

FAST SALMON AND TECHNOBURGERS

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*Report from the Consensus conference on
genetically modified food, 18-21 October 1996*

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About the organizers

The National Committees for Research Ethics, NEM, NENT and NESH are independent bodies with mandates from the Ministry of Education, Research and Church Affairs. NEM deals with medicine, NENT with science and technology, and NESH with social science and humanities.

The Committees are to function as watchtowers, sources of information, and advisers in research ethical issues. The Committees shall submit reports and propose guidelines of research ethics. They shall also inform researchers, the administration and the public of current and potential questions of research ethics, and promote informed discussions in society of ethical questions relating to their areas of responsibility. Papers published in the Committees' publication series do not necessarily reflect the views of the Committees, but are the responsibility of the authors.

Further information about the Committees can be found at Internet: <http://www.etikkom.no>

The Biotechnology Advisory Board is an official independent advisory body appointed by the Government. The Board's mandate covers biotechnology and gene technology in relation to humans, animals, plants and micro-organisms. The Board shall evaluate principles and general issues in connection with activities in biotechnology, and put forward proposals for ethical guidelines for such activities. It shall also make recommendations in cases that are dealt with under The Gene Technology Act and The Act Related to Application of Biotechnology in Medicine. The Board shall also inform the general public of biotechnology.

Further information about the Board can be found at internet: <http://www.bion.no>

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REPORT BY THE LAY PANEL

INTRODUCTION

The initiative leading to a layman's conference was taken by the National Committees for Research Ethics and the Norwegian Biotechnology Advisory Board, which saw a need to include non-experts in order to obtain the views of ordinary people on the genetic modification of food.

The panel consisted of 16 people, 8 men and 8 women, aged from 18 to 72, from various parts of the country and with different backgrounds. Members were not to have close links with occupations or organizations with established policies in this area.

In its work, the panel was advised by Professor Gunnar Handal, of the University of Oslo's Department of Educational Research.

The panel held two preparatory meetings in addition to its concluding conference, at which experts delivered statements and answered questions, and the panel presented its report.

The questions published in the report were put to the experts so that the panel could obtain more information on the subject. The answers - contained in the statements and given in response to the questions - formed the basis of the views the panel has formed on different matters, although the report does not necessarily answer each of the questions directly.

The aims of the work were to give coordinated advice on genetically modified food to politicians, authorities and the food industry, to establish a forum for dialogue between experts and non-experts, and to contribute to an all-embracing and well-informed public discussion of the subject.

The panel hopes that the present report will contribute to the realisation of those aims.

The panel found its task very interesting, instructive, stimulating and enjoyable.

It is the panel's opinion that there is no need for genetically modified food in Norway today, because the selection, availability and quality of ordinary food are satisfactory. Too many uncertain factors attach to genetic engineering in this connection. This also appeared from the statements by the expert panel.

The panel points out circumstances to which attention ought to be paid if developments nevertheless move in that direction.

The conclusions presented later in the report should be seen in the light of this statement of principle.

In the panel's view, the most important measure that can be adopted in this area is probably to contribute to the education, where the genetic engineering of food is concerned, of a well-informed, aware and critical public. This could have a beneficial effect, among other things on the shaping of policies, the drawing up of rules, practice with regard to decision-making and controls, and influence on consumers.

The report is presented in eight main sections.

The lay panel:

Karl Erik Birkeland, 20, student, Ålesund

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Else Stjernstrøm, 47, head of department, Tromsø

Tone Ystanes, 34, housewife, Skjetten

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The expert panel:

Helge Klungland, Department of Animal Science, Norwegian University of Agriculture, Ås

Askild Holck, Matforsk - Norwegian Food Research Institute, Ås

Guri Tveito, the Ministry of Environment, Oslo

Hilde Kruse, National Veterinary Institute

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Nils Uddenberg, Swedish Institute for Futures Studies, Stockholm

Åse Fulke, Norwegian Food Control Authority, Oslo

Stine Wohl Sem, Consumer Council, Oslo

Odd Arne Rognli, Department of Biotechnological Sciences, Norwegian University of Agriculture, Ås

Rune Blomhoff, Institute for Nutrition Research, Oslo

Marte Rostvåg Ulltveit-Moe, Nature and Youth, Oslo

Torben Hviid Nielsen, Centre for Technology and Culture, University of Oslo

Reidar Almås, the Centre for Rural Research, Norwegian University of Science and Technology, Trondheim

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I GENE MODIFICATION

1 How are genes modified?

1a How precise is genetic engineering technology?

