Reports

This part of the EJRR hosts reports in which our correspondents keep readers up to date on the most recent developments in different areas of risk regulation. Our aim is to fuel the debate and trigger future research on cutting-edge risk subjects. The Reports are organised under different policy sections. Further sections will be added at regular intervals. If you are interested in contributing to any of the existing sections, please contact the Reports Editor at enrico.bonadio.1@city.ac.uk

Biotechnology

This section aims to update readers on decisions related to marketing products of modern biotechnology (e.g., GMOs, animal clones) at EU level and on national measures concerning their production. Special attention is devoted to problems of competence between Member States and the EU in regulating biotechnology issues; the institutional dynamics of decision making regarding products derived from modern biotechnology; the relationship between the EFSA and the EU institutions on green biotech-related issues; the evolution of EU regulatory framework and of national attitudes towards the risks and benefits of biotechnology derived products and their production. This section will also delve into the interaction between the EU legislation and WTO law regarding advances in the application of biotechnology within the agri-food value chain.

It's (just) Chemistry, Stupid! Or Not?

*Justo Corti Varela**

When first GM seeds were under assessment in the 90', there was a strong debate about their convenience and necessity. GM crops were supposed to improve yields, lower costs for farmers and reduce agriculture's environmental impact. At that time there was a high concern with the fact that first commercial GM seeds were, essentially, part of a technological package that also required the use of an herbicide patented by the same firm that was researching and promoting the biotech seeds. However almost all stakeholders agreed that agricultural biotech was something that went beyond this event and it was just a matter of time that new GM crops would arrive and succeed. With Bt maize things moved in that direction. Moreover others interesting promises, like the golden rice or the drought-resistant wheat, reinforced the attractiveness of GM and the prospect of a new era of designed agriculture.

Nevertheless, twenty years later gross figures show that GM seeds are still being linked to a higher degree to herbicide tolerant modification. Either alone or stacked with Bt, glyphosate tolerance represent 3 of each 4 GM seed commercialized worldwide. In the US, the first country authorizing GM crops and still the main GM crop producer, the glyphosate tolerance represent almost 90% of the total of soybean (94%), cotton (91%) and maize (89%) planted. With such concentration there is uncertainty on whether all GM expectations could be met, particularly the assertion that implantation of glyphosate tolerance seeds would reduce the use of herbicides.

According to USDA herbicides used on corn, soybeans and cotton did fall in the early years of GM crop adoption, dropping 15 percent between 1998 and 2001. But as weeds developed resistance, farmers applied more, and total herbicide use increased 26 percent between 2001 and 2010. Also the technological package means that weeds´ control (which could be done by tilling, manual removal, coverings, irrigation, crop rotation, or chemical methods) is now

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only concentrated on glyphosate. Since the introduction of GM seeds in 1996 the global amount of glyphosate used on crops in the US has increased from 27 million pounds in 1996 to 250 million pounds in 2009. It is true that, with GM seeds, farmers can reduce costs, particularly related to tillage, which clearly has environmental advantages. However, we cannot deny that these farmers are now more dependent on the use of agrochemicals and its consumption increases with the expansion of GM crops.

This factual context explains the importance for biotech industry of the 20 March 2015 evaluation on glyphosate made by the International Agency for Research on Cancer - IARC (WHO) and its decision of qualifying it as a probably carcinogenic agent

When glyphosate was approved in the eighties, the US EPA originally classified it as "possible carcinogenic to humans" (1985). However, in 1991 it re-evaluated the study on which the first decision was based and changed its classification to "evidence of non-carcinogenicity in humans". That was before the massive use of glyphosate that the GM seed promoted and, since then, its negative effects have increased because of the accumulation on soil, water and air.

Since the beginning of this century many scientific studies, the controversial Séralini's study (2011) probably being the most known but also others like the one of Swanson (2014), have raised, at least, serious doubts on the possible relation between glyphosate and health problems, with GM crops being, of course, the vector that makes possible a super intensive use of the herbicide. These studies could be classified into two categories. On one hand, there are some studies based on laboratory investigation, mainly using mice, which try to prove the direct effect of the agent on human health. In this group there are not clear evidences of a highly harmful effect of glyphosate, at least, in comparison with others chemicals. On the other hand, we can find interdisciplinary research studies that analyses the effect of glyphosate in a context, comparing the presence of the chemical in soil, air, water, animals and human beings (including, for example, water of the river Mississippi, urine of dairy cows, and even human blood) and fixing connections with the increase of endocrine diseases and metabolic dysfunction, according to epidemiological data. These last studies take into account the accumulative effect and the interaction with other toxics; however, it is also true that it is more difficult to establish a clear causal relation between the agent and diseases. According to the chemical industry there would not be an accumulative effect if farmers would follow good agricultural practices, something that it is very difficult to enforce when GM technology, which guarantees the immunity of crops face to glyphosate, encourages an excessive use of the herbicide.

We will not take part in the debate but we can just conclude that there are some evidences that raise doubts on the possible harmful effect of the increasing use of glyphosate. From our point of view the key element is the intensity of the use of the herbicide, and it would never be possible without GM technology. Consequently, the risk analysis should be a comprehensive one and we have to apply all the principles used for GMO including, of course, the precautionary approach. According to it, at least in Europe, this evidence should be enough to impose a restrictive regulation, including bans, if we were talking on biotechnology. However, glyphosate is being assessed just as a chemical, and that is why the decision of the IARC was so contested, starting, of course, by Monsanto, but also by national risk assessment agencies.

Last year and analyzing almost the same scientific data, Germany (through the *Bundesinstitut für Risikobewartung* –BfR- and acting as the European Union rapporteur member state) submitted a glyphosate renewal assessment report to the EFSA, recommending the re-approval of glyphosate for use in Europe with an increase in the acceptable daily intake (ADI) from 0.3 to 0.5 mg per kg body weight per day. The report was criticized because it did not reveal its authorship; meanwhile some members of its Committee for Pesticides and Their Residues were under suspicions of having links with the industry; and because the review of some of the published toxicology studies was conducted by Glyphosate Task Force, a consortium of chemical companies that lobbies in favor of glyphosate.

Just three days after the publication of the decision of the IARC, the BfR strongly defended its previous findings and attacked IARC conclusions mainly because laboratory findings were "limited" and epidemiological studies had not been confirmed by review research because the weakness of the cause-effect link.[1]

1 Bundesinstitut für Risikobewartung "Does glyphosate cause cancer?", *BfR Communication* No 007/2015, 23 March 2015.

One month later, BfR got back its institutional role and "recommended" the consideration of the IARC report in the EU-Approval process, not as any other input but though an European Panel of experts lead by EFSA to "examine" the results giving, of course, to the ECHA the opportunity to get involved in the very early stages of discussion.[2]

2 Bundesinstitut für Risikobewartung "BfR-contribution to the EU-approval process of glyphosate is finalised" *BfR Communication* No 008/2015 from 2 April 2015.

Now EFSA, and in the last instance the European Commission, have to decide the role that the IARC declaration (and probably the most important, the scientific data that bases it) will play in the renewal assessment of glyphosate. The Danish prohibition of glyphosate in 2003, and the Dutch (2014) and French (2015) bans for non-commercial use are putting some pressure on how glyphosate risks should be assessed and managed: either following a truly precautionary approach, as we are doing with GMOs; or following the old fashion *there is no ban without scientific certainty of damage*, the way we still regulate chemical products.