

Kommentering af udkastet 'room document “Recommendations of the Council concerning safety for applications of recombinant DNA organisms in industry, agriculture and the environment” forud for møde i OECD

Rådgivningsnotat fra DCA – National Center for Fødevarer og Jordbrug

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Baggrund

Landbrugsstyrelsen har i en bestilling sendt til DCA – Nationalt Center for Fødevarer og Jordbrug ved Aarhus Universitet (AU) ønsket relevante kommentarer til et udkast af en opdatering af "Recommendation of the Council concerning Safety Considerations for Applications of Recombinant DNA Organisms in Industry, Agriculture and the Environment", som skal drøftes på det kommende møde i OECD i Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (HROB).

Landbrugsstyrelsen har bedt om at kommentarene fremsendes på engelsk, hvorfor det resterende notat er på engelsk.

Comments

General comments

1. Due to fact that the injudicious usage of fertilizers and pesticides may have negative effects on ecosystem functioning and human health, alternatives need to be found. One of these alternatives is the use of microorganisms for bio-stimulation of growth and as bio-control agents for pest control. Some of these microorganisms might in the future be genetically modified notably with the new modification technologies. This has to be taken into account in this harmonization.

2. A number of veterinary and human vaccines based on living genetically modified microorganisms (notably virus) are now available on or on their way to the market. They are indeed produced in industrial settings under GILSP conditions. However, they are also released to the environment notably due to different kinds of shedding from vaccinated individuals; e.g. might vaccination with some of the Covid-19 vaccines, which are based on live genetically modified virus, be considered as the first and largest worldwide release of modified microorganisms to the environment? Although, the hazards seem to be negligible, it would be nice to consider this in an international context.

3. The recommendations set a very general framework for the risk assessment of recombinant DNA organisms. To the degree the recommendations made in 1986 have worked positively for a smooth process of risk assessments without hampering technological development, the suggested updates and changes in the draft document appear timely and appropriate.

General Applications

Regarding recommendation b), we have one specific comment: It states that review and control should be performed " *while avoiding any undue burdens that may hamper technological developments in this field*". However, the question is maybe not so much whether technology development would be hampered (this is mainly obtained in a research path), but whether the technology can be utilized without being hampered, e.g. by high costs for approval procedures (Recommendation b, p.3).

Industrial Applications

An update on GILSP during the last 35 years including the microorganisms in use and how they are biologically contained would be very advantageous for the further development of the industrial applications worldwide (Recommendation h, p.4).

An international overview of the levels of allowed releases through waste, wastewater, and air due to the industrial applications would also be very relevant, as very little information is in fact available on this topic. This might include methods used for estimating these releases (Recommendation i, p.4).

Agricultural and Environmental Applications

Remove the word *considerable* in a). it is a loaded term (Recommendation j, p.4).

The statement that a risk assessment must " *Use the existing considerable data on the environmental and human health effects of living organisms to guide risk assessments,*" should further include that the risk assessment must include the most recent risk assessment guidelines, which may request new data, where previous data does not suffice according to the new guideline criteria. Moreover, the risk assessment should, in agreement with the case-by-case approach, consider if new data is needed (recommendation j, p.4).

In this section it is argued that existing data should be used. This recommendation is not in agreement with the later suggestion that risk assessment should be made in a stepwise fashion potentially including large-scale field testing (Recommendation j, p.4). Such large-scale field testing would rarely be possible using only existing data (Recommendation l, p.5).

For agricultural applications in particular, the changes in the text are limited, but those that are made appear appropriate. In particular, the recommendation for a case-by-case evaluation is kept and the option for exclusion of various classes is underlined, giving room for flexibility with respect to assessment of recombinant DNA organisms based on the development of new technologies (Recommendation k, p.4).

It is important to maintain a case-by-case and the stepwise fashion (Recommendation k, p.4).

Referencer

Room Document No. 2. (18th of May 2022). *DRAFT UPDATED "RECOMMENDATION OF THE COUNCIL CONCERNING SAFETY CONSIDERATIONS FOR APPLICATIONS OF RECOMBINANT DNA ORGANISMS IN INDUSTRY, AGRICULTURE AND THE ENVIRONMENT" - TRACK CHANGE VERSION*