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Sweden

Biotechnology

A Swedish Policy on Biotechnology

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Approved by:

Lana Bennett

U.S. Embassy, Stockholm

Prepared by:

Aasa Lexmon

Report Highlights:

The Parliamentary Committee established to examine the issues related to biotechnology recently released its final report which contained a proposal for a Swedish biotechnology policy. Among other things, the Committee recommends compulsory labeling of all products containing genetically modified organisms. It also stresses the need for a system for close coordination between the various government agencies that deal with biotechnology matters.

Includes PSD changes: No
Includes Trade Matrix: No
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Summary

In October, 1997, the Government of Sweden (GOS) established the Parliamentary Committee on Biotechnology to examine potential benefits and risks related to biotechnology. Three years later, in December, 2000, the Committee presented its conclusions in its final report: "Att spranga granser- Bioteknikens möjligheter och granser" (SOU 2000:103). A summary in English entitled "Breakthroughs- A Swedish Biotechnology Policy" is available on the internet site www.utbildning.regeringen.se/propositionermm/sou/index.htm.

The Committee states the following with regard to its proposed biotechnology policy for Sweden:

The proposal for a Swedish biotechnology policy aims to strengthen Sweden's capability to take advantage of the opportunities offered by biotechnology, for the benefit of the individual, industry and the environment. This biotechnology policy aims to promote the accumulation of knowledge in the sector, to facilitate the conversion of the results of research projects to practical applications, under ethically acceptable conditions and with the risks overcome. The practical opportunities of the individual for knowledge, participation and influence in the biotechnology sector must be strengthened considerably.

In the report summary, the proposal for a Swedish policy on biotechnology is presented in 21 points. The 16 points related to agriculture are quoted below. Swedish government officials have stressed the importance of compulsory labeling of all GMO-containing products and the need for an improved organizational structure for coordination of the various GOS agencies that deal with biotechnology matters.

Sweden's Policy on Biotechnology in 16 Points

1. The present organisation of the authorities that deal with genetic technology and other biotechnology matters is impractical. Greater co-ordination is desirable in view of the opportunities and risks involved in biotechnology. The Swedish Genetic Technology Advisory Board therefore, should be restructured into a Biotechnology Inspectorate, which would complement other authorities in the sector. The primary function of the Biotechnology Inspectorate would be to monitor fundamentally important and new applications, and conduct supervision.
2. Biotechnology is developing at a very rapid rate. It is not easy to keep up to date with the opportunities and risks involved in the technology. There is a great need for technological evaluation and a broad national debate. There are also corresponding needs in other areas of technology, which would require the establishment of a Technology Council. The Technology Council could promote the accumulation of knowledge, disseminate information, and create an active dialogue between researchers and other specialists, politicians and other citizens.
3. The demands of consumers for a free and informed choice regarding foods must be fulfilled. Compulsory labeling is to be required, for all products resulting from genetic technology, at all

stages of the production process, from raw material to final product.

4. Sweden should work to ensure that the risk assessment of products that include, or consist of, genetically modified organisms, is developed into a technology-neutral risk and benefit assessment. This assessment should apply to all products, irrespective of the method of production. The assessment should be based upon the qualities of the products, and consider any risks to people's health to the environment, with regard to both the development and production of the product, and its use. All risk and benefit analysis should include an ethical assessment.
5. Developing countries have a great need to access the opportunities afforded by biotechnology. Shortage of both technical and legal expertise, and economic resources, limit their opportunities to benefit from biotechnology. Increased funding should be provided to relevant organizations and research projects to enhance the opportunities to benefit from biotechnology. Cooperation in research projects, and transfer of skills and expertise should be stimulated to enhance the technical and legal expertise of developing countries, and to increase their possibilities of using and monitoring this technology.
6. A restructuring is taking place in the biotechnology sector, as in other sectors. The large companies are tending to become even larger through acquisitions and mergers. This has created large groups with interests in drugs, chemicals and foods. This can create problems by forming monopoly situations and reducing competition. The risk of the companies abusing their market dominance must be monitored carefully.
7. Research into the risks to the environment caused by biotechnology, and its other consequences for the public, should be supported. Special resources should be allocated to directed programmes.
8. Before genetically modified organisms are released onto the market, it is vital that there be better background material for risk assessments from experimental release. Experimental release of genetically modified organisms into the environment should therefore be implemented and evaluated in a scientifically approved manner, in order to compile as much information as possible.
9. Deliberate release into the environment of genetically modified organisms with antibiotic resistant genes should cease. Other and better technology should be developed.
10. Advances in the biotechnology sector have increased the opportunities of replacing experiments on animals with experiments on cell and tissue cultures. At the same time, increasing knowledge about human and animal genes has meant that experimental animals can be used for new purposes. This can increase the use of experimental animals. Research into the replacement of experimental animals with other methods should be stimulated through the allocation of resources to special programmes.
11. Inventors conducting research can require help with the commercialisation of their results. In addition, they often have difficulty in finding financial backing for the earliest stages of development. The conversion of research findings into product ideas should be facilitated.

Cost-free advice about commercial development should be provided. Society and industry should together facilitate the contacts between researchers and companies to increase access to seed money at an early stage of development.

12. The establishment of new business ventures and the development of new products in the biotechnology sector often occur at the front line of research. Co-operative links between research and industry must be stimulated. This can be attained by putting more resources into industrial postgraduate programmes, by making efforts to combine research institutions and companies in innovation centres, by encouraging exchanges of personnel between the academic world and industry, and by making co-operation with industry, patents, and product development worthwhile for researchers.

