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Lecture

Assessing Systemic Risks - A Holistic Concept

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Key Note Lectures

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Risk means the probability that specific decisions, actions or events could lead to a particular intended gain or an undesirable damage or harm. Risks are dealt with in practically any field of human life. Risk analysis attempts to formalise procedures to identify potential pathways along which risks can develop. Usually, quantitative statements for the involved probabilities are sought.

Risk assessment of technical systems is based on well established routines. An important part is the calculation of probabilities of failure, based on experience with similar situations. Even for complex technical systems the approach can be expanded by investigating the probability of malfunction of any of the involved components and identifying the probabilities of co-occurrences. An implicit operation basis of conventional risk assessment is the assumption of an inherent limitation of negative events: In the worst case scenario, a technical system usually could be closed down. In case of chemical hazards, substances dilute and degrade over time. In the case of radioactive contamination, the material takes more or less time to decay.

Genetically modified organisms (GMOs) are different. With technical systems, they share the property of being engineered to serve an intended purpose. With natural living systems, they share the property that they can self-multiply, grow, disperse, recombine, and evolve beyond what was initially intended. The self-reproduction potential implies that risk assessment and safety analysis of GMOs must be stricter and more comprehensive than the assessment of physical or chemical risks and cover a wide range of risk dimensions:

If only one of the several billions of oilseed rape seeds imported to Japan for processing should get lost and give rise to an invasive population, the resulting damage could be self-amplifying and even re-growing. Therefore, the level of improbability of undesirable events which have to be evaluated or tested in advance must be accordingly low.

There are two basically different risk categories which need to be distinguished: elementary risks and systemic risks. Elementary risks are those which are based on a direct cause-effect relation and can usually be calculated in probability terms. Gain and loss in gambling or occurrence frequencies of car accidents can be considered as elementary risks. Systemic risks are different. They are not based on single interactions or direct cause-effect chains but on the overlay and the co-operation (or co-functioning) of a large number of single events, all of which, in isolation, may be harmless. Systemic risks (sometimes also called emergent risks) arise when a larger number of elementary events come together in a particular context of boundary conditions and bring up qualitatively new effects on a higher level of organisation. Systemic risks do not exist at the level of elementary interactions. A traffic jam can be considered as an example: Any single driver could go down any road, when acting in isolation and no others need to be taken into account. However, if large numbers of drivers attempt to go the same direction at the same time, they may block each other. A credit crunch would be an example of systemic risks occurring in the economy.

Both types of risks need to be considered for GMOs. The GMO risk assessment must take into account all relevant types of interactions organisms are potentially involved in. GMO risk assessment must initially be based on knowledge of the biotic properties of the parent lines and the role of the hereditary material used for genetic transformation. The molecular alterations and the induced biochemical and physiological changes serve as a starting point of the analysis. It is quite obvious that some, but not all, of the potential effects can be investigated or detected at the molecular level at which the genetic transformation is done. This is because the modification itself operates at the molecular level but is intended to bring up effects at the level of the individual organism.

The consideration of potential systemic effects has an important implication. It can be used to develop a guiding framework for organisation of the overall risk assessment focussing on the connectivity of effects that can potentially aggregate to unintended outcomes. A systematic assessment needs to follow the organisation of science, in particular the biological sciences. This "automatically" brings up a linkage of assessing a network of elementary as well as systemic interactions. This is because the different levels of biological organisation are interlinked and all have their particular properties – emergent properties, which represent the level-specific characteristics. Each level requires specialised knowledge, specific terminologies and methods to capture the particular properties of the level.

