SEVEN REASONS TO BAN GLYPHOSATE - IT'S TIME TO STAND UP TO MONSANTO!

What is glyphosate, and why should you be worried about it?

Glyphosate is a chemical used in herbicides such as Monsanto's *Roundup* and recently became the <u>most used agricultural chemical of all time</u>. It is a so-called 'total herbicide' - meaning that it is not specific against any particular weed, but kills all herbage, be they weeds or beneficial organisms. Despite its widespread use, there's a good chance you won't have heard of it, and the chemical giants would probably be happy if it stayed that way.

Why? Well, in addition to being so extensively used, there are also serious concerns about its safety for human health and the environment. The license for its use in the EU expires at the end of June 2016, granting the Commission a perfect opportunity to place an effective ban on the substance. However, on 24 February 2016, the Commission brought forward a draft implementing act to do exactly the opposite: it wants to extend the license for 15 years until 2031, the maximum period possible, and even lift existing restrictions. Moreover, it does not propose any legally binding conditions on the use, but instead passes the buck to Member States to 'pay particular attention' to important risks. All it suggests is no longer allowing one very problematic co-formulant in glyphosate-based pesticide formulations as if this was the sole culprit.

The draft act will be the subject of a meeting of EU government officials on 7-8 March at which they are expected to give their opinion, a necessary step for any decision on approval (for more details, see "The Approval Process"). With such a tight deadline, it is vital that the arguments in opposition to the renewal of the approval of glyphosate are aired as soon as possible.

In coming to its decision, the Commission was required to consider three key elements (see Art. 13(2) of Regulation 1107/2009):

- its own review report, taking account of the conclusions of the <u>European Food Safety</u> <u>Authority (EFSA)</u>
- the "precautionary principle"
- any other factors legitimate to the matter under consideration.

We don't think that glyphosate passes these tests, and below we set out seven reasons why the member states should reject the draft implementing act and refuse to grant Monsanto - and 23 other companies - license to continue using this dangerous substance.

Chemical giants like Monsanto are used to getting what they want. If not, they will take court action - and indeed, chemical companies have a long track record of doing so systematically in case of non-approval of their substances. This case could have been an opportunity for the Commission to show courage and put people's health and environment protection before corporate profit, but they are afraid of the court challenge by Monsanto et al.. As the Commission has decided not to take that opportunity, it falls on the Members States in the Standing Committee to show the leadership required to make agriculture more sustainable for future generations.

The Approval Process

The Commission will present their draft implementing act to the Standing Committee on Plants, Animals, Food and Feed. This is scheduled for 7-8 March.

- If the Committee delivers, by qualified majority vote (QMV), a positive opinion on the proposal, the Commission shall adopt the draft implementing act and **the glyphosate license** will be approved.
- If the Committee delivers either a negative opinion, or no opinion (i.e. no QMV either in favour or against), the draft will not be adopted, and **the glyphosate license will expire**.

Amend or Appeal?

The Commission can then submit an amended proposal, or resort to an Appeal Committee.

- If the Appeal Committee then delivers a positive opinion by QMV, the Commission shall adopt the draft implementing act, and the glyphosate license will be approved.
- If the Appeal Committee then delivers no opinion, the Commission **may** adopt the draft implementing act, renewing the glyphosate license.
- If the Appeal Committee delivers a negative opinion, the Commission shall not adopt the draft implementing act, and **the glyphosate license will expire.**

For further information, see Articles 5 and 6 of Regulation 182/2011

REASON ONE: Glyphosate could be seriously damaging your health

There is a ferocious <u>scientific debate</u> ongoing as to whether glyphosate is **carcinogenic** or not. While the renowned International Agency for Research on Cancer of the World Health Organisation has concluded that glyphosate is "<u>probably carcinogenic in humans</u>", EFSA found the opposite. Classification of glyphosate as a probable human carcinogen would in principle disqualify glyphosate from further approval (with the possibility of two narrow exemptions).

