

Workshop "New Techniques in plant biotechnology"

8th May 2015, morning

Presentation: see separate file

Discussion:

Debate on process versus product: looking at the product is not enough. Knowledge today relies only on the minimal data delivered in dossiers by applicants. This is even more difficult when we cannot even define the product.

A representative of Nigeria requests a short overview of those new techniques. Eric Meunier (Inf'OGM) gave a summary of the most widely used, current new techniques (oligo-directed mutagenesis, CRISPR¹, TALENS², Zinc Finger). We are already faced with products from new techniques, for example in Germany with CIBUS 'Clearfield' oilseedrape (in field trials). In a preemptive move, the German competent authority (BVL³) has declared oligo-directed mutagenesis not to be considered as giving rise to GMOs in the national context. Developers want to purport the narrative that transgenesis is old and, interestingly, 'unprecise' and that they have now new more precise and safe techniques. Along with this goes the implicit narrative that more precision means more control which is, of course, a fallacy. If they are not considered to be GMOs, there will be no safety testing whatsoever, no labeling and no traceability or coexistence rules applied! Developers are pushing at the international level for these techniques targeting, in particular, countries with GMO regulations, in a move to avoid liability, responsibility and regulations.

A number of German NGOs did send a letter to the European Commission and got a meeting appointment by the end of September to discuss this question of defining the status (GMO or not, falling under the scope of the legislation or not) of products obtained through these new genetic engineering techniques. A Government official stated that it was said several times that the existing GMO definition does not fit the new techniques. For that reason and because CIBUS says that ODM is so precise the "Bundesland" (federal state)-authorities in Germany are not criticizing the decision of BVL. Again, the issue of precision is conflated with control.

It was emphasized that there is a lack of harmonized methods to detect off-target effects of the new genetic engineering techniques although offsite mutagenesis is a common problem and frequently reported in the scientific literature.

The issue of patents on these new products was raised and the internal contradiction pointed out. If the products arising from these techniques are nothing new and could be achieved just as well through normal breeding methods, they are not an invention nor a new product of engineering and, thus, should not be patented in any form. If they are considered unique novel products of engineering, they are so for both patenting purposes and safety purposes and have to be fully regulated. A German regional government representative explains that patents can cover a process and not a product, which, according to others, is true but does not change anything as the patent on a process does cover products obtained through this process (although not always). The question remained unresolved of how a patent can be claimed and granted if the products are truly indistinguishable from conventional, non-patentable processes. A representative from IFOAM raises the issue that the lack of traceability is very bad for the organic farming system. Here lies a true problem for the actors in the field.

It becomes clear in the discussion that legal and economic issues tied to intellectual property rights really constitute the fundamental 'novelty' aimed to achieve with these new genetic engineering techniques and, thus, form the core of the problems. Prime motivation of the developers behind these novel technologies is to avoid regulations, assume zero responsibility or liability but maintain full property rights and profits. A win-win for developers and a potential lose-lose (in the waiting) for consumers and society at large. To many, this is unacceptable.

African representatives stated that they need more information on the new engineering techniques of biotechnology (description and political considerations) and no regulator in any African country would be up to

1 Clustered regularly interspaced short palindromic repeats

2 Transcription activator-like effector nucleases

3 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit - Federal Office of Consumer Protection and Food Safety

the task of assessing and regulating the products of these novel technologies. They want to start discussing this issue with their legislators and working with farmers to know how innovative and effective these new technologies are. In-field, on-farm socio-economic analysis is of prime importance to them. Regarding science, it was stated that there is a lack of comparison between these genetic engineering methodologies and the natural process of evolution.