1b Is the process irreversible, for instance if genetically modified organisms (GMO) are deliberately released into the natural environment?

1c What is the difference between traditional breeding/selective breeding and genetic engineering?

1d Which advantages/disadvantages does genetic engineering entail with regard to the speed of progress?

2 Which categories of genetically engineered food exist?

2a To what extent do the end products contain modified genes?

3 Why is gene modification a topical research subject?

In genetic engineering, gene modification is a technique which principally consists of isolating a gene with a desired characteristic and then transferring that gene to another organism. Although the technique was only developed a relatively short time ago, it has developed by leaps and bounds since 1973, when scientists first succeeded in transferring a gene from one species to another.

The technique used to find and isolate a gene which codes for a desired characteristic has proved to be precise. The introduction of the isolated gene into a host, on the other hand, is very imprecise. To make it easier to distinguish hosts which have incorporated the new gene in the desired way, marker genes are introduced at the same time. Thus it is easy to cultivate only those organisms which have incorporated the gene in question. But because of the difficulty of controlling just where the injected gene locates itself in the DNA chain, it is not possible to predict all unwanted effects.

Once a gene has been introduced into an organism, it can in practice not be removed. To stop the effect, the organism containing the modified gene, and any "offspring" it may have had, must be destroyed. This can be done for instance by making the organism sterile or making it dependent on a particular environment.

Like traditional breeding, genetic engineering is based on the selection of organisms. Nevertheless, it is important to be aware of certain differences. In theory, genetic engineering opens up the possibility of crossing all the boundaries between different species, which is impossible in traditional breeding and breed improvement.

Like all technologies, genetic engineering offers both advantages and disadvantages. Quicker results are an example. They can on the one hand provide us with a great deal of knowledge in a short space of time, but on the other they involve the risk of not having an overall view. The urge to begin using a technique as quickly as possible (unwillingness to wait for a better technique) increases the risk of unwanted long-term effects.

The following categories of genetically engineered food exist (*examples in italics*):

- * Food consisting of genetically engineered organisms:

genetically modified tomatoes

- * Food containing genetically engineered organisms:

soup powders containing genetically modified tomatoes

- * Food produced using genetically modified organisms which remain in the product:

bread baked using genetically modified yeast

- * Food produced using genetically modified organisms but which no longer contain modified genes:

soya oil made from genetically modified soya beans

Why is genetic engineering a topical research subject?

- * The technology has been discovered and the techniques are available
- * There are many possibilities
- * The subject affects all groups in society
- * The field offers opportunities for high financial profits

The panel recommends:

- * That the focus of research be shifted from basic research to deliberate release and its effects
- * That the focus of basic research be put on problems relating to the introduction of genes into organisms

II THE PRESENT SITUATION AND CURRENT REGULATIONS

4 What genetically modified products are available today on the Norwegian, European and international markets?

4a What products are being tested (in laboratories and deliberate release experiments) with the aim of reaching those markets?

5 Both basic and applied research are being carried out in this area. Who runs and finances such research? Are those engaged in the various types of research cooperating?

6 In the field of genetically modified food, research is being carried out under both private and public auspices. To what extent does Norway/should Norway exercise central control of such research?

7 Which Norwegian statutes and rules currently regulate research into and development, production, imports and distribution of genetically modified foods?

7a What need is there to update statutes and rules?

7b Is such updating currently taking place?

7c How far, and by what means, is it possible to influence national legislation through special interest organizations?

8 What international laws/rules are currently under preparation?

8a To what extent will international legislation influence Norwegian rules (legislation) - and vice versa?

8b What will be the results of Norwegian legislation which is "stricter" than the international rules?

9 How much scope does the food industry have for taking public attitudes into account when marketing genetically modified food - and does it do so?

Several products are currently in use in other countries, such as tomatoes, corn, soya beans, papaya, squash, potatoes, and rape seed. In addition, applications for approval of a number of species have been submitted both in the EU and in Norway.

According to the experts, there are currently no GMO products on sale in Norway.

Norwegian authorities have four main sets of rules to relate to where regulation of genetically modified organisms is concerned:

1. The Act relating to the production and use of genetically modified organisms (The Gene Technology Act) (1993)
2. EU Directives concerning deliberate release and contained use
3. The UN Convention on biodiversity
4. The WTO Agreement

The Gene Technology Act can be said to cover today's situation, but probably not tomorrow's.