Glyphosate-based formulations are not only used in agriculture, but also in public and private gardens, potentially putting both farmers as well as consumers at risk. According to EU chemicals legislation, carcinogens should not be sold to the general public.

The ultimate decision on the proper classification of glyphosate lies with the European Chemicals Agency. However, this process is only about to start, and is likely to take at least 18 months. To renew the license for glyphosate before a final determination has been made would be to take a significant gamble with human health.

Further, there are <u>studies</u> that show that herbicides containing the chemical act like <u>endocrine</u> disrupters - substances which play havoc with our hormones, and which can impact inter alia on fertility. And as the substance was not properly tested for such effects, EFSA could not rule out that it may act like an endocrine disrupter. This is important insofar as endocrine disrupting substances are also legally disqualified from approval (with the possibility of two narrow exemptions).

In spite of these potential dangers, we continue to be exposed to this dangerous chemical in our everyday lives. Residues are found in food and its levels were found to <u>increase in our bodies</u>.

The pesticides regulation explicitly empowers the Commission to take provisional risk management measures necessary to ensure a high level of health "in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists" (Art. 7(1) of Regulation 178/2002, referred to in Art. 13(2) of Regulation 1107/2009). This is clearly the case here with regard to the probable

carcinogenicity of glyphosate as well as possible endocrine-disrupting properties of glyphosate-based formulations, but disregarded by the Commission. For this reason, the Member States should reject the Commission's proposal.

REASON TWO: Glyphosate is a threat to animals and plants, too

It's not just human health that may suffer as a result of glyphosate. According to the pesticides regulation, active substances in pesticides shall have no unacceptable effects on the environment (i.e. inter alia animals and plants other that the pest to be controlled = non-target species), including on biodiversity. However, as a total herbicide, glyphosate affects "non-target" species - not only beneficial plants, but also animals. EFSA found a **high long-term risk to mammals, in particular herbivorous mammals** (e.g. farm animals such as cows and sheep), **as well as wild species** (e.g. birds and the common mole). For mammals, the high long-term risk was related to major applications, such as pre-planting and post-planting use on all crops. For small herbivorous animals, the high long-term risk was indicated for use in orchards. For birds, the high risk was found when used in pre-harvest applications for cereals.

However, instead of restricting the approval accordingly, the Commission considers these high risks to be acceptable, and passes the buck to Member States to 'pay particular attention' to them, and to include risk mitigation measures in the condition of use only 'where appropriate'. The conditions indicated by the Commission in the draft implementing act are not only non-binding, they are also so vague that they become meaningless.

Importantly, in doing so, the Commission disregards a decision by the Ombudsman of 18 February 2016 that stated that the "Commission cannot discharge its responsibility for ensuring effective protection of human health, animal health and the environment when approving active substances if it allows Member States almost absolute discretion as regards the definition of mitigation measures for potentially unsafe substances", paragraph 48). The ombudsman goes on to state that "this situation is even more problematic in circumstances where the Commission does not verify that the necessary precautions are in fact taken and that the restrictions or instructions, envisaged by the Commission's approvals of use of active substances, are complied with" Indeed, the Commission has no powers to directly check compliance with any conditions set. In other words, the Commission is not only passing the buck with regard to how to address major risks, it also rids itself of any responsibility for checking compliance with any (window-dressing) conditions it sets.

Moreover, the German Environment Agency has found significant adverse effects on biodiversity due to pesticides in general and glyphosate in particular. Glyphosate does not only kill target weeds, but also useful herbage in and close to fields treated with glyphosate. These plants are an important source of food for insects and other wild animals. The German Environment Agency states that the widespread use of total herbicides such as glyphosate in intensive agriculture represents a significant danger for certain birds and is co-responsible for the continuous decrease of such populations. While it clarifies that glyphosate is not the sole culprit, it explicitly states that it is the main culprit since it accounts for by far the highest amount used (one-third of all herbicides used in agriculture). The German Environment Agency demands that ecological compensatory measures (e.g. biodiversity strips, fallow lands) become an integral condition for any approval, and that the proportion of organic farming without such pesticides should be significantly increased.

