practice.

However, as the intended use of glyphosate – and the same applies for other herbicides – is to eliminate competing plants, it is possible that foodwebs[24] could be influenced. Therefore, measures to reduce such risks that are linked to agricultural practices and land conditions (e.g. no-spray zones, drift reduction technology[25]) are considered and, where necessary, imposed by Member States when granting authorisations for glyphosate-based pesticides.

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19 Explanatory note on scientific advice for the regulatory assessment of glyphosate in plant protection products. https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_glyphosate.pdf.

20 It should be noted though, that in accordance with Article 29(3) of the Plant Protection Products Regulation, the Commission may at any time review co-formulants used in plant protection products. Commission Implementing Regulation (EU) 2016/1313 banned the dangerous co-formulant POE-tallowamine from glyphosate-based products.

21 EFSA has published in 2015 a factsheet outlining the differences in the assessments (e.g. the data sets used, which are determined by the rules that govern each agency) and the outcomes between the IARC and EFSA evaluations. https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf.

22 https://echa.europa.eu/chemicals-in-our-life/hot-topics/glyphosate.

23 https://www.efsa.europa.eu/en/topics/topic/glyphosate.

24 Foodwebs are natural connections of food chains that integrate to form a network. They represent realistic feeding relationships in an ecosystem.

25 Drift reduction technology refers to the devices/systems/technologies that have been scientifically verified to reduce the drift of pesticides during application, thus reducing exposure to the environment. For example, special nozzles can be fitted to sprayers so that the product is directed downwards without drifting and being deposited in unintended areas.

In accordance with Article 11 of the Treaty on the Functioning of the European Union (TFEU), the protection of the environment, ecosystems and biodiversity is a cornerstone of EU legislation, and has to be integrated into sectoral policy including the Common Agricultural Policy[26]. EU Member States must consider it when granting authorisations for plant protection products. It should also be noted that many of the available chemical alternatives that can do the same job as glyphosate carry higher risks. There are also non-chemical alternatives to glyphosate although these have some limitations and are not always a better option.

3.1.3. Conclusion

The approval or non-approval of substances such as glyphosate falls under the Commission's implementing powers under the Plant Protection Products Regulation. Given the comprehensive scrutiny of all available information, there are currently no grounds to call into question the scientific assessments and conclusions on glyphosate carried out in the EU. On that basis and given that the scientific assessment of glyphosate by EFSA is favourable with regards to human and animal health and the environment, in November 2017 the Commission submitted to Member States a draft Implementing Regulation for the renewal of the approval of the substance for 5 years. On 27 November 2017, a qualified majority of Member States supported the draft Implementing Regulation and the Commission adopted it on 12 December 2017. This renewal period is significantly shorter than the maximum of 15 years foreseen in EU legislation but the Commission also took into account the views of the European Parliament and other legitimate factors when setting the appropriate period of renewal. In fact, the Commission has taken into account possibilities of rapid future developments in science and technology: while a large amount of information on the active substance glyphosate already exists, additional information on glyphosate is being published at an exceptionally high rate compared to other active substances and a priority re-assessment of glyphosate over other substances should therefore be ensured. Moreover, the Commission has acknowledged that there has been considerable debate on glyphosate in the public sphere, as illustrated by this Citizens' Initiative and the two Resolutions adopted by the European Parliament on the matter[27]. It should also be highlighted that the Commission can, at any time, review the approval of glyphosate if new scientific evidence emerges that indicates that the substance no longer fulfils the approval criteria laid down in the Plant Protection Products Regulation.

For the same reasons, the Commission has no basis to submit to the co-legislators a proposal to ban glyphosate[28]. However, Member States have the obligation to evaluate all authorisations for glyphosate-containing plant protection products and may decide to introduce restrictions or bans for some or all of them where this is warranted on the basis of evidence related to the particular circumstances in their territories.

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26 https://ec.europa.eu/agriculture/cap-overview_en.

27 Full details on the process followed for the renewal of approval of glyphosate, the Commission's draft Implementing Regulation and discussions with Member States can be found on the dedicated glyphosate webpage of the Commission: https://ec.europa.eu/food/plant/pesticides/glyphosate_en.