The present Gene Technology Act does not cover all forms of GMO products, for instance processed products.

It is our understanding that the Norwegian authorities are waiting to see what rules the EU issues, but where EEA Directives are concerned, Norway can exercise a veto. Norway has experts on various international committees who urge Norway's views on GMO products.

European consumer organizations cooperate on food questions, among other things so as to have an influence on the EU Commission, the EU Parliament, etc.

The following example can serve to illustrate the problem which arises if Norwegian laws conflict with imports of foreign goods:

The EU has refused to accept imports from the USA of milk products produced using the genetically modified growth hormone BST, but is applying pressure to have the refusal reversed. In the next instance - and in other cases - such pressure may be directed against Norway.

The panel's opinions:

* By virtue of Section 1 on the purpose of the Gene Technology Act, Norwegian legislation differs from legislation in other countries. In our opinion, the concepts *socially justifiable* and *sustainable development* must be upheld. The definitions of the two concepts need to be gone into more thoroughly.

* Norway must be prepared to exercise its right of veto to prevent imports of GMO products into Norway. In the event of imports, Norwegian authorities must emphasise sustainable development and usefulness to society.

III CONSEQUENCES FOR HEALTH

10 What health hazards and health gains, if any, does genetic modification of food entail?

10a Will genetic engineering lead to nutritionally better products, and will this be given priority?

10b Will genetic modification possibly replace harmful artificial additives?

10c What do we know about the possible effects of genetically modified food on the genetic structure of human beings?

11 In what ways can genetically modified food involve advantages/disadvantages in relation to allergies?

12 Genes which lead to resistance to antibiotics are used as markers in genetic engineering. Such drugs are also in international use in medicine and veterinary medicine. Is there a risk of increasing numbers of resistant bacteria strains, and if so how can this be avoided?

13 How far should we rely on medical guarantees?

13a Are scientists given enough time in which to reach certain conclusions concerning effects on coming generations?

13b Are scientists in a position to ask the "right" questions?

We can see that this technology opens up important opportunities for improving the nutritional content of food, and our impression is that this is emphasised in the debate on genetically modified food, but on the basis of the work to date we cannot see that this area of research has been given priority.

The use of additives is one area in which genetic modification may have beneficial effects on food quality. If the keeping quality of a food is improved, there may be less need for preservatives. But this does not appear to be a prioritized research field, either.

Allergies are often mentioned in connection with genetically modified food. One can remove the proteins which cause allergies, but in transgenic plants an allergenic gene may have been introduced which may have serious consequences for persons with allergies.

Genes which lead to resistance to antibiotics are used as markers in genetic engineering. There is broad agreement among experts that the use of antibiotics in that context may accelerate the

development of resistance to antibiotics. Alternative marker genes have been developed which ought to be used instead of antibiotic resistance genes.

It is not unlikely that the use of antibiotics as marker genes in food may have a harmful effect on the intestinal microbial population in humans. That the use of genetically modified food may have other harmful effects on the body is regarded as unlikely.

This will be confirmed or disproved in time. Whether or not the time-spans allowed for such experiments today are generous enough is hard to tell with any certainty, since research in this area is relatively new. But we have every reason to be cautious.

Seeing that researchers are creative and curious by nature, there is a good chance that they will come up with the right questions. Of course there are limits here, in terms of knowledge, time and imagination.

As to whether or not medical guarantees can be relied on where harmful effects, if any, of genetically modified food are concerned, the answer is that medical guarantees of that nature are impossible to give, in this as in other fields.

The panel's recommendations

* To enable consumers to derive the greatest possible benefits from food-related genetic engineering, priority should be given to improving the nutritional content.

* Researchers should concentrate more on what may happen to our bodies when we eat genetically modified food. We know too little about whether effects over long periods of time can have consequences for genetic structures.

* Genes which lead to resistance to antibiotics must not be used. There are alternatives.

* We must be prepared to wait and allow scientists the time they need to acquire more knowledge.

* To increase the possibility that they will ask the right questions, scientists must listen to the world around them, for instance by participating in the ongoing debate in society and meeting various other participants.

We accept that genetic engineering research into food can open up opportunities for beneficial advances. But we see so many reasons for uncertainty that we have decided for the time being to reserve our position.

