Threshold values for products from genetically modified plants

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Statement by the DFG Senate commission for the assessment of chemicals used in agriculture

The adoption of threshold values for the introduction of genetically modified plants (GMPs) is currently being discussed in Europe. The issues arising from the adoption of threshold values were debated on the occasion of a specialist discussion staged by the DFG Senate commission for the assessment of chemicals used in agriculture (SKLW) in Bonn on the 30th and 31st August 2001. The issue of a detailed documentation of the contents and results of the specialist discussion is scheduled for the beginning of 2002.

The new EU guideline 2001/18/EG makes provisions for a common procedure to set threshold values for technologically unavoidable and coincidental additions of raw materials from genetically modified organisms (GMOs) that are permitted in the EU. The EU Commission is planning a decree in which threshold values are determined for food and animal feed as well as seed. A threshold value of 1% is proposed for food and animal feed, while phased threshold values of 0%, 0.3%, 0.5% and 0.7% are being discussed for seed. If the threshold values are exceeded, the respective products have to be specially labelled. The Senate commission is of the opinion that such labelling neither enhances the safety of the food nor serves the purpose of informing the consumer about possible risks. Rather, it takes into consideration the right of the consumer to know about how food and animal feed has been produced and his right of free choice (consumer sovereignty). This right has a high status. On the other hand, threshold values must not impede, let alone prevent, the responsible use of genetic engineering in agriculture and the food and animal feed industries.

So far, no risks to humans, animals or the environment that would go beyond those risks entailed in the use of conventionally bred plants have been identified in the large-scale growing of GMPs in a current area of more than 40 million hectares. GMPs are intensively assessed in terms of their risks before they are released. Stringent isolation measures can be defined in individual cases. If necessary, the introduction of genetic modifications via, for instance, pollen, can be prevented altogether.

The threshold value of 1% in food and animal feed is in line with the insight that increased growing of GMPs results in an accumulation of GMP material within the production chain (plant-growing, harvesting, transport, storage and processing), which means that it is virtually impossible to observe lower threshold values (below 0.5%). Moreover, considerable technical problems arise in detecting very small additions of genetically modified raw materials in food.

Very low threshold values would have considerable consequences, not only for ecological safety research, but also for the entire molecular-biology research on plants, especially for genome research. They would result in hardly any farmland being available for the release of GMPs. With a threshold value of 0% (zero tolerance), fieldwork with GMPs would come to a standstill, and this would have grave consequences for research on useful plants in Europe.

In determining GMP additions in seed, it has to be taken into consideration that production takes place in quasi-natural conditions on farmland. Depending on the plant species, cross-pollination and the introgression of genes into plants of the same species may occur. Both phenomena are unavoidable and inevitably lead to a certain level of GMP seeds in conventionally produced varieties. Threshold values below 1% would have a strong impact on

seed production. This is why it ought to be considered whether higher threshold values really are incompatible with the consumer's right to know about the how food has been produced.

Monitoring threshold values requires a considerable effort that becomes disproportionately high in relation to the lowering of the threshold values. This also explains the error rate in determining the GMP share. The Senate commission holds that there is a considerable requirement for research with a view to improving detection methods currently in use and, in particular, to developing micro-array technologies for the simultaneous detection of different GMPs for routine application.

Threshold values for the introduction of GMPs into food and animal feed as well as seed cannot be compared with the exposure limits to hazardous substances that are already in use. The latter values are defined for substances that trigger a measurable biological reaction (e.g. the LD50 rate). But just like with DNA from conventional plants, the intake of DNA from GMPs that have been newly introduced does not trigger any reactions among humans or animals. So there is no need for limits from a toxicological angle. The substantial difference between genetic engineering threshold values and conventional limits has to be clarified in legislation.

The planned EU guidelines on threshold values can only be a partial solution. They do not address the world-wide shipping routes for seed and farm produce. Minimum standards with an international law status have been created for safety controls and authorisation of GMOs with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. On the one hand, it demands the mutual recognition of authorisation, while on the other, no threshold values are provided below which trafficking in seed and farm produce with low levels of GMOs would be tolerated. From a scientific angle, there is no need to make provisions for lower threshold values or even zero tolerance for the introduction of genetically engineered modifications of GMPs that are tested and authorised according to equal criteria in countries outside the EU but have not (yet) been authorised in the EU itself.

Summing up, the Senate commission states that:

- threshold values do not supply a scientific basis for the introduction of GMPs, but that establishing them is required in terms of consumer sovereignty and for reasons of legal security,
- threshold values do not raise safety standards for the consumer but serve the purpose of informing him,
- very low threshold values have grave negative consequences for research and the further development of GMPs and
- threshold values require a considerable effort in detecting the introduction of GMPs that cannot be mustered using the conventional administrative monitoring capacities.

On the basis of this, the Senate commission makes the following recommendations:

- A maximum of sensitivity should be observed in determining the levels of threshold values in order to comply with the right of the consumer to be fully informed about the production of food and animal feed on the one hand and to prevent a responsible development and use of genetic engineering in agriculture and in the food and animal feed industries from being impeded on the other.

- A uniform threshold value not below 1% should be defined for seed.

- Assessing the safety of the introduction of genetically engineered modifications from GMPs released into neighbouring field plots should be related to individual release, as is currently the case.

- The Senate commission has identified a considerable requirement for research on the development of detection methods for the introduction of very low levels of genetically engineered modifications in plants. More support should be provided for micro-array-based methods. Currently, it would generally be impossible to observe threshold values for transplastome GMPs because a precise detection cannot be accomplished owing to the high copying rate per cell.

- Furthermore, much research is called for to develop sampling methods. This applies not only to sampling of seed material but also to food and animal fodder.

Scientifically based instructions for action to avoid the introduction of GMPs are urgently required to ensure that the threshold values proposed are also observed when GMPs are grown on a larger scale.