28 According to Article 11(4) of the Treaty on European Union, a European Citizens Initiative cannot call for the adoption of a legal act by the Commission - such as a Commission Implementing Regulation on non-renewal of the approval of an active substance – but only for a proposal from the Commission for a legal act.

3.2. Aim 2 of the Initiative: "To ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry"

3.2.1. Transparency related to studies that are used for scientific evaluation

The studies and other information that must be submitted by the industry for the evaluation of active substances and plant protection products ('data requirements') are specified in legislation[29,30], which is regularly updated in the light of technical and scientific progress. They have to comply with internationally recognised protocols (e.g. test guidelines developed by the Organisation for Economic Co-operation and Development – OECD) and be conducted in compliance with the standardised principles of Good Laboratory Practice[31] (GLP), a system for the management and quality control for research laboratories and organisations[32]. Test facilities that conduct such studies are regularly inspected by national monitoring authorities and, in case of doubts, specific audits can be carried out by such authorities[33].

Applicants must also include scientific peer-reviewed open literature on the active substance in their dossier. This system ensures that scientific assessments are consistent and rigorous (as a standard set of safety studies is always required), taking into account all available information so that conclusions are balanced and scientifically sound. Risk assessors are therefore provided with information from various sources and not only from the specific company that seeks to put its product on the market.

From the data package submitted by applicants and from the assessment by Member States and EFSA, a significant part is already made publicly available. This includes the summary dossier, the Assessment Report of the Rapporteur Member State on which EFSA carries out a public consultation, all comments from Member States' experts and the public and the responses thereto, reports of peer review expert meetings, and the EFSA Conclusion. Over 6,000 pages were made public in the case of glyphosate.

The interplay between the various transparency and confidentiality rules and its impact on the acceptability of the risk assessment by the general public has been highlighted in the context of the Fitness Check of Regulation (EC) No 178/2002 on General Food Law ('General Food Law Regulation'), [34] which is about to be finalised. Such rules are laid down in the multiple authorisation procedures in EU secondary legislation, including the

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29 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. (OJ L 93, 3.4.2013, p. 1).

30 Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, 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. (OJ L 93, 3.4.2013, p. 85).

31 http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en.

32 The principles of GLP are laid down in Directive 2004/10/EC of the European Parliament and of the Council Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances. OJ L 50, 20.2.2004, p.44.

33 Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28).

34 Regulation (EC) No 178/2002 of the European Parliament and 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 (OJ L 31, 1.2.2002, p. 1).

general provision on confidentiality in the General Food Law Regulation and the EU rules on access to documents (*i.e.* Regulation (EC) No 1049/2001). The confidentiality rules result from the obligation to protect business secrets and other confidential information in line with the TFEU and the relevant case law of the Court of Justice of the European Union. Addressing a perceived lack of transparency may require an adjustment of certain procedures while continuing to ensure the legitimate balance between the interests of stakeholders wanting a maximum of transparency and the protection of legitimate business secrets of applicants in authorisation proceedings before EFSA.

The Commission fully agrees that transparency in scientific assessments and decision making[35] is vital to ensuring trust in the regulatory system and will take measures to clarify and increase transparency of the current risk assessment process. The Commission will propose changes to the legislation to increase the transparency of studies commissioned by industry that are submitted in application dossiers, while respecting the principles set in the Treaty regarding the protection of legitimate confidential business information, including measures such as public access to raw data from study reports, thus reducing the need for stakeholders to have recourse to access to documents procedures.

3.2.2. Commissioning of studies by public authorities

The system in place for active substances is similar to the ones applied in other sectors such as industrial chemicals, food additives, biocides and pharmaceuticals.

The principle is that public money should not be used to commission studies that will eventually help industry put a product on the market, especially since individual studies cost between several thousand to several million euro each, and each dossier can contain up to several hundred studies.