IV ENVIRONMENTAL AND ECOLOGICAL CONSEQUENCES

14 When genetically modified organisms are released, is it possible to prevent them from spreading and/or cross-breeding with "natural" plants, micro-organisms and animals?

14a May the spread of released, genetically modified micro-organisms, plants and animals disturb the ecological balance?

14b What may the consequences be of the uncontrolled spread of micro-organisms, for instance those which are resistant to antibiotics?

15 How is it possible for transgenic plant species to lead to less use of harmful weedkillers and pesticides?

15a What proportion of research is directed at the development of plants which are resistant to sprays, as against development of plant species which are resistant to disease and damage?

16 Genetically modified plants may make it possible to cultivate plants in new environments, shortening the distance from the producer to the consumer. On the other hand, foods with better keeping qualities can be transported long distances. Will transport, and the energy consumption and pollution that goes with it, increase or decrease?

Nature itself is dynamic; the environment around us is constantly changing, but the changes may only become noticeable over time. In genetic engineering we see the possibility of rapid and extensive changes in the living components of ecosystems (micro-organisms, plants and animals). At the same time, we need to consider every new technology in relation to existing environmental problems. We accordingly believe that ecological considerations are very important in the debate on genetic engineering.

It is difficult to predict what the long-term consequences may be of deliberately releasing transgenic species. There appears to be a reasonable degree of agreement that if plants and animals - for instance salmon - are released it is not possible to prevent spreading or cross-breeding with other species, but a great deal of uncertainty about what the consequences of this may be, or how serious they may be. In our view, the greatest potential dangers are at the micro-organism level. The uncertainty there is aggravated by the possibility of horizontal genetic transfer (movement of genes between and within species).

In our modern agriculture, monocultures are increasingly replacing multiple crops, a trend which genetic engineering may reinforce in practice. That will put biological multiplicity under ever greater pressure. It is important to emphasise the value of biological multiplicity because the total genetic variation constitutes our gene bank.

Where the use of sprays is concerned, the genetic modification of plants does open up opportunities for reducing it (e.g. insect-resistant plants). At the same time, however, we may in some connections become dependent on other sprays. We do not know the long-term effects of so-called "harmless" sprays, and it is a cause for concern that it is often the same large companies which produce both transgenic plants and sprays. We do not, therefore, see reduced use of sprays in itself as a clear argument in favour of genetic engineering of plant species.

We see no reason why genetically modified foods should lead to less transport of the goods.

The opinion of the panel:

* Reservations concerning effects on the environment/ecology appear to be greater among ecologists than among bio-engineers. We find it natural to attach greater importance to the views of the ecologists.

* The panel believes that we have time to wait in this connection, too.

Respect for complexity ought to be our guideline.

V ECONOMIC AND POLITICAL CONSEQUENCES

17 In a national and a global perspective, what will the consequences of genetically modified organisms (some of which are patented) be for individual food producers, both economically and with regard to markets?

18 Will genetically modified foods be available only to a few, or will that be the fate of "conventional" foods?

19 What impact will the genetic modification of food have on global distribution policy?

20 Will an increase in production benefit those who need it (e.g. developing countries)?

20a How will this affect population growth and the environment in developing countries?

21 Who will define the concepts "socially justifiable" and "sustainable development" in the Norwegian Gene Technology Act?

The commercial production of genetically modified food will have an impact both on economies and on markets. The technology is still expensive to use.

High investment costs will favour the big food producers in the primary industries. Smaller producers who lack the capital to adopt the new technology will find it difficult to keep up with developments. On a global scale, nearly all Norwegian producers are small. Together with the patenting of genetically modified products there may be a risk of heavy concentration in the production of raw materials.

As mentioned, the production of genetically modified food is costly, so it will be concentrated among large producers and aimed at rich markets. Niche products are likely to be the least affected by the technology and to retain their traditional production methods.

One result of patenting GMO may be that primary producers will to some extent lose their privilege of "taking seeds from their own crops" without paying fees to the originating company. The panel can not see genetically modified foods as such solving global distribution problems. Because their economies are too weak to make use of it, genetic engineering will not be readily available to most developing countries. For food resources to be more evenly distributed, the first need is for political decisions to give the third world opportunities and the necessary competence to develop.

Nevertheless, the panel does not discount the possibility that this technology may be a tool with which to improve both the quantity and the quality of global food production. At the same time,

we must remember that most third-world countries will be unable to benefit from genetic engineering until they have the necessary technological and economic resources.

