BIO-SAFETY CRITIQUE & GUIDELINES RECOMMENDED BY DR BHARGAVA

EXCERPTS FROM: 'URGENT INTERIM APPLICATION' FILED BY PETITIONERS IN AUG '08

Six outstanding issues sum up just how faulty and perfunctory the Regulator's approach to bio-safety has been. Even the current inadequate norms for safety testing have NOT been applied to GM food crops like Bt okra and Bt brinjal before they were field tested.

A. *"In No case has there been an appropriate and comprehensive risk assessment".* For example, focusing on some of the more important tests for bio-safety, i.e. long term testing, DNA fingerprinting, testing for new allergens (unintended effects), which are only possible through proteomics analysis (the study of the proteins that are expressed at a particular time, i.e. under particular conditions, in a cell, or cell type (tissue)), study of surface properties and studies on reproductive interference, *"have not been done" ---and* wherever *effect on Bt plants on soil have been studied, no study has been done on the microflora spectrum or the trace element content of the soil".*

B. Tests have been carried out by the Applicant (crop developer), or by an outside agency (for example Rallis), to whom samples were provided by the applicant. *"Thus, it is perfectly possible, (and, given the track record of the companies concerned, and the fact that no independent and reliable validation procedure exists in the country, even probable) that, say, for toxicity tests, animal tests and allergenicity tests, the samples that were given or used were of normal, non-genetically engineered material. IN SUCH A CASE ANY ADVERSE EFFECT OF THE GMO WOULD NEVER COME TO LIGHT. It is un understandable that in all these*

facilities for all the tests that need to be done would exist so that any test report given by the company asking for the release of the GMO, could be validated. It cannot escape anyone's notice, that this situation has benefited the companies marketing the GMO, and one cannot, therefore, rule out a motive for <u>not</u> setting up such an organisation. IN FACT, THIS POINT ALONE WOULD MAKE ALL THE TESTS DONE SO FAR ON THE BASIS OF WHICH CONFINED OR MULTILOCATIONAL RESEARCH TRIALS AS A PRELUDE FOR COMMERCIAL RELEASE OF GMO HAVE BEEN APPROVED AS INVALID". It is to be noted that the GEAC has accepted in principle the need for such an institution at agenda item 4: point 5.5 of the 85th Meeting.

C. All tests have used a *surrogate protein* not the actual "*protein derived from the GM plant. Assuming identicality of the two is scientifically untenable".*

D. "*No chronic toxicity tests have been done. It is amazing that it is not recognised that in many cases the effects may be only long-term effects. Examples would be aflatoxin and many agents that cause cancer.*"

E. "*EVENT-BASED approval, to which GEAC has been resorting till now, without further experimentation, may not be justified on account of differences in the case of different hybrids, in the nature and the extent of glycosylation of proteins".*

F. CBI (Confidential Business Information) "*is a lame excuse for not giving the detailed primary data, which, if given, may go against the Applicant as has happened in the past".* (Dr. Bhargava is referring to Mons 863

8. Dr. Bhargava asks a series of questions, which highlight the gaps, flaws and cover-up in bio-safety regulation in India, as follows:

i. **Was appropriate risk assessment done before Bt-cotton crops were released?**
ii. **Were the field trials adequately done and appropriately monitored?**
iii. **Do certified and professionally reliable and competent facilities exist in the public sector at one place, in which people would have trust, for assessment of all risks mentioned (in Dr PMB's bio-safety guidelines which follow) and validation/cross-validation of data provided by the companies seeking release of their GMOs?**
iv. **Have there been any glaring fallacies in existing procedures on the basis of which approvals have been given or are being considered for open release of GMOs?**
v. **Does any system exist for punishment in case of violation of existing laws?**

THE REQUIRED BIOSAFETY TEST PROTOCOL AS OUTLINED BY DR. BHARGAVA

10. Dr Bhargava submitted his Note on a suggested bio-safety protocol for GMOs in a communication dated 14th April '08 to the GEAC. Its basis is the strong scientific evidence in high-quality scientific literature, requiring the tests he outlines, to be conducted before the release of any GMO into the environment. He also underscores the irreversible nature of GMOs once they have been released into the environment and therefore the point that

market". He lists 3 essential steps as part of the procedures of the biosafety protocols: (a) "*First, it should be ascertained after careful analysis of existing information (and, if need be, relevant new information that could be generated within a short period) that there are no alternatives to the GMO and that the GMO will, if it meets the stipulated requirements, bring substantial benefit to the country and to one or more classes of its citizens (such as farmers); (b)If the GMO is truly required, the risks implicit in the risk assessment must be recognized; (c)* even *after the risk assessment is done, which should be done (where appropriate) before any open field trials are permitted – and done by an independent, competent and accredited organisation of high public credibility set up for this purpose, there would always be a residual risk left. We must then, at that time, do a risk–benefit analysis in respect of the residual risks".*

