Precise Precaution versus Sloppy Science

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The Convention on Biological Diversity opens the possibility to negotiate a legally binding Biosafety Protocol to assess and minimize risks in the field of transboundary transfer, handling, and use of organisms modified by genetic engineering. Two principles - the Precautionary Principle and the Principle of Familiarity - guiding the risk assessment as basis of import decisions on such organisms are discussed. Developing and European industrialized countries favor the Precautionary Principle. The US, Australia, Japan, and some others call for the Principle of Familiarity. These two principles exihibit opposit effects on scientific progress in general and on scientific methodology of risk assessment in particular. With the example of risk assessment by the U.S. company Monsanto discussed below, it could be illustrated that the Principle of Familiarity opens the way for superficial evaluations based on citing arbitrary references while the Precautionary Principle is an incentive for developing and applying sound methodology in experimental risk assessment.

Since May 1997, negotiations on a legally binding Biosafety Protocol to assess and minimize risks in the field of transboundary transfer, handling and use of living modified organisms (LMOs) are taking place in Montreal, Canada. LMOs are organisms that are modified by means of genetic engineering. They contain new combinations of genetic material which could not have been gained by conventional breeding and that have been transfered between sexually incompatible organisms, thus overcoming natural barriers of reproduction. The Montreal negotiations focus on the transboundary transfer of such LMOs, for example, on the international exchange of and trade with transgenic seeds, grains, animals or bacteria. The negotiations are based on Articles 19.3 and 8(g) of the Convention on Biological Diversity, elaborated during the Earth Summit in Rio de Janeiro, Brasil, in 1992 and on Decision II/5 of the Second Conference of the Parties to this Convention in Jakarta, Indonesia, in 1995 (see the appendix; for more documents, see www.biodiv.org). Until the Fourth Conference of the Parties in 1998, 172 states ratified this Convention. This Conference decided to finish the Biosafety Protocol in February 1999. In 1998, transgenic crops were allowed to be planted in eight countries of the world. As the country with the largest acreage of transgenic crops (74%) and as the main trader of LMOs, the United States cannot become member of the Protocol until they it has ratified the Convention on Biological Diversity.

Is the Precautionary Principle Incompatible With Sound Science?

One of the main demands of civil society organizations during the Montreal negotiations calls for the Precautionary Principle as the basis for scientific risk assessment and political decision-making under the Biosafety Protocol. Civil society organizations witnessed that some delegations try to establish contradiction or even incompatibility between the Precautionary Principle and sound science. It is the view of civil society organisations that at their best, sound science as a methodological concept and the Precautionary Principle as guideline for decision-making are mutually supportive and can operate in perfect harmony.

What does this mean within the context of the Biosafety Protocol? The Precautionary Principle enhances

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the search for scientific knowledge by initiating a scientific risk assessment and thus collecting data and providing scientific evaluations on ecological, health and socio-economic risks of LMOs on biological diversity and human health. Sound science serves precaution because it contributes to an early warning system supporting political efforts to minimize already obvious harm and to prevent the emergence of new negative impacts.

Different Positions in the Biosafety Negotiations

However, not all delegates share this concept of mutual supportiveness between science and precaution. The legal frame work of the US, which is the leading exporter of LMOs and products therof, stresses the Principle of Familiarity as basis for decision-making in the context of modern biotechnology (FDA 1992). What task does this assign to science? Science has to provide risk assessment on the intended novel traits of a given LMO. However, as far as the unintended changes are concerned, science has to provide arguments for avoiding further risk assessment and has to support the judgement that the differences in the composition of genetically engineered and non-engineered organisms are insignificant. Thus, science is turned into an instrument for stopping scientific curiosity and hindering the quest for new scientific knowledge. The promotion of the Precautionary Principle seems to civil society organisations the appropriate and necessary safeguard to counteract the risks of such science which is based on and reduced to serving the interests of exporting companies. Precaution is the only chance for all countries and populations to prevent harm. Moreover, it is the only chance for poor for mitigating adverse effects of modern biotechnology because they will not be able to finance remedial actions.

The non-adherance to sound standards of science and the strange lack of inquisitiveness in the type of science that is not exposed to the stimulus of the Precautionary Principle will be demonstrated below in the attached evaluation of Monsanto's attempt to prove the familiarity of consumers and environment with Roundup Ready® Cotton.

Case Study: Roundup Ready® Cotton

Roundup Ready® Cotton was engineered by means of gene technology to resist Monsanto's herbicide Roundup Ultra®. In addition to the main product-that is, cotton fiber-residues from processed cotton bolls are used as animal feed and for human nutrition, notably, cotton protein and cotton oil. To register herbicide resistant Roundup Ready® Cotton in the United States, Monsanto had to prove its substantial equivalence to conventional cotton. In 1996, Nida et al. published an article meant to provide the supporting scientific evidence. One of the features that were analysed by the authors was the content of gossypol, a toxic terpenoid constitutent of various parts of the cotton plant.