The panel's recommendations:

* The right of primary producers to take "seed from their own crops" must be upheld. The situation may arise in which the "seed" seller may demand a fee on a patented process. In such cases, support schemes should be considered.

* The idea may be worth considering of having producers who take out patents pay a fee to a "patent support fund". Money from such a fund could be used to build up competence in genetic engineering in developing countries.

VI SAFETY AND CONTROL MEASURES

22 Is there the same degree of control over research under public and private auspices?

22a Is the control sufficient according to laws and regulations? If not, how can it be improved?

23 If despite all control measures harm should be done to people and the environment as a consequence of genetically modified products - who bears the responsibility?

24 Will cheap production of genetically modified foods be achieved at the expense of safe production?

Since genetically modified foods are new products and may lead to unexpected legal problems, it will be important to have adequate legislation. This applies particularly to product liability, responsibility in research environments, and questions relating to patents.

The most important Norwegian legislation regulating genetically modified foods is mentioned in Section II. The Norwegian Gene Technology Act is unique in that it includes the terms "sustainable development" and "socially justifiable" in its opening Section on the purpose of the Act.

The terms "sustainable development" and "socially justifiable" are somewhat vague, and it would be helpful if the politicians defined them more closely. It will also be necessary for the values underlying those terms to find expression in future sets of rules and in their application.

We would draw attention in particular to § 23 of the Gene Technology Act, which states that "The person responsible for an activity pursuant to the present Act has liability for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission...".

Two different principles are conceivable for the control of genetically modified food: either general approval of particular methods of production, or case-by-case approval of new genetically modified foods.

One consequence of genetic engineering is that it may become lawful to patent genetically modified plants and animals. In our opinion, any patents must be taken out on production processes and not on end products. That makes it possible to require documentation and thereby improve the control and insight of the authorities. A patent could thus also serve as a means of exercising control.

The opinion of the panel:

- * It looks as if the existing statutes and rules are sufficient for the exercise of the necessary control, but in practice this will depend on how the expressions "socially justifiable" and "sustainable development" are interpreted.
- * In the opinion of the lay panel, the principle of case-by-case approval of genetically modified foods should be retained, because examples have been seen abroad (in the USA) of negative consequences of new approvals based on earlier approvals.
- * The panel believes that the guidelines for internal control should be reviewed so as to take into account the new situation and the new problems to which genetic engineering gives rise. This applies to internal controls both in research and in manufacturing environments. We applaud the early start that has been made to the preparation of new guidelines.
- * The authorities set to control safety in the development and production of genetically modified food must be granted enough funds to enable them to carry out satisfactory controls.
- * Scientists attached to public institutions must be given working conditions which enable them both to continue their basic research and to engage in follow-up research on genetically modified food.

VII MEASURES: INFORMATION AND LABELLING

25 What steps are the authorities taking to ensure that consumers receive sufficient, reliable and easily understood information, to enable them to take an informed attitude to the genetic modification of food?

25a What steps are the authorities taking to ensure that genetically modified food is adequately and clearly labelled?

26 How ought genetically modified food to be labelled?

How much information is it necessary and reasonable to require the labelling to contain, taking into account:

- practical difficulties
- financial consequences
- the needs/wishes of particular groups (special interest groups, allergic subjects, people with various faiths or philosophies, etc.)

27 Do we know how information and labelling influence consumers?

Genetically modified food has not as yet been on sale in Norway, but such products are likely to become available in our shops in the future. Labelling is therefore a topical issue.

Section 14 of the Gene Technology Act states that "The King may issue regulations concerning the marking of products that consist of or contain genetically modified organisms." In addition, the Storting instructed the Government in 1995 to see that both genetically modified raw materials and processed foods were marked. The Ministry of the Environment is awaiting the preparation by the health authorities of such a regulation.

Marking is certainly a large and difficult question. In principle, anyone who, for whatever reason, does not want any form of genetically modified food at all, should be able to avoid it. But to require all genetically modified products, and food made from them, to be marked in every link of the production and distribution chain would give rise to problems.

Considerable disagreement is therefore to be expected concerning what to mark and how to mark it. There are many conflicting considerations to take into account. The interests and attitudes of special groups, such as allergic subjects or religious or philosophical groups, must be respected. Marking must be informative and clear enough to leave no one uncertain.

