Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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The Norwegian Biotechnology Advisory Board

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN
(bitte bei Antwort angeben)

DATUM April 27, 2018

The Gene Technology Act – Invitation to Public Debate

Dear Madam / Sir,

As the German competent authority according to Directive 2001/18/EC we welcome the opportunity to comment on the recommendations of the Norwegian Biotechnology Advisory Board concerning the future regulation of genetically modified organisms.
We have ordered our comments according to the questions addressed by the Biotechnology Advisory Board.

How should organisms covered by the Gene Technology Act be regulated?

Re *Levels based on genetic change* and table on page 3:
"Level 1": In our view organisms with changes that can arise naturally do not fall under the GMO definition in Article 2 (2) of Directive 2001/18/EC. This would, for example, encompass organisms in which mutations have been induced by whatever technique that could also arise naturally and which do not have any foreign genetic material inserted into their genome.
"Level 2": When thinking about the future regulation of organisms with "species-specific genetic changes" it should be considered on a case-by-case basis whether the genetic change in question could also arise naturally. In that case it should not be regulated as a GMO in our opinion (cf. our comment to "Level 1").
"Level 3": "Involve" is a very broad term. If this criterion should be taken up into a legal text we recommend to use a more specific wording. For example, must a synthetic DNA sequence be incorporated into the host's genome in order to get a modified organism submitted

to this category? Another question is what “synthetic (artificial)” means in this respect. What if the synthetic DNA is a copy of a species-specific sequence?

Re *Levels based on an initial assessment of ”public morals”*
Ethical justifiability and risk are not connected. Therefore, the level of ethical justifiability should not have an influence on the level (depth, speed) of risk assessment in our opinion. Directive 2001/18 clearly separates in its Article 29 a consultation on ethical issues of a general nature from the administrative procedures for single applications. To impose a broader discussion on ethical defensibility on single applications, for example for GMO field trials; might block a decision on those applications for a long time.

What should be regulated by the Gene Technology Act?
In our opinion, there are no reasons to assume a higher level of risk for organisms made using genetic engineering or genome editing than for organisms with similar changes made with conventional breeding techniques or that arise naturally, for example in terms of unintended effects.
Therefore, the regulation of modified organisms should be based on the alteration(s) of the genome, not on the method that was used to achieve it. If an alteration that was obtained using genetic engineering or genome editing could also arise naturally or by conventional breeding techniques, the modified organism should not be regulated differently than a conventionally bred organism.
For some conventional breeding techniques, like mutagenesis using chemicals or irradiation, the probability of unintended effects is higher than for modern gene editing techniques. However, those conventional breeding techniques have a long safety record in plant breeding. Existing breeding schemes and plant variety registration requirements have been shown to effectively safeguard the safety of products from those techniques for human health and the environment. In our view these decade old “safety measures” should also be sufficient for products of gene editing with comparable genetic modifications.

How should contribution to societal benefit, sustainability and ethics be weighted?
We cannot see a good reason why organisms created by gene technology of whatever kind should have an intrinsically higher requirement to be socially beneficial, sustainable and ethically justified than any other crop or livestock. Therefore, a comparable approach to conventionally bred organisms should give a good enough answer.

Sincerely

Detlef Bartsch