11. The Bio-safety studies suggested by Dr PMB have been tabulated below for clarity and ease of comprehension. Of a total of 29 studies, only 4 form part of the current bio-safety procedures of the GEAC and those are judged to be so bad as to be deemed *"as good as not done".* (Please refer to Dr Bhargava's summary statement in his 'Critique' to Petitioner No 1 annexure B2 Colly). This conclusively belies the GEAC statement that the "*tests enumerated by Dr Bhargava are being done"*

ANALYSES OF DR. BHARGAVA's BIOSAFETY TEST PROTOCOL

TESTS THAT MUST BE CARRIED OUT BEFORE A GMO IS RELEASED INTO THE ENVIRONMENT

TESTS PRESENTLY NOT DONE FOR ANY GMO	TESTS PRESENTLY NOT DONE FOR ANY GMO
• DNA fingerprinting and proteomics analysis and full characterization, both structurally and functionally, of the differences between the GMO and the parent organism • The total sequence of the transgene-flanking regions and the transgene, and identification of the site(s) of integration of the transgene in the GMO • Changes in the glycosylation pattern • Determination of any selective increase in transcription and translation, thus including a study of the transcriptome • Changes in the relative concentration of major and important intracellular metabolites • Changes in surface properties that may affect normal interaction between species, and with the environment, studied through scanning electron microscope and atomic force microscope • Reproduction interference • Gene flow • Dispersal into areas where positive harm could be done (as happened with water hyacinth and parthenium) • Development (if not already available) of a technique to determine with accuracy 0.01 percent contamination with GMO or its product • In the case of GM food material, possible interaction with commonly used drugs, especially probiotics • Acute toxicity studies with native **(not "surrogate")** protein, GM seeds and other GM plant material that is normally ingested by animals, including cattle. These studies sh	• Chronic toxicity studies (including carcinogenicity) as above • Effect on cattle GI microflora • Effect on soil micronutrients in every region concerned (rain-fed, irrigated, semi-arid, etc.) where GMO is likely to be released or find its way • Development of resistance to the trait that is introduced • Increasing requirements for refuge crops, if any. • Increase in susceptibility to pests and infectious agents other than those that may be expected to be killed by the transgene. • Comparison of the growth characteristics of the GMO and the parent organism. • Emergence of new dangers, for example of super weeds, following prolonged use of herbicide-resistant GM crops. • Effect on the population density of non-susceptible pests, following at least five successive plantations – for example in the case of GM Bt plants. • Automated karyotyping and gross chromosomal analysis. • If the GMO is a plant, its biomass productivity in comparison to the parent. • Comparison of inputs required for optimal growth of the GMO in comparison to the parent organism. • Impact on ecology in controlled field trials (for example, on population of bees, and other useful insects). This would require total mapping of insects and other living species in every region where the GMO is intended to be released, over a substantial period of time.

TESTS CLAIMED TO BE DONE BUT AS GOOD AS NOT HAVING BEEN DONE
• Stability of the transgene product in the whole organism and/or parts thereof, under various conditions of storage or handling (e.g. cooking in case of an edible GMO) • Efficacy on useful insects. • Effect on microflora of the soil

Extracts from

Some specialities in the Norwegian Gene Technology Act

Presentation at the Bogor Training Course January 2006.
By Jan Husby, Senior Adviser, The Norwegian Institute of Gene Ecology (GenØk).

The Norwegian Act

The Norwegian Gene Technology Act has some elements that we usually don't find in other countries legislation. In the purpose of the act it is stated that we shall ensure that production and use of genetically modified organisms takes place in an ethical and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment. This is further elaborated in the approval section of the Act where it is stated that significant emphasis shall be placed on whether deliberate release represent a benefit to the community and a contribution to sustainable development. I will come back to these elements of the Act after presenting some of the main provisions.

According to the Act everything that is not approved as contained use, is defined as deliberate release. Therefore, especially GMOs in; green houses (glass houses), aquaculture facilities and animal accommodations need approval as contained use, and if they do not have that, they need to have an approval for deliberate release. Also field experiments, commercial use, and import and transport are defined as deliberate release and therefore need approval. In the ongoing revision of the regulation on transport, import, handling and packaging of GMOs, we also find the new requirements on labelling, transport documentation and export.