The problems connected with marking indicate caution: the complexity of the issue must not be used as an argument for reducing the importance of marking (or avoiding it).

Studies carried out in several European countries show that information does not necessarily make consumers more or less sceptical, but does lead to more shades of opinion.

The panels' recommendations:

* In the opinion of the panel, genetically modified products ought as far as possible to be marked. We believe consumers should be in a position to choose the kind of food they eat. Marking proposals: bar codes, G-numbers, both offering opportunities to obtain further information via a scanner and computer monitor, or a small folder, brochure or the like.

* The panel urges the authorities to provide sufficient, reliable and easily understood information on how genetically modified food is produced and what the purpose of genetic modification is.

VIII ETHICAL CONSIDERATIONS

28 The question arises of how far we human beings can take the manipulation of life itself, without losing some of our humanity.

Is there a danger that gene technology is moving our ethical boundaries in a negative direction?

29 In what ways does the genetic modification of food raise ethical problems in relation to various philosophies of life, views of nature, and views of man's role in relation to animals?

30 What ethical requirements are researchers/research projects required to meet?

30a What rules of research ethics have been codified in this area?

30b Do such rules apply equally to research in the public and the private sectors?

30c What are the functions in this area of the National Committees for Research Ethics and the Norwegian Biotechnology Advisory Board?

30d Do any ethical rules/quality assurance systems exist which can be applied in the course of the research/development/marketing process?

It is the panel's view that the genetic modification of food is ethically quite distinct from traditional breeding/plant breeding. This is something new. We need to stop and see where we are going.

It is widely believed that in the long run man will be obliged to take a more humble attitude to nature, in which case the unreserved acceptance of genetically modified plants and animals would seem to exercise a regrettable influence to the contrary.

Respect for life and nature is part of our identity. If we uncritically adopt genetic engineering in our food production, what does that do to us? Are we in danger of becoming insensitive and unresponsive?

Many people will have serious ethical reservations against the use of this technology on animals. One question is how heavily its usefulness weighs against the suffering we may cause animals? A further point may be that it is not a question of weighing benefits against harm, but of the inexcusability of genetically modifying animals at all.

The question is how confident we can be that research in this area is subject to ethical guidelines, and whether the ethical aspect of such research has been taken into consideration and in the event embodied in rules and regulations.

Genetic engineering research is not regulated by any specific ethical rules. In so far as the research falls within the scope of the Gene Technology Act, the attention of the Biotechnology Advisory Board can be drawn to it. Experiments with animals are also regulated by the Act relating to the protection of animals and regulations governing biological experiments. The responsibility for research projects as such lies with the National Committee for Research Ethics in Science and Technology.

The panel's opinions:

- * The panel is opposed to the inclusion of the genetic modification of animals in food production, because we cannot see that its current usefulness is such as to justify it.
- * By researching into and adopting this technology, we are moving boundaries, also in a historical perspective, which may lead to changes in ourselves and in nature.
- * We do not know enough about the currently observed rules of research ethics to be able to say that they are inadequate. We nevertheless wish to emphasise the importance in this area of good rules which are familiar to all researchers. Why not try a cautionary code for research?

THE CONSENSUS CONFERENCE ON GENETICALLY MODIFIED FOOD: ORGANIZATION AND PROCEDURE

Choice of conference format and theme

Increasing attention is being paid to how the use of modern technologies can change society. Some believe that technologies can be managed so as to serve beneficial purposes and so that harmful use can be avoided. Others argue that some technologies have certain values "built into" their uses.

Where the introduction of complicated new technologies is concerned, elected representatives often seek expert advice. The numbers of experts being small, the same people tend to be consulted on a variety of issues. By virtue of their technological expertise, a small group of people consequently exercise great influence on social developments. Where interdisciplinary questions are concerned, moreover, it is difficult to decide which are the most relevant specialists.

Laymen's conferences, or consensus conference as they are known internationally, are a form of technological assessment in which groups of ordinary citizens arrive at a considered joint opinion before a technology is adopted. The assessment comprises different aspects of the introduction or use of a technology, including ethical, economic, political, social and legal perspectives in addition to the narrower technological considerations. This gives the politicians an insight into the opinions of a selection of "ordinary people". Such conferences are thus instruments of active democracy.

