

Editorial: The Future of Biotechnology in Support of Bio-based Industries

A Differentiated Assessment of the Future of Biotechnology

A perspective from an EU member state

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While the Editorial of the latest issue of *ESPR* [1] described the US perspective (Dr. Alvin Young), this Editorial presents the point of view of the EU. Dr. Alvin Young wrote, "...regulatory oversight of genetically engineered organisms can evolve hand-in-hand with both the development of supporting science and the continuation of commercialization of the technology."

The OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology, which I currently have the pleasure and task to chair, tries to exactly strike that necessary balance between science, technological development and accompanying meaningful regulation in the area of applications of genetically modified organisms (GMOs). The results of that OECD Working Group over the last couple of years, such as so-called Consensus Documents on the biology of crop plants and micro-organisms, certain traits as well as a product database of approved genetically modified products [2], have shown that this balance can be successfully achieved and is in the interest of all the stakeholders involved.

In that respect, I can agree in principle to the approach supported by Dr. Young. However, with respect to the implementation of biotechnology in various industrial and agricultural applications, I would like to put forward a differentiated perspective on the basis of a few observations which I will outline in the following. Working for one of the so-called Competent Authorities (CAs) for deliberate release and placing on the market of GMOs (one of the Austrian CAs), I have to stress that the above-mentioned concept is not a lesson to be learned by the European Community in the future, rather, as in other industrialized countries, we have been working on that basis for many years.

Experience and international collaboration, such as the OECD Working Group described above, have shown that the scientific and regulatory basis between the EU and the USA is not so different at all, on the contrary, there are a lot of commonalities. On the other hand, there are clear differences concerning the state of the actual application of products in certain areas such as agriculture. Why is that so? I would like to provide three points for consideration:

1. The different meaning of biotechnology versus applications of GMOs only
2. The context of the agricultural structures for which products are provided
3. The role of the public

Let me start by discussing the **first point**. In the EU we believe that biotechnology is a whole variety of technologies based on living organisms, not just the technology of genetic modification or genetic engineering. The "Strategy for Europe on Life Sciences and Biotechnology", which has been adopted in 2002 [3], and the recent second progress report on this strategy [4] clearly show that Europe has a lot of interest to focus on and pursue biotechnology as a key set of technologies for future sustainable development. Many ideas reflected by Dr. Young are the driving forces behind our interest in biotechnology as well; just to name one, environmentally friendly, resource and energy saving product developments with the help of organisms or their products, such as enzymes. However, we see GMOs as only one possibility of applying biotechnology in industry and/or agriculture, it is certainly not the only one and currently sometimes not the most suitable one. Numerous examples in a series of published studies dealing with the possible benefits of biotechnology [5,6], in many cases, show that naturally occurring organisms or a mixture of them as well as other conventional applications of biotechnology, in principle, can do the job in an excellent way. Technological optimization, both on the side of the organisms as well as on their technical applications (computerized fermentation, bio-catalysis, etc.) have led to remarkable progress. However, GMOs have so far not really been economically successful in some of these areas such as environmental cleanup.

I think that we should use and further explore the potential of the whole variety of biotechnological methods and applications rather than pushing GMOs as the only solution. This would broaden the view on the best available technologies providing the tailor-made solution for the problem at hand. In other words, we should follow a problem-oriented rather than a technology-focused approach. The above-mentioned EU strategy on life sciences and biotechnology highlights the fact that the progress and success of a certain set of technologies is dependent on a whole variety of facts and developments, such as the economic viability and competitiveness, the R&D expenditure, the regulatory climate, the patenting system and the socio-political climate, just to mention some of them. GMOs may have a role to play in certain cases and then they should be part of the solution, but their potential should not be overestimated and should always be put into context.

Secondly and now focusing on agriculture: the agricultural structure in many EU member states, and certainly in my home country Austria, is quite different from the agricultural structure and production system in the USA. In Austria,

for example, we basically have a small-structured, diverse landscape with similar types of agro-ecosystems. The high percentage of alpine ecosystems and forest require that we devote a big part of our remaining land to agriculture. In the agricultural production area we also have to care a lot about environmental and nature protection. This has resulted in a very high percentage of organic farming in Austria, in fact more than 10%. This ranks us second highest throughout the world [7]. In principle, this general assessment of agricultural structures is also true for other EU member states, although of course there are certain differences with respect to the types of crops planted, the average size of fields and the level of organic production. As a whole, however, this has led the EU to look – in addition to scientific risk/safety assessment of GM crops, which we perform in a similar way as the US – to other factors such as compatibility with the agricultural production systems as a whole or the question concerning whether a co-existence of GM crops with conventional and organic farming can be performed. The European Commission has published a Communication on co-existence in July 2003 [9], since then the GMO debate in many EU member states and the European Commission has been dominated by that topic. Practical, efficient, non-discriminating solutions to the co-existence problem have to be found in the near future, which could include the establishment of GMO-free production zones if these appear to be the only economically-viable solutions in certain regions.

These developments lead to my **third point**: the role the public plays in influencing and shaping the debate on GMOs. Labeling of GMO products and their traceability have been a strong request from the European public for years. This request has not been based on scientific considerations, neither was it purely linked to the potential risk of GMO products. Potentially risky products would neither receive authorization in the EU nor in the US. Labeling and traceability was and is regarded as an instrument for free and informed consumer choice and not as a risk management tool. This difference is crucial. Now that we have these labeling and traceability rules in place, in the context of a new and partly centralized approval system with a strong role of the European Food Safety Authority (EFSA) [9,10], we will label GMO products and products derived from GMOs in order to give consumers a choice to buy or not to buy them. We are not using this system as a way of informing consumers of possible risky products. It is clear that these strong public concerns have influenced to a certain extent the regulatory developments in the EU.

In summary, I would like to stress that the research and development interests and programs, as well as the basic economic expectations to biotechnology, seem to be quite similar for the EU and the USA. However, with a sensitive public and a smaller structured, agricultural structure, the EU approach seems to be more cautious, based on the precautionary principle which is explicitly mentioned in various EU regulations [see e.g. 11], and taking into account the level of uncertainty with GMOs. Biotechnology is more than applying GMOs in industry or agriculture, it is a huge variety of methods and techniques waiting to be assessed and implemented, provided they are safe and useful. In addition, the remaining questions concerning the risk/safety of GMO products have to be fully assessed [12–14].

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Further comments from the readership will be appreciated.