Nida et al. (1996) showed by their experimental results that there is a statistically significant difference, and not an equivalence, in the gossypol content between the seeds of two tested LMOs (n=6, Ms=1.32 and 1.01%) and the parental, non-modified line (n=6, M=1.19%). How did the authors then proceed to prove that these significant differences are within the range of familiarity? Did they continue the experimental approach or did they just make use of available publications? Admittedly, it is cheaper and faster to rely on preexisting publications. However, choosing an experimental approach is the very way in which science increases the range and depth of its knowledge. Moreover, this is especially appropriate for research on unintended effects. Nida et al. quoted, "previously reported [gossypol] levels for cottonseed grown under various field conditions, 0.39-1.70% (Berardi & Goldblatt, 1980; Abou-Donia, 1976)"(p. 1871).

The comparision of sets of data generated under different conditions to prove the equivalence of the analysed biological entities is one of the most demanding scientific challenges. The experimental approach would imply a series of comparative analyses, covering LMOs, with their parts and products, and covering corresponding unmodified organisms, with their parts and products. This should be preferably performed within the same laboratory applying the same methods. The second approach compares data taken from publications that were not designed to be stricly comparable. The nonexperimental approach which Monsanto has chosen (see Figure 1) has to adhere to the same stringent standards of sound science as the experimental approach (Nida et al., 1996). Does the article by Nida et al. (1996) do so? One could think so because their choice of references passed the peer review of the publishing scientific journal. Monsanto made use of it as proof of substantial equivalence. The Principle of Familiarity then freed Monsanto from conducting a risk assessment. Are the data comparable and is their interpretation conclusive?

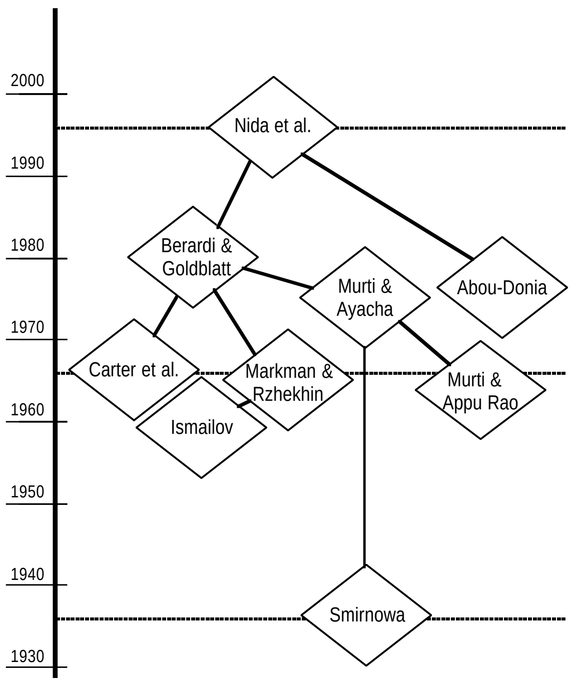

Figure 1. References Cited and Visualization of Their Interrelationship

Analysis of the Publications Cited by Nida et al. (1996)

Direct References

Abou-Donia (1976) wrote one sentence on the gossypol content in cottonseed: "Cottonseed usually contains 0.4 to 1.7% gossypol.". These numbers were cited correctly by Nida et al. (1996). However, Abou-Donia (1976) neither stated the source of these data, nor the cotton vareties, nor the country and year of the field trials that provided these data. Therefore, this reference is a very questionable proof of the gossypol content of cottonseed.

Berardi and Goldblatt (1980) give more details:

> Ranges of 0.68-2.36% gossypol in kernels of various cottonseed varieties grown in India and of 0.33-2.40% gossypol in kernels of seed grown in the USSR were reported (Markman & Rzhekhin, 1969; Murti & Achaya, 1975). Carter *et al.* (1966) reported that gossypol contents of seed from 11 (cultivated and noncultivated) species of the genus *Gossypium* varied from 0% for the glandless varieties of *G. hirsutum* L. to more than 9% for *G. klotzschianum* var. *davidsoni* (Kellogg). (pp. 192-193)

The reference of Nida et al. (1996) to this set of data lacks two important features: (a) The numbers are not correctly quoted, and (b) the data are not comparable, as the different authors are not using the same parts of the cotton boll for their chemical analysis.