Many topics lend themselves to treatment in laymen's conferences. Ideally, the issue should be politically topical, but should not have been so thoroughly debated that the parties have settled their standpoints. Problem areas which are suitable for laymen's conferences are typically ones over which opinions are divided and which raise normative questions which concern large sections of society.

Organizers define the themes of laymen's conferences broadly. Within wide limits - in the present case, the heading "genetically modified food" - it is left up to the lay panel to define the contents of the conference more closely. This is done by formulating the questions which they want the experts to answer and which the conference is to be concerned with. It is also the laymen who reach the conclusions and draw up the final report on the conference.

The model was developed by the Danish Board of Technology. In the 1987 to 1996 period, the Board has held fourteen such conferences, four of them on subjects relating to genetic engineering. In Britain, a consensus conference on plant biotechnology was held in 1994. Three have been held in the Netherlands, respectively concerning transgenic animals (1993), predictive genetic research (1995), and ethical aspects of the development of nature (1996).

The layman's conference on genetically modified food was the first to held along these lines in Norway.

Laymen's conferences are not the only form of technological assessment. For the National Committees for Research Ethics and the Biotechnology Advisory Board, technological assessment is part of the daily routine, as it is for other institutions, such as the Data Inspectorate. The choice of genetically modified food as a subject on which to test the layman model was made for the following reasons:

* There is as yet no genetically modified food in Norway, but there is likely to be in the immediate future.

* In Norwegian society, opinions differ on genetic engineering and probably also on genetically modified food.

* Although genetically modified food is a subject which affects the entire population as consumers, the discussion so far has only been carried on among experts. But expert groups disagree, and it is not clear who possesses the "definitive" expertise where genetically modified food is concerned.

Aims

The aims of the conference, as defined by the organizing committee, were:

* to give unanimous advice on genetically modified food to politicians, the authorities, and the food industry,

* to create a forum for dialogue between experts and non-experts, and

* to contribute to a wide-ranging and informed public discussion of the subject.

Selection of laymen

On 30 May 1996, advertisements in ten nationwide and regional newspapers called for laymen to participate in a conference on genetically modified food. Some four hundred responded.

The four hundred were from all over the country. Distribution by gender, age, occupation, education and other demographic factors was satisfactory. Many of the letters of application revealed involvement in the subject, but few expressed very strong views on the question of genetically modified food.

The letters varied from about half a page to two pages in length. Some were quite comprehensive, others short and to the point. Very few of the applicants claimed any specialised knowledge of or occupational or organizational connections with the subject.

The panel of sixteen laymen was selected as follows:

First, the very few who did not meet the definition of laymen were excluded: who was considered "lay" and who "professional" was a matter of judgement. Normal membership of an organization with no views on or special interests in the subject was not a disqualification, but the few applicants with prominent posts in such organizations were not defined as lay.

The project staff then sorted the remaining letters into batches according to gender and age, from which about forty letters were drawn, in equal numbers from each batch. The draw was partly random, but partly also took account of places of residence, occupations, and educational qualifications. The emphasis placed on other factors than age and gender was a matter of discretion. Great importance was attached to arriving at a broad composition of the group on the basis of what the letters had revealed about the writers.

The organizing committee and project staff finally selected 16 persons, aged from 18 to 72, on the basis of the same criteria.

Preparations by the lay panel

The sixteen members of the lay panel met for two week-ends prior to the actual laymen's conference, in August in Oslo and in September in Ålesund. At these preparatory week-end meetings, they were made acquainted with the form of the conference and the subject, genetically modified food. They read background material, including a memorandum prepared by the project staff, discussed questions among themselves, and heard two expert lecturers give broad surveys of the topic. The lecturers were Matthias Kaiser, head of the secretariat of the National Committee for Research Ethics in Natural Science and Technology and of the conference's organizing committee, and Reidunn Aalen, Senior Lecturer at the Division of General Genetics at the University of Oslo and a member of the Biotechnology Advisory Board and of the organizing committee.

Much of the time at the preparatory week-end meetings was devoted to drawing up the questions which the conference was to be concerned with.

Guidance in these preparations was provided by Professor Gunnar Handal, of the University of Oslo's Department of Educational Research. Acting as facilitator, he was neutral where the theme of the conference was concerned; his task was to ensure that the laymen had good working conditions, functioned well as a group, and all participated in the panel on an equal footing.