In the Cartagena Protocol we find the special category of LMOs (GMOs) that in Article 11 is defined as "LMOs intended for direct use as Food, Feed or Processing (FFP`s)". In accordance with the Norwegian legislation all LMOs intended for this type of usage is defined as deliberate releases and therefore need a thorough risk assessment and an approval from the authorities as any other usage for deliberate release or marketing.

Section 10 is the approval section for deliberate release. It states that the "step by step" principle has to be used in connection with applications fore deliberate release of field experiments (a), commercial purpose (b), green house, aquaculture facilities etc (c) and when applying for marketing (f) under section 9.

The "Step by Step" principle defined by OECD, states that the development of a GMO has to be carried out in a stepwise procedure; starting in appropriate contained laboratories, before released into e.g. green house, microcosm etc, before continue in small scale experiments, large scale experiments, and ending up at the finale stage of commercial application. If any unexpected effect happens during one of the developing stages, the intention is that the GMO shall be taken back to an appropriate security level to sort out what caused the unexpected effects. The obtained knowledge of the organism in question will during the different steps in this regard be very useful in any future risk assessment.

There is also a request that the GMO in question should be tested in the natural environment that will be affected by the intended use. This is quite important and is regarded as the basis for relevant knowledge about any possible environmental or

ecological impact; issues that should always be evaluated in an appropriate risk assessment before any release.

In the Norwegian Act we use the terminology "impact assessment" instead of "risk assessment", due to the fact that we have a broader perspective than risks when evaluating the possible impacts from GMOs, in this regard also the possible benefits. The impact assessment shall also include information related to the Purpose Section of the Act regarding ethical, socially justification and sustainability issues. The risk assessment is of cause a comprehensive part of the overall impact assessment but not the whole.

In section 12, we find the obligation to inform the public in accordance with our "Freedom of Information Act". We can still keep confidential business information confidential, but some issues in an application can never be kept confidential. In this regard we will also challenge any applicant if they try to keep information in an application confidential, e.g. information that the authorities believe should not be confidential. We have also amended the regulation so that inn connection with commercial release applications there will always be a public hearing before any decision is taken.

Some of the other important sections in the Act

Section 13: Public consultation
Section 14: Marking requirement (Labelling)
Section 15: Conditions of approval
Section 16: Alteration and revocation of approval
Section 17: Supervision
Section 18: Right of inspection
Section 19: Duty to provide information
Section 20: Order to cease activity
Section 21: Duty to prevent and limit damage
Section 22: Fees
Section 23: Compensation
Section 24: Coercive fine
Section 25: Penalties

Under the Act it is also established an independent Biotechnology Advisory Board, something we find in many countries. The board or committee is giving recommendations and advices only, and is therefore not an authority that takes decisions. They take initiatives for public debate connected to important or outstanding issues linked to gene technology and GMOs. They also give recommendations to politicians, authorities, Parliament and the Government when asked, or on their own initiative. They constitute of 21 appointed representatives from public organisations and relevant researchers and scientists, and are appointed for three years periods. They have in their mandate the special task of elaborating questions linked to ethical, social justification and sustainability issues.

Ethics, socially justification and sustainable development in the Norwegian Act

The regulations on Ethics, Social Justification and Sustainable Development are quite exceptional to find outlined in regulations connected to GMOs.

In section 10 of the Act, we also find that significant emphasis shall be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.

The Norwegian authorities therefore asked the Norwegian Biotechnology Advisory Board to make a system of how to operate the purpose of the act into practical management regarding: Sustainable development, Socially justification and Ethical considerations. The result was a guiding document, and I shall give a presentation of some of the main headings and conclusions of the document.

The Biotechnology Advisory Board, is appointed by the government to give advice, and have representation from different stakeholders e.g. Non Governmental Organisations and different scientists from relevant institutions and different research fields. It is especially in their mandate to give advice to the government and the authorities regarding these issues.

First the Biotechnology Advisory Board made an interpretation of the Gene Technology act that was the basis for their further work with the guideline document as follows:

The NBAB was of the opinion that the Gene Technology Act (§§ 1 and 10) should be understood in a way that the demand for sustainable development, socially utilitarian value and other ethically and socially considerations, are requirements in a decision that alone can give conclusive weight against approval of an application, but this shall also be considered in proportion to the risk for harmful effects, when this is low.

The definition of the precautionary principle under CBD was used as a starting point. In this regard they listed under what connections there could be a doubt about the information that makes the basis for a decision. The advisory board listed five important points:
Doubt about the cause end effect connection,
Doubt about the probability estimates,
Doubt about the risk assessment,
Doubt about cumulative consequences, and/or
Doubt about whether restrictive and management measures are working as expected.