13. Industrial and other applications of the findings of research projects should be facilitated. Publicly accessible research applications have been shown to be a hindrance to future patents and commercialisation of the results. Making applications for research funding temporarily confidential should therefore be considered.

14. Further biotechnology expertise is needed to satisfy the demands of the labour market. Schools play a fundamental role here. To increase interest at academic level, teaching in biotechnology needs to be strengthened, both in compulsory schools and upper secondary schools, and also in basic teacher training and continuing professional development of teachers.

15. A special national resource centre should be set up, with responsibility for pedagogic development and the development of skills of teachers in biotechnology. Like already extant centres for other natural scientific subjects, this resource centre should be placed at a university or another institution of higher education.

16. Special courses in the natural sciences, technology and ethics at academic level should be offered to people who, in their professional activities, come into contact with biotechnology issues and their ethical implications. The aim of this would be to stimulate the dissemination of knowledge, and promote a broad society-wide debate on biotechnology and its applications.

Additional Information and Comments

Swedish Authorities Dealing with Biotechnology

Currently, six different government agencies are responsible for oversight and the development of legislation concerning genetically modified organisms. These agencies issue regulations dealing with GMOs within their respective areas of responsibility (see table 1 below).

Table 1.

Area of Responsibility	Lead Agency
Deliberate release of GM micro-organisms, nematodes, insects and spiders.	The National Chemicals Inspectorate
Deliberate release of GM aquatic organisms	The National Board of Fisheries
Deliberate release of GM forest trees	The National Board of Forestry
Other GMOs	The National Board of Agriculture
Placing GM feed on the market	The National Board of Agriculture
Placing GM food on the market	National Food Administration
Placing GM micro-organisms, nematodes, insects and spiders on the market	The National Chemicals Inspectorate
Placing GM aquatic organisms on the market	The National Board of Fisheries
Placing GM forest trees on the market	The National Board of Forestry
Placing other GMOs on the market	The National Board of Agriculture
Contained use of GM micro-organisms	The Swedish Work Environment Authority
Contained use of GM aquatic organisms	The National Board of Fisheries
Contained use of other GMOs	The National Board of Agriculture

Currently, the six lead agencies are obliged to consult the two coordinating organizations, the Swedish Environmental Protection Agency (EPA) and the Swedish Gene Technology Advisory Board, regarding new GMOs and before issuing regulations. The EPA must report yearly to the European Commission on Sweden's control of the use of products placed on the market. The Gene Technology Advisory Board operates under the directive to support the use of GMOs within the context of an ethical framework. The EPA and the Board of Agriculture (BOA) are the focal points for the implementation and discussion of EU Directives 90/219/EEC and 90/220/EEC concerning contained use of GMOs and deliberate release of GMOs into the environment.

As mentioned in point 1 above, the Committee on Biotechnology wants to restructure the Swedish Genetic Technology Advisory Board into a Biotechnology Inspectorate. Under such a scheme, the Biotechnology Inspectorate would take the lead in consideration of products yet to be "accepted" in Sweden. The currently responsible agencies would continue to handle those products for which use is already "established and accepted." However, the Committee has not defined which applications should be considered as established and accepted and which should not. A separate committee will be formed to work out the details on how to organize the new Inspectorate. At this stage, it appears that the Inspectorate, if established, would be a rather small organization. It is unclear at this point how it will be staffed with a sufficient number of experts to handle the envisioned role. At present, the expertise lies within the six agencies.

Although Parliamentarians involved in the Committee pushed for the establishment of a Biotechnology Inspectorate, other Committee members did not agree. While the aim is to increase public confidence in government control of biotechnology, some fear that the formation of an inspectorate which is dedicated solely to this technology would heighten public suspicion of GMOs. The Committee's proposal to control gene technology separately from other techniques also appears to be in contradiction to what the Committee recommends in point 4, i.e., risk and benefit assessments of genetically modified products should be done without consideration of the technology by which they are produced.

Technology Council

The Committee additionally recommends that a Technology Council be established to create an active dialogue among specialists, politicians and the public (point 2). The Council would also cover techniques other than gene technology. How this Council would be organized is not clear, but it shows the desire of the Swedish politicians to increase public awareness, transparency and inclusiveness concerning technology application issues.

Risk Assessment and Labeling

The Committee believes that better background information prior to conducting risk assessments of experimental releases is needed. They maintain that each GM product must be evaluated and approved by Swedish authorities, including products approved by the EU, before it is released on the Swedish market. In line with the EU decision, the Committee believes that Sweden should require compulsory labeling of genetically modified products (point 3). As of yet, there is no official opinion regarding thresholds for GMO content in products labeled GMO-free.

The Committee has strived to maintain a relatively balanced view on biotechnology. It clearly sees the benefits of this technology, both in Sweden and in developing countries. The Committee's recommendations reflect its desire to increase consumer confidence in the Swedish Government and its control system for GMOs. Whether or not its proposal for a Biotechnology Inspectorate is a good way to achieve that is uncertain. However, as points 11-13 indicate, the Committee's intention is to facilitate the release of GM products (labeled) on the Swedish market. In fact, Sweden considers that biotechnology will, along with information technology (IT), become a pillar of the country's economy.