Glyphosate has harmful effects on animal health and unacceptable effects on biodiversity. It therefore fails to comply with the approval criteria laid down in the Regulation and Member States should therefore not agree to grant a continued license. The decision by the Ombudsman with regard to the Commission's responsibility for proper risk mitigation measures is a very

legitimate factor to be considered. Member States should not allow the Commission to disregard such legitimate concerns.

REASON THREE: GMOs and Glyphosate, two sides of the same coin

In many ways glyphosate and GMOs can be seen as two sides of the same coin. Of the 61 GMOs authorised in EU for import, more than half of them are glyphosate tolerant plants, designed to be used with that specific herbicide. They are both tools for the same kind of agriculture - one that is intensive, harmful to the environment and health, and bad for the local rural economy. Many cases of cancer and physical deformities have been reported in people and animals in South America, where extensive areas of land have been planted with glyphosate-tolerant GM soya in order to export animal feed to Europe.

When the European Parliament objected to the last four GM plant authorisations for import (for maize and soybeans), one of the reasons given was their tolerance to glyphosate. Many Member States are against authorisations of GMOs. Given the direct link of many GMOs to glyphosate, those Member States should be very wary of re-approving glyphosate.

By rejecting glyphosate, we can stand up for the health of people in the EU and beyond, the environment, show support for local economies and stop the expansion of GMOs.

REASON FOUR: The expansion of harm

Glyphosate is harmful all by itself. But herbicides such as *Roundup* contain **a cocktail of chemicals** that can be <u>more toxic</u> than glyphosate alone, with even more risks for farmers as well as the general public. While the pesticides Regulation of 2009 granted the Commission the power to establish a negative list of unacceptable co-formulants, the list is still empty. After decades of use of *Roundup* and similar products, some Member States have woken up to this problem and have launched an <u>investigation</u> into all co-formulants in pesticides, in particular for glyphosate-based preparations. In light of all the controversy around glyphosate, the Commission now wants to ban one of these co-formulants from glyphosate-based preparations (so called POE-tallowamine), and assess others with a view to putting them on a negative list. While this long overdue action is welcome, it does not go far enough, and seems to be designed to let glyphosate off the hook.

In addition, glyphosate-resistant "super weeds" have already spread in the USA and Canada due to overuse of *Roundup* applied on glyphosate-resistant GM crops. To stop the proliferation of these super weeds, even more resistant genetically engineered plant variety have been approved for commercial use that are resistant to multiple herbicides, including possibly more toxic and environmentally disruptive than glyphosate. This agriculture model based on wide herbicide use and creating monster resistant plants is no longer effective. It has an impact on the environment and on the farmers who are dependent on these products for their work.

Glyphosate is not only used to kill weeds. It is also used widely for 'pre-harvest desiccation'. Desiccation means drying out the plants, and this is done to accelerate the ripening of the fruits prior to harvest. In other words, a substance with known and/or probable serious risks to human health and the environment is used prior to harvest to gain some time. This has been criticized by the <u>German Environment Agency</u>, which states that 15% of the total consumption could be reduced by no longer using glyphosate for desiccation. But instead of actively prohibiting this application, the Commission wants to do the opposite by approving glyphosate for any use, lifting the existing limitation of the approval as a herbicide.

Action on harmful co-formulants is welcome, but cannot justify re-approval of glyphosate. Glyphosate stands for an ever more harmful agricultural model. Given the absence of any measures to reduce the use of glyphosate, Member States should refuse the re-approval proposed by the Commission.

