The new European Transparency Regulation: a panacea for EU risk assessment?

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Published online: 28 January 2022

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1 Introduction

On 6 October 2017, the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" submitted to the European Commission 1.070.865 signatures in support of the banning of the herbicide glyphosate. This had been preceded by scientific outputs from the European Food Safety Authority (EFSA) and the European Chemical Agency (ECHA), which, in consultations with experts from national agencies, concluded that glyphosate fulfils the criteria for safe use¹ and that glyphosate is not a carcinogenic compound.² In opposition to this, experts from the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) classified glyphosate as "probably carcinogenic to humans".³ Following the controversy in regulatory outcomes, long discussions on acceptance of toxicological studies conducted by the industry, as owner of the pesticide, versus those studies published in the open literature, broke out. Those glyphosate evaluations were hotly debated by the public to an even greater extent than within the scientific community, and the discussion had an enormous emotional component, far beyond science. Glyphosate continued to be the most controversial chemical for a long period of time, revealing the deep mistrust felt by public towards the work of regulatory agencies.

2 A new transparency regulation was born

In 2017, the European Commission concluded that neither scientific nor legal grounds existed that justified a ban of glyphosate, and the and the approval for glyphosate was

renewed until 15 December 2022. However, the European Commission made a commitment to strengthen the transparency of future EU risk assessments in the food chain, and to enhance governance over the conduct of industry studies submitted to the EFSA for conduction of risk assessment. The Transparency Regulation⁴ was born and became applicable on 27 March 2021. Although the glyphosate case acted as the initial point of ignition, the new Transparency Regulation gained a much broader applicability and is the targeted amendment of the General Food Law Regulation,⁵ concerning eight sectorial legislative acts.

3 No unfavourable studies will be hold back

The main elements of the new Transparency Regulation include ensuring more transparency, increasing the independence of studies, and comprehensive risk communication. The public will thus have access to all studies submitted by the industry, excluding the type of information that may be considered significantly harmful for commercial interests. The EFSA will be notified of all commissioned studies in order to guarantee that no unfavourable studies will be withheld.

The responsibility for the notification of studies lies with both the industry, as the data owner, and the laboratories performing the studies. Any lack of declaration will invalidate (any kind of) application and/or will lead to time delays. The advantage of this step lies not only in transparency for the public, but also in the fact that by consulting the new register the

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¹ European Food Safety Authority (EFSA) 2015

² Committee for Risk Assessment (RAC) 2017

³ IARC monographs on the evaluation of carcinogenic risks to humans 2022

⁴ Regulation (EU) 2019

⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 2002

study repetition by different data owners can be avoided, which is especially important when it comes to studies on animals. In cases of a strong discrepancy between outcomes, the EFSA can commission additional studies for verification purposes and will perform fact-finding missions to verify the compliance of laboratories and studies with applicable standards.

Regarding risk communication, the European Commission will develop a communication strategy in close cooperation with the Member States and with the EFSA, combined with open dialogue amongst all stakeholders. The aim is not only to improve the understanding of risk assessment terms such as “hazard” and “risk”, but also to present and to clarify the responsibilities from the scientific assessment to the decisions made by the risk managers and policy makers and, of course, to explain the responsibilities of the companies. In addition to the need to explain the risk assessments performed at the EFSA and national agencies, the transparency of the decisions made by the European Commission in the setting of maximum residue levels or in the approval of substances or processes along the farm to fork chain has to be improved.

The EFSA already has a highly proactive approach to transparency. Even before the new Transparency Regulation came into action, data, calculation methods and tools, and the tracking of expert discussions were made available on the EFSA website. For all contributing experts in the Scientific Panels and Working Groups, conflicts of interest have to be excluded with this information being publicly available. All risk assessments and background information are published. Moreover, this proactive approach is further strengthened and advocated by the Transparency Regulation.

4 Expert judgment will remain

Nevertheless, it would be naive to believe that the new Transparency Regulation is the panacea that will solve all controversies in regulatory risk assessment. Interpretations of statistical versus biological significance of an effect, borderline increases in incidences of tumours, use or non-use of historical control data in toxicological assessments, to name a few, will always be part of expert judgement and potential disagreements. It is a fact that data and processes transparency does not mean an unified expertise. To quote Franklin D. Roosevelt: “There are as many opinions as there are experts”.

5 What are the reasons for consumers to question the work of regulatory agencies?

EFSA Units and Scientific Panels have invested an enormous amount of effort in the implementation of the most recent scientific knowledge, to create and promote use of guidance documents and scientific opinions, and to harmonise the methodology used in scientific evaluations. Is it the scientific language used by regulatory agencies in their communication with the public that is not really coming through? The fact is that if public information gets presented in an understandable, digestible form, it will bring more trust from the consumers.

Or is it that prior to Transparency Regulation, most studies conducted by the industry were not disclosed and therefore not available to the public? For sure, making primary data accessible and transparent will bring more confidence in the evaluation of data, even for non-experts.

Or is it the controversial scientific discussion between the agencies? For glyphosate, there were different scientific evaluations from EFSA and ECHA on one hand and WHO/IARC on the other, reflecting the use of different bodies of scientific evidence and methodologies. Again, access to primary data and the presentation of information in an understandable, digestible way will most probably bring regulatory agencies more trust from the public.

In addition to discussions of risk assessment and safety standards in Europe, a controversy exists between public expectations concerning food production and reality. Hence, we can legitimately question whether our habit of having cheap access to food from all over the world without seasonal restrictions is sustainable. In this context, it is important to clarify that the EFSA is responsible for risk assessments and not for lifestyle or production systems. This will be addressed by other policy areas like the “Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system”⁶ of the European Union.

The new Transparency Regulation is not a panacea to solving all problems in risk assessment. However, it is a huge step forward towards a better common understanding of regulatory work in the food safety area. In the light of the ongoing evaluation of glyphosate in the renewal procedure, the new Transparency Regulation will be of the utmost importance.

⁶ Farm to Fork Strategy (europa.eu)

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