Selection of experts

During the spring and summer of 1996, the project staff asked a large number of sources, including the contributors to the conference, industrial enterprises, researchers and special interest organizations, to propose matters which the lay panel ought to be aware of and experts who could address the conference. The project staff and the organizing committee added further names, so that the staff finished up with a list of some sixty experts in various fields from which to choose.

Of those sixty, about forty expressed willingness to participate. The point of departure for the selection from among them of the panel of fifteen experts was the instructions given by the lay panel concerning the kinds of expertise they wanted. Importance was attached to the following:

* In addition to their professional expertise, they should be good communicators.

* Those of the experts who were engaged in genetic engineering should as far as possible also possess food-related knowledge.

* The overall composition of the expert panel should be such as to cover the areas relevant to the conference theme. But this criterion had to be waived if no representative could be found for a relevant discipline or for a group with additional knowledge concerning genetic engineering and food.

* In the most important areas, such as genetic engineering, genetic engineering and society, and genetic engineering and ethics, more than one expert should take part.

* A broad range of participating organizations and institutions should be sought, as well as representation from other Nordic countries.

The fifteen experts received the questions they were to answer in their contributions a fortnight or so ahead of the conference. They were asked to answer 4 to 6 questions each. The majority of the questions, and especially the normative questions, were put to more than one expert.

The conference, day by day

The first day of the conference, Friday 18 October 1996, was devoted to the experts and their 20-minute contributions in answer to the questions each of them had been asked by the lay panel.

On the morning of Saturday 19 October, the lay panel asked the experts to go into some of the points in their talks more closely and asked follow-up questions. Time was also allowed for some questions and reactions from members of the public. After lunch the conference continued behind closed doors. The lay panel then withdrew to prepare its final report.

The lay panel continued its work on the final report on its own throughout Sunday 20 October and on into the small hours of Monday 21 October.

On Monday 21 October 1996 the lay panel presented its final report to the expert panel and an audience. A provisional draft of the document was handed out. The presentation was followed by time for questions, in which the experts were able to comment on points of fact so that any errors could be corrected in the final document. This was followed by a general debate on the contents of the document, with both experts and members of the public participating.

The conference was held at the Soria Moria conference centre in Oslo on October 18, 19 and 20 October, and in the University of Oslo's ceremonial lecture hall on 21 October.

After the conference, an editorial committee of three members of the laymen's panel considered which of the experts' objections should be regarded as corrections of matters of fact and which should be considered expressions of divergent views. A few minor adjustments were then made in the provisional draft of 21 October, and the final printed report was produced.

Evaluation

The conference will be evaluated both externally and internally. The external evaluation will be carried out by the Norwegian Institute for Studies in Research and Higher Education (NIFU). Its report is scheduled for early 1997.

Media response and TV programs

The conference got good TV and radio coverage, as well as featuring in national, regional and local newspapers and professional journals. During the first three weeks after the conference, the project staff registered about ninety news items on the conference.

In addition, NRK2 (a Norwegian Broadcasting Corporation channel) is planning to screen four half-hour programs on the conference in the "Akademiet" series, on consecutive Tuesdays beginning on Tuesday 7 January 1997.

Organizing committee, project staff and contributors

The conference was planned by an organizing committee and run by a project staff. The members of the organizing committee were:

- * Matthias Kaiser, head of the secretariat of the National Committee for Research Ethics in Science and Technology (NENT) (chairman)
- * Dag Elgesem, head of the secretariat of the National Committee for Research Ethics in the Social Sciences and Humanities (NESH)
- * Jon Fixdal, research scholar at the Centre for Technology and Culture (TMV)
- * Svanhild Foldal, Senior Executive Officer, the Biotechnology Advisory Board
- * Knut Ruyter, head of the secretariat of the National Committee for Research Ethics in Medicine (NEM)
- * Reidunn Aalen, Division of General Genetics, University of Oslo.

The project staff consisted of

- * Per Sandberg, project manager
- * Nina Kraft, information consultant
- * Hilde Storvik, executive officer.

* Kim Paulsen, administrative assistant

The realisation of the conference was made possible by contributions from:

* The Biotechnology Advisory Board

* The National Committees for Research Ethics

* The Ministry of Fisheries

* The Ministry of Agriculture

* The Ministry of the Environment

* The Research Council of Norway

* The Ministry of Industry and Energy

* The Centre for Technology and Culture

* The Ministry of Health and Social Affairs

* The Norwegian Food Control Authority

The total budget was in the region of NOK 1 million.