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.

Will Chemical Packages be the only Future for Biotechnology? Why the Bayer-Monsanto Merger Could be a Good Opportunity to Put Things in the Right Place

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The agricultural biotechnology issue has always been a question of chemicals more than of laboratory design. As clear proof of that, glyphosate resistance events represent 90% of the GM seeds in the market. However in Europe there has been a strong campaign to highlight the difference. On the one hand, anti-GMO wanted an argument that would justify the use of different and drastic measures. On the other, the European chemical industry was comfortable with the idea since it focused attention on a technology dominated by Americans and, consequently, it permitted them to negotiate longer periods of adaptation to REACH. The regulatory gap between chemicals and biotech products does not make sense, especially when practice has demonstrated that the main damage linked to GM crops concerns the abuse of chemicals that they tolerate (as is happening in South America) rather than to its specificity as a "new product".

However time puts everything into perspective. Slowly, authorities, the industry and stakeholders are coming to understand the strong interaction between biotech and chemicals. In 2016 the EU was obliged, for the first time, to manage agrochemical risks in a similar (precautionary and politically interfered) manner, like biotech ones. The difficulties that the Commission had for renewing the authorization of glyphosate last June, based on a positive provisional report of the EFSA, was proof that things were changing. The inclusion of political (and consequently non-scientific) arguments, lead by France; and the strong campaign of NGOs for the prohibition (yes, prohibition, not just regulation or best practices) smelled more like a GMOs authorization discussion rather than a renewal of a chemical product that had been

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on the market for the last four decades. The main argument was the contradiction between the provisional report of the EFSA (saying that glyphosate was not carcinogenic) and the 2015 report of the IARC. At the last minute, the Commission saved the chemicals industry (and with it large scale farmers) from the disaster with a provisional 18 months' authorization until the final report of the ECHA, expected for next year.

The second act of this transition is the mega merger between Bayer and Monsanto that was confirmed September 2016. The main argument for the transaction was that the business of the two companies were perfectly complementary. From Bayer's eyes, the agreement will permit the new company to sell farmers seeds and agrochemicals together (it harks back to the "technological package" popularized by Monsanto in the nineties) and, of course, to foster innovation. As a chemical giant, it is not very difficult to foresee Bayer's interest in focusing on Monsanto's abilities in seed design. It's true that the whole industry is experiencing a process of convergence (Dow Chemical and Dupont are negotiating for their own marriage, and Syngenta was taken over by China National Chemical last December); however the impact of Monsanto-Bayer merger will be particularly important for the biotech sector. Firstly, because Monsanto was the main actor in the commercialization of GM seeds (with around 25% of the global market) but also because it is the first big EU-US merger in the sector. The fact that the buyer is the second largest chemical producer in Europe (just below Basf) and, consequently, a European Champion with a long and established presence in Brussels, will probably give the agreement more chance of being accepted by competition authorities.

Competition control should, however, be as strict as possible. Both authorities, the American and the European, have said that they are concerned about the effects of the merger, particularly because of possible restrictions in the offer. Proponents argue that the combined business benefits outweigh costs, mainly thanks to the integration of product portfolio across crops and indications with a comprehensive offering of seed and crop protection products; the creation of a leading platform in digital farming; and leading innovation capabilities and R&D technology platforms, with an annual pro-forma R&D budget of approximately EUR 2.5 billion. These three benefits, however, do not have a clear positive impact on consumers, except that they could guarantee lower prices. All of them are concentrated in the reduction of costs and imply, directly or indirectly, a reduction in the offer of products. In fact, the combined business has as its main aim the reinforcement of the relation between biotech seeds and "crop protection products", reducing even more the scope of such seeds to a mere vehicle for selling agrochemicals.

During the assessment, competition authorities should take into account not only the impact on prices and offer of current products, but also the impact on research, particularly in the development of new biotech seeds that would need to be connected to agrochemicals. The new company will control a budget of EUR 2.5 billion in research on biotech food, which is around 10 times of the USDA's agricultural research budget and 15 times of what the Horizon 2020 invests annually in agriculture. The impact of this will be huge both in the development of research lines and in the creation of expertise that, in the future, will feed regulatory agencies. It is thus necessary to have transparency in the selection of research lines and, particularly, the establishment of an independent committee to guarantee that this research will not be conducted only to reinforce the sales of other products of the company, particularly when they are protected by a patent.

It is a fact that biotech research was born and has matured nurtured by the private industry. That has created problems of conflict of interest for regulatory authorities, particularly in committees of expertise, and the continuing suspicion of manipulation of risk assessment. Biotech and chemicals have been marketed as a packaged product when, in reality, they could respond to other necessities. Now, with this merger, competition authorities have the opportunity to change history and reset the process.