This is why the EU Plant Protection Products Regulation places the burden of proof to demonstrate that an active substance and the products containing it can be used safely and to generate the necessary information for such demonstration on those who stand to benefit from its approval, i.e. the companies manufacturing or marketing the substance and the products. Studies required for application dossiers are commissioned directly by industry on their own initiative. There are claims that since industry pays directly for the conduct of the studies this may be an incentive for the laboratories to deliver results that please their clients to secure future business. However, as explained in the preceding section, test facilities carrying out such studies are subject to rigorous inspections for their adherence to the principles of GLP, and if these test facilities are found to manipulate the results of studies either as part of a regular inspection or a specific study audit, they will lose their GLP certification.

A systematic approach that would oblige public authorities to commission all studies for active substances and plant protection products – while maintaining the principle that the costs are covered by industry - may prove to be challenging given the high numbers of studies required to support all applications for active substance approval and product authorisation.

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[35] In this context, in February 2017, the Commission proposed to amend the Comitology Regulation, increasing transparency and accountability in the procedures for implementation of EU legislation, available at: http://europa.eu/rapid/press-release_IP-17-264_en.htm.

The Commission will propose to amend the legislation to strengthen the governance for the conduct of such studies, which could include for example, an involvement of public authorities in the process of deciding which studies need to be conducted for an application dossier[36], enhanced auditing of studies conducted in accordance with the principles of GLP, measures to increase transparency as to the findings of such studies as discussed in the preceding section, and the possibility to exceptionally commission ad-hoc studies in case of serious doubts or conflicting results, for example, in case of widely used substances[37].

3.2.3. Allocation of Member State conducting the initial assessment

Applicants can choose the Member State to whom they submit applications for the first approval of active substances and the application will be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it. Nevertheless, as explained above, the assessment by the Member State authority is only the first step in a multi-step process, followed *inter alia* by a peer review by other Member States, as described in Section 2.1.

However, for the renewal of approval of active substances, which constitutes the majority of scientific evaluations, it is not applicants but the Commission which allocates in a Regulation the Rapporteur Member State during the establishment of renewal work programmes. In so doing, the Commission strives for a balanced distribution of the workload between the different Member States, taking into account a number of factors including their resources and capacity, the grouping of substances with similar profiles to facilitate more coherent and efficient evaluations and past experience that may be beneficial to the review.

Therefore the Commission considers that overall the system is appropriate.

3.3. Aim 3 of the Initiative: "To set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future."

3.3.1 Achieving a pesticide-free future

EU policy in the area of pesticides is not directed towards the total elimination of all pesticides. There will be cases where resort to the use of pesticides is necessary. Instead the policy of the EU is directed towards ensuring that we achieve a sustainable use of pesticides. Achieving sustainable use will reduce our dependency on pesticides and go a long way towards addressing the aspirations behind Aim 3 of the European Citizens' Initiative.

Going forward the Commission aims to ensure that the Member States comply with their obligations under the SUD and reduce EU dependency on pesticides by fully applying

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[36] In the context of (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) the REACH Regulation, registrants submit testing proposals that have to be validated by the European Chemicals Agency (ECHA) following a public consultation. Likewise, under the evaluation process of REACH, ECHA can oblige registrants to conduct additional studies to clarify an initial concern.

[37] The United States National Toxicology Programme (NTP) is an example of how a public authority, in this case funded by public money, can be used to commission scientific research into the properties of chemical substances. However, this programme can only cover a limited number of chemicals or agents of public health concern, and targets certain high profile topics to strengthen the science base in toxicology.https://ntp.niehs.nih.gov/.

the eight principles of Integrated Pest Management set out in Annex III SUD. The Commission will aim, in collaboration with Member States, to convert the IPM principles into prescriptive and assessable criteria, enabling verification of their compliance at individual farmer level, an area where Member States need to make additional efforts. This will be supported by a series of Better Training for Safer Food courses on the practical implementation of this verification at farm level starting in 2018. The Commission will also follow up implementation through meetings with Member States, audits to Member States starting in 2018, and the assessment of the revised Member States National Action Plans, which should be submitted to the Commission during 2018.

One of the reasons why the Citizens' Initiative is requesting a move towards a pesticide free future is the perception that farmers are using pesticides on a regular basis and not "as last resort" in cases of heavy pest infestations. It is important to point out that similar limitations for the use of pesticides are set out in the SUD. In particular, in accordance with IPM principles set out in the Directive, it is required that "other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control" and that where pesticides are used they must be "as specific as possible to target and shall have the least side effects on human health, non-target organisms and the environment".

