Environment & Climate Change - Switzerland

Regulations on genetic engineering

Contributed by **Pestalozzi Attorneys at Law**

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Introduction

Federal regulations on genetic engineering cover a wide range of legal areas, including:

- environmental law;(1)
- agricultural law;(2)
- food law;(3) and
- labour law.(4)

The main statutes on genetic engineering are:

- the Federal Act on Non-human Gene Technology;
- the Agriculture Act;
- the Release Ordinance;
- the Containment Ordinance;
- the Ordinance on Genetically Modified Food;
- the Ordinance on Genetically Modified Feed Lists; and
- the Cartagena Ordinance.

Furthermore, Switzerland has entered into international treaties(5) on the issue.

Background

In 2005 a national referendum accepted a proposal to ensure that Swiss agriculture was free of genetic engineering, with a moratorium banning genetically modified plants and seeds and banning genetically modified animals from being imported and placed on the Swiss market. The moratorium was laid down in the Federal Constitution(6) and the Federal Act on Non-human Gene Technology.

The original five-year moratorium lasted until 2010. Thus far, the Federal Parliament has extended the duration of the moratorium twice – first until 2013 and again until 2017.

In the meantime, the Federal Council has submitted a draft ordinance on the Co-existence of Genetic Engineering and Conventional Cultivation for consultation. During the political consultation, the draft was heavily criticised. A revised draft is expected to be presented during 2015.

Rules on genetic engineering

The main rules on genetic engineering concern agricultural products, foodstuffs, industrial activities and research and international commerce. The rules are summarised below.

Agricultural products
Genetically modified plants, seeds and animals cannot be imported and placed on the market. Nevertheless, the Federal Office for the Environment may, for scientific purposes, grant exceptions to the release of genetically modified plants or seeds. For example, in August 2013 it authorised a Zurich University study to release genetically modified wheat with improved resistance against the fungal disease mildew. The authorisation included a number of strict requirements and conditions to ensure that the genetically modified material will not be carried away from the designated area of release. The study is expected to run from 2014 to 2018.

In addition, certain kinds of genetically modified organism are allowed for the production of

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feedstuffs and might therefore become part of the final product. Such organisms and feedstuffs are listed on the Ordinance on Genetically Modified Feedstuff.

Foodstuff
The use of genetically modified organisms that become part of food is subject to approval. The Ordinance on Genetically Modified Food regulates the requirements and application procedure to obtain approval, as well as the tolerance values of certain traces of non-authorised substances in food.

So far, five companies have obtained approval for the use of various types of genetically modified corn, soy, vitamins, enzyme and protein. Renewal requests for some of these approvals are being processed by the authorities.

In addition, genetically modified materials for four types of genetically modified corn are tolerated without particular approval if they meet the following cumulative requirements:

- the concerned substance has been approved as suitable for the use in foodstuffs and the approval has been granted by a foreign authority in a procedure similar to the Swiss procedure;
- the percentage of the modified substance in the final product does not exceed 0.5% weight by weight;
- health risks can be excluded, based on existing scientific knowledge; and
- appropriate verification procedures and reference materials are publicly available.

Once authorised, any genetically engineered food product must be labelled such. Only in very limited exceptional cases is such labelling not required. In addition, a documentation requirement applies to genetically engineered products.

The Ordinance on Genetically Modified Food also covers products which are free of genetically modified organisms. Accordingly, a label stating that a food is 'produced without genetic engineering' may be used only if a number of requirements are met, including, but without limitation, a complete documentation of the ingredients and production process.

Industry and research
Activities that involve genetically engineered organisms and are conducted in contained systems (eg, laboratories, production facilities, greenhouses or animal houses) are subject to notification or approval, depending on the related risks. Prior notification of the competent authority is required for activities with no risk, negligible risk or low risk for human beings, animals, the environment and biological diversity. In contrast, activities with a moderate or high risk require prior approval. Depending on the risks of a specific activity, the competent authority is either the Federal Office of Public Health or the Federal Office for the Environment. Approval is granted if the applicable safety standards are complied with.

International commerce
Switzerland signed and ratified the Cartagena Protocol, which aims to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organism. On January 1 2005 the implementing Ordinance on the Cross-Border Movements of Genetically Modified Organisms entered into force.

According to the Cartagena Ordinance, any person who imports or exports genetically modified organisms or who is responsible for their transit must take the precautions required by the situation in order to prevent the organisms endangering human beings, animals or the environment. In addition, the responsible persons must ensure that the handling, packaging, labelling and transportation of the concerned organisms comply with all national and international requirements. Any cross-border movement requires a specific documentation as detailed in the ordinance.

If genetically engineered organisms are imported for handling in the environment, Release Ordinance approval is required. If they are imported for handling in a contained system, the Containment Ordinance applies.

Any party which intends to export genetically engineered organisms to a specific country for the first time for handling in the environment must obtain the prior consent of the competent national authority. In addition, the responsible person must:

- keep a detailed register of each export;
- make the register available to the Federal Office for the Environment; and
- retain the relevant information for at least 30 years following the last export.

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Endnotes

(1) In particular, the Federal Environmental Protection Act, SR 814.01; the Federal Act on Non-human Gene Technology, SR 814.91; the Release Ordinance, SR 814.911; the Containment Ordinance, SR 814.912; the Cartagena Ordinance, SR 814.912.