The recommended guideline document also list up some of the fundamental ideas behind Sustainable development. Sustainable development is building on a set of ideas that applies to:

1. *The global effect of human activity.*
2. *The idea of an ecological border, and that these borderlines already is exceeded in many areas.*
3. *The idea of satisfying the basic human needs.*
4. *The idea of a just distribution between the generations.*
5. *The idea of a just distribution between poor and rich countries.*
6. *The idea of a new shape for the economical growth.*

They also made a decision structure in three points that should be followed on a case by case basis in practical management of the applications:

1. Risk of negative effects on environment and health:
   a) What are the possible negative consequences?
   b) What is the probability that these negative consequences occur?
2. Precautionary principle:
   a) Is the risk assessment associated with grounded uncertainty?,
   b) Is it a possibility for huge or irretrievable damage?

3. Is it:

a) In accordance with the principle of sustainable development?
b) Of utilitarian value for the society?
c) Ethically and socially justifiable?

First the traditional risk assessment regarding possible environmental and human health should be considered. Then they put the emphasis on the precautionary principle, and then the rest of the purpose of the gene technology act regarding sustainable development, value for the society and the ethical dimension.

In connection with the socially justification and the possible value of a GMO for the society, the advisory board is listing some important questions that makes out the information needed to assess whether or not the GMO is acceptable in this regard:

Socially justifiable / Socially utilitarian value

- *Is it reasonable to say there is a need, by demand, in one way or another, for the product?*
- *Is it reasonable to say the product can solve, or contribute to solve, a problem for the society?*
- *Is it reasonable to say it is considerable better than corresponding products already on the market?*
- *Is it reasonable to say that other alternatives are better than the product regarding solving, or contribute to solve, the actual problem for the society?*

Other relevant aspects listed are:

Production and use of the product; indicative list of relevant aspects to consider:

- *Does it contribute in making new employment opportunities?*
- *Does it contribute in making new employment opportunities in the countryside especially?*
- *Does it contribute in making new employment opportunities in other countries?*
- *Does it contribute in making problems for existing production that otherwise should have been preserved?*
- *Does it contribute in making problems for existing production in other countries?*

In connection with ethical consideration the NBAB finds it appropriate to distinguish between ethical norms and values associated with humans and those associated with environmental ethics (the integrity of nature).

The procedure proposed by NBAB outlines ethical reflections which aims at enabling us to undertake assessments of what is right or wrong, i.e. morally good or evil, in a more systematic and justifiable way. Further NBAB states that ethical reflections in connection with moral dilemmas are often based on an intuitive experience of the situation as problematic, without actually being able to pinpoint what is alarming. In many respects this is the situation when dealing with the scientific knowledge regarding safety aspects of GMOs. Scientists working within different, but relevant research fields, often tend to interpret data connected to risk assessments differently, and make value judgments with a basis in their own research traditions and experiences. This makes it difficult for authorities when receiving advices in connection with decisions, because the emphasis on risks of possible effects will vary depending on whom you ask and their professional background, integrity, standpoint and conviction.

Regarding ethical considerations connected to humans, the NBAB has developed the following control questions:

Is approval/prohibition of the product, its production and use, in accordance with the general public normative opinions and values?

Is the product and its production in conflict with ideals of solidarity and equality between humans, especial taking into account susceptible or week groups in the society?

Indigenous population, people in special traditional cultures and susceptible groups, can be subjected to consequences of grate disadvantage due to the larger society's decisions.

Is marketing and trade of the product against such norms and values?

Regarding environmental ethical considerations the NBAB has developed some indicative questions that are not intended to be exhaustive, and it should also be noted that all questions are not necessary relevant in all cases:

- *Are the product and its production in conflict with animal species intrinsic value?*
- *Does the production imply any unnecessary suffering for animals?*
- *does the production imply that any barriers between species is exceeded in ways that are distinctively different from what usually happens when breeding, or in the wild, and that it is considered incompatible with the value and importance of separate species?*

The NBAB has commented that an assessment of other ethical and societal issues should be based on a discussion in connection with all collected answers related to an application.

Knowledge about the public opinion and values regarding this type of questions is important if this type of assessment is to reflect reality. It is therefore necessary to have meeting points for debate and discussions between politicians, authorities, scientists, the biotech industry and the public. Debate and meeting points will enhance the authorities' knowledge of the different opinions within society. In Norway, all new applications for marketing release of GMOs is subjected to public hearings where different opinions may come forward. During many years the NBAB has also arranged public meetings and consensus conferences where important biosafety related topics have been the main focus. This type of activity increases public knowledge regarding biosafety and GMOs and the authorities and politicians will have important feedback related to many of the issues and questions outlined above.