The most central component of the cotton seed is the kernel which has the gossypol-producing glands. As such, the seed is composed of the kernel and gossypol-free coating layers (hull and, in North American species, the fibrous linter layer). Whilst Nida et al. (1996) used delinted seed, Berardi and Goldblatt (1980) refered to kernels. The concentration of gossypol in kernels is approximately twice as high as in whole seed.

First Level of Indirect References

Carter et al. (1966) analysed the gossypol content in kernels of different species of the genus *Gossypium*, including wild species. This dated publication provides genuine experimental data. A comparision of a distinct transgenic cotton line with any other cotton species might be useful for a general understanding of different levels of gossypol production; yet, to use such a comparision to establish substantial equivalence through familiarity is seriously doubtful.

Markman and Rzhekhin (1969) reviewed Soviet literature on the gossypol content of various parts in different cotton varieties and species. Berardi and Goldblatt (1980) chose one table on kernel data published in that review, originally compiled by Ismailov in 1959.

Murti and Achaya (1975) reviewed Indian publications on the composition of various parts in different cotton varieties and species. Data on gossypol contents in kernels are taken from Carter et al. (1966), Narayana Rao and Krishnamurthy (1953), Raghavendar Rao (personal communication), and Anonymous (no date). From this review, Berardi and Goldblatt (1980) have chosen data, originally compiled by Narayana Rao and Krishnamurthy (1953) and Raghavendar Rao (personal communication). The publication of Narayana Rao and Krishnamurthy (1953) is not publically available to the international scientific community; personal communications are in general not appropriate in a sound risk assessment. In addition to the above citations, Murti and Achaya (1975) also present data on the gossypol content of whole seeds of four cotton species by citing the results of Murti and Appu Rao (1963) and Smirnova (1936), respectively. These data are the only data which may lend themselves to comparison with the LMO data of Nida et al. (1996), yet they were not used.

Second Level of Indirect References

Ismailov (1959) compiled data on the gossypol content of cotton kernels from varieties within six cotton species. This publication is not publically available to the international scientific community. Again as argued above, kernels and whole seeds are not comparable entities.

Murti and Appu Rao (1963) present data (0.27%-0.82%, as cited in Murti & Achaya, 1975) that contradict the assumption of substantial equivalence of Monsanto's Roundup Ready®-Cotton. The whole seed they used contained approximately half the amount of the toxin gossypol than did the seeds of Monsanto's cotton plants. Again, this publication is not publically available to the international scientific community.

Smirnova (1936) uses whole seeds (0.15%-1.59%, as cited in Murti & Achaya, 1975) and has some aspirations to be comparable with Nida et al.'s (1996) results. Again, this publication is not publically available to the international scientific community. This data was produced 60 years before Nida et al., and methods of analysis have changed. Strict comparability could be better served by more recent research data.

Conclusion

All documents negotiated in Rio de Janeiro should introduce the Precautionary Principle as formulated in § 15 of the Rio Declaration into international legislation. In the field of assessing risks of organisms and their products altered by genetic engineering, existing European legislation adheres to the Precautionary Principle while the national legislation in the United States is based on the Principle of Familiarity. In the Montreal negotiations, the European countries together with the G77, representing the developing countries, call for the inclusion of the Precautionary Principle in the Biosafety Protocol. Apart from the advantages that this principle gives parties to ensure effective health and environment protection, the implementation of the Precautionary Principle in the Biosafety Protocol will have direct effects on the quality of science and progress of knowlegde. While the application of the Principle of Familiarity causes a lack of incentives for new scientific investigations, the application of the Precautionary Principle will stimulate scientific accuracy and progress in risk assessment. The above case study on the gossypol content of Roundup Ready® Cotton is one of several possible examples to illustrates the inediquacy or the Principle of Familiarity as basis for sound risk assessment. The final round of the Biosafety Protocol negotiations in Cartagena, Columbia, in February 1999 is the last possibility for the governments to create a Protocol with innovative and demanding legal and scientific instruments to ensure optimal protection of human health and biological diversity.

APPENDIX
The Biosafety Protocol Is Based on International Law

1992 - Convention on Biological Diversity

§ 19.3

The Parties shall consider the need for and the modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

§ 8 (g)

Each Contracting Party shall, as far as possible and as appropriate:

. . .

(g) Establish or maintain means to regulate, manage or control risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risk to human health;

. . .

1995 - Jakarta-Mandate II/5:

The Conference of the Parties, . . . Affirming that international action on biosafety should offer an efficient and effective framework for the development of international cooperation aimed at ensuring safety in biotechnology through effective risk assessment and risk management for the transfer, handling, and use of any LMO resulting from modern biotechnology that may have environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health, and taking also into account Articles 8(g) and 19, paragraph 4, of the Convention, . . .

1. Decides to seek solution to the above-mentioned concerns through a negotiation process to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of bioogical diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement; . . .

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