REASON FIVE: Critical gaps in the evidence

EFSA indicated as a 'critical concerns' that eight out of 24 applicants, including Monsanto, presented specifications for glyphosate that were not supported by the toxicological assessment. In other words, the test data these applicants provided were for substances other than those they actually want to sell. A 'critical concern' means that the assessment does not allow concluding that the glyphosate-based pesticide may not have any harmful effect on human health or animal health or on groundwater or any unacceptable influence on the environment. It is highly worrying that one third of the applicants have submitted toxicologically irrelevant data to defend their applications. The Commission tries to deal with this issue by obliging Member States to ensure equivalence between the substance to be commercialised and the test material to be used in toxicological studies for their approval of glyphosate-based products. This does not instil confidence.

EFSA lists as a concern that it could not rule out that glyphosate may act like an endocrine disrupter, as the assessment with regard to endocrine disrupting properties could not be finalised due to data gaps (see also point 1). The Commission tries to deal with that by obliging the applicant to provide 'confirmatory information as regards the absence of endocrine disrupting properties that may cause adverse effects in humans' by 1 August 2016. In other words, despite stated concerns about incomplete assessment, the Commission wants to first grant approval, demanding that the missing data, data that concerns a key approval criterion, can be handed in later. This flies into the face of the decision by the Ombudsman of 18 February 2016, which stated that the Commission should only grant approval subject to "confirmatory data" in a more restrictive manner and with particular caution and restraint (see paras 22 and 23).

Altogether, the EFSA report lists 22 data gaps in the evidence - a "List of studies to be generated, still ongoing or available but not peer reviewed". However, the Commission does not indicate any follow-up to most of them, thus leaving key issues such as the detection of glyphosate in certain plants, in animal fat, all animal matrices and in soil without confirmed methods (submission date proposed by the applicant is unknown to EFSA).

Given the critical concern about invalid test data, concerns about missing data with regards to a key approval criterion, and a long list of data gaps - and given the known and probable risks to human and animal health due to glyphosate, we should be looking to ensure that we have all the necessary evidence before approving a substance for such sweeping use. Indeed, the precautionary principle would surely suggest such an approach.

REASON SIX: Lack of Transparency

Not only are there gaps in the evidence, key studies are being hidden from public scrutiny. In addition, key conclusions of the EFSA report with regard to the carcinogenicity of glyphosate are based on exactly those unpublished studies, all of which were produced by the industry themselves. It is unacceptable that the unpublished studies are being allowed to outweigh the publically available information. This does not create a level playing field, nor allow for independent scrutiny and calls into question the credibility of the EFSA assessment.

Further, more than 80% of the national experts involved in the EU's official assessment of glyphosate refused to have their names disclosed to the public, thus not allowing any assessment of possible conflicts of interests (see CEO article).

At the same time, industry and industry-funded scientists are given access to draft assessment reports (see study Greim et al.), while EFSA as well as the rapporteur member state refuse access to such reports to NGOs and other interested stakeholders. The system suffers from a serious bias towards pesticide companies.

Leading scientists published a <u>consensus statement</u> on 17 February 2016, stating concerns over use of glyphosate-based herbicides and risks associated with exposure and calling for a fresh and independent examination of the toxicity of glyphosate-based herbicides.

With significant concerns outlined in the findings of published, peer-reviewed studies from independent science, the Commission should not be allowing glyphosate to remain in use on the basis of secret, industry funded reports assessed by people who did not publicly declare their interests.

REASON SEVEN: There are Alternatives!

Organic farmers have demonstrated the same thing time and time again - <u>glyphosate is not necessary for productive farming</u>. The farming of the future must be based on high biodiversity and a high variety of crops and structures, crucially avoiding the vast monocultures that attract pests in the first place, or the continuous cropping on fields that allows the pests to build up in soil and vegetation.

The use of glyphosate is linked to a highly intensive agriculture that is simply not sustainable. There are safer, non-chemical alternatives to glyphosate, starting with crop rotation and shallow ploughing and mulching, which are equally effective ways of tackling weeds (see statement by German Environment Agency). For this reason, and for all the others set out above, the glyphosate license must be rejected.