3.3.2 Setting mandatory reductions targets for pesticide use

The SUD requires the reduction of risks and impacts from pesticide use. The risks from pesticides depend not only on the volumes applied, but also on other factors, notably:

- substances used as pesticides encompass a wide range of compounds with different characteristics, including low-risk substances such as acetic acid, and biological substances;

- the conditions of application, e.g. whether operators are trained to use pesticides safely and spraying equipment is tested for accurate and safe application.

Member States experience so far is that mandatory volume reduction targets alone do not necessarily reduce the risk from pesticide use. Some countries like Denmark[38] started out with the aim of reducing the overall quantity of pesticides used. Now, however, they have moved towards a more sophisticated approach to risk reduction which considers various criteria such as relative toxicity rather than just volume. The rationale is that pesticides have different intrinsic properties and rates of use, and using more of a pesticide with a relatively benign environmental and/or toxicological profile may entail a lower risk than using a lower quantity of pesticide with a less favourable profile.

Given the above, the focus of the Member States and of the Commission's work is on reduction of risk from pesticide use rather than a simple volume reduction of all pesticides. In order to monitor trends in risk reduction from pesticide use at EU level, the Commission will establish harmonised risk indicators, in 2018 in addition to existing national risk indicators. These would enable the Commission to determine the effectiveness of measures in the context of assessing future policy options.

The Commission does not envisage at this stage to submit a proposal to establish EU level reduction targets for pesticide use . Following the assessment of the new National Action Plans and the targets established in these, and the results of audits in Member States, the Commission will re-evaluate the situation in the context of a second report to

[38] http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3897.

the European Parliament and the Council to be produced in 2019. The report will take account of the experience gained by Member States in implementing national risk reduction targets. Should this assessment and any subsequent trends in harmonised risk indicators demonstrate that sufficient progress has not been achieved, the Commission could consider the opportunity of setting an EU-wide mandatory target on reduction of risk from pesticides.

4. CONCLUSIONS

In reply to the European Citizens' Initiative "*Ban Glyphosate and Protect People and the Environment from Toxic Pesticides*", the Commission concludes as follows:

The Commission welcomes the mobilisation of European citizens in relation to the use of pesticides in the EU. The Citizens' Initiative has provided an excellent opportunity to critically examine the regulatory system for plant protection products in the EU. The Commission will continue to evaluate this framework in the context of the ongoing REFIT evaluation and the forthcoming opinion of the Scientific Advice Mechanism. The Commission also underlines that achieving a sustainable use of pesticides through implementation of the SUD would go a long way towards addressing some of the concerns behind the Citizen's Initiative.

On the first aim to ban glyphosate-based herbicides, the Commission considers that there are neither scientific nor legal grounds to justify a ban of glyphosate, and will not make a legislative proposal to that effect. In particular, the scientific evidence does not support the conclusion that glyphosate has the potential to cause cancer. Therefore, the Commission's decision to renew the approval of glyphosate (for 5 years) is fully justified.

On the second aim, the Commission fully agrees that transparency in scientific assessments and decision-making is vital to ensuring trust in the regulatory system. It also attaches continued importance to the quality and independence of the scientific studies that are the basis of the EU risk assessment carried out by EFSA. The Commission will thus come forward with a legislative proposal by May 2018 covering these and other aspects such as the governance of EFSA, drawing on the results of the Fitness check of the General Food Law and after a public consultation to be launched shortly.

Finally, on the third aim, the Commission will strengthen efforts for the continuous and measurable reduction of risk from pesticide use. The Commission expects Member States to improve their NAPs to establish more clear and measurable targets for risk reduction and to address the identified shortcomings on implementation. It also intends to establish harmonised risk indicators to enable the monitoring of trends at EU level and to use the resulting data as a basis for determining future policy options. The Commission will re-evaluate the situation, initially in the report to Council and the Parliament to be produced in 2019.

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For the Secretary-General,

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EUROPEAN COMMISSION