If we briefly go through the levels of biological organisation for a GMO risk assessment we pass the following "stations":

- The level of molecular interactions which take place in the cell. Cellular metabolic processes can be captured in relevant parts when employing integrative biochemical methods – among others there are metabolomic methods to quantify a large number of metabolites synchronously.
- The level of sub-organismic interactions of cells, tissues and organs up to the level of the individual. Histological methods, assessment of growth performance, and phenological rating are among the approaches used at this level.
- The level of single populations, with their characteristics of spatial distribution, age distribution, dispersal and others, are assessed using well established methods of population ecology, including population viability analysis.
- The level of organismic interaction, bi-tropic, tri-trophic and multi-trophic interaction is highly important. For GMOs this is in particular relevant to the interaction of the GMO with target/non-target organisms. Aut-ecology of different species, taxonomic competence and physiological expertise are among the various qualifications required at this level.
- At the level of the ecosystem in particular an integrated investigation of biodiversity, the composition of the community of organisms and energy flow and matter transfer takes place. Ecosystem services are also assessed at this level: Effects of ecosystem functioning on pollination serices, water budget self-regulation, nutrient retention and the ecosystem functions and services have to be assessed.
- The landscape and the regional context are the next higher level. The cultivation of GMOs can well have implications for the landscape structure and the overall landuse system, which need to be assessed. Neighbourhood relations on the larger scale require an assessment at this level. Gene flow through cross-pollination of crops and dispersal processes between different locations and ecosystems usually need to involve the expertise of landscape ecology.
- Linked to landscape processes, socio-economic implications come into the picture. Changes of landuse patterns and implications for the sustainability of the used system are of crucial interest, e.g. for regulation which does not focus on the level of single farms or ecosystem locations, but requires applicability across larger spatial extents.

It has to be emphasised, that such a systematic approach in risk assessment of GMOs is not yet an established standard – neither in the biotechnology companies nor at the level of competent authorities in the course of the approval procedure. So far, GMO risk assessment operates more on a weakly structured basis of collecting case specific ideas that tend to remain incomplete, in particular regarding the characterisation of the receiving environment - which for example is an requirement of the Cartagena Protocol The method of systematisation which is outlined here facilitates a targeted review of what needs to be investigated before deliberate release or placing on the market takes place. What is required is the assigning of any of the executed investigations during the risk assessment to a corresponding level of organisation. This brings up a synopsis that helps to identify remaining knowledge gaps:

- Are primary and secondary metabolic changes in the GMO sufficiently understood in all relevant details?
- Is the behaviour of the organism in the target environment well tested with regard to the potentially affected parameter?
- Are effects on relevant target and non-target organisms tested to a satisfyingly representative extent?
- Are there ecosystem implications in particular on the sustainability of the cultivated systems and the ecosystem services?
- Has the receiving environment been systematically characterised and assessed?

Answering these questions yields an overview, not only of what has been done, but also of what the field of interactions is that has *not* yet been surveyed.

Is this a holistic approach?

- ***No,*** in the sense that no executable assessment procedure would be absolutely comprehensive. It would not provide "absolute safety" and assurance that any possible risk will be anticipated and evaluated in advance.
- ***Yes,*** in the sense that any potential question and issue has its well-defined location in a system where you would expect it. This increases the probability to identify existing relevant gaps and involve the required expertise. It allows a more critical and well-informed survey.

The outlined approach is targeted and science-based. It would be irrational to argue that any of the organisation levels listed here would not be relevant for risk assessment. Expertise at all these levels is constitutively required for a risk assessment according to the state-of-the-art. This has significant institutional implications. Risk assessment of GMOs can not be managed as a task of "GMO-specialists" with a homogeneous qualification profile. It is practically not possible to cover expertise ranging from the molecular level to the landscape level encompassing agriculture and the full range of ecological relations without involving the full spectrum of specialised expertise. It must be demanded that for a competent assessment the coverage of expertise on both sides, the applicant as well as the risk assessors of the authorities prove the coverage of the required expertise. In practical cases this will usually require to involve a network of institutions – not only a single GMO-branch or -department. The crop protection service of a country, the conservation agency, agronomic expertise, for specific purposes in land use analysis also the weather service, and remote sensing data may be required – all being required to contribute to an overall picture.

A look at the current institutional practice suggests, that there is lot of opportunity and room for improvement. A systematic coverage of relevant risk dimensions requires a structural broadening of the involvement of different levels of expertise in the assessment.

As an outlook, the presentation will point to issues so-far neglected in safety assessment, in particular with regard to landscape analysis. Unintended dispersal plays an important role. If GM organisms disperse outside of their intended cultivation location, what do we need to know? In principle, precisely all of what could bring up unintended and undesirable effects – including combinatory effects that may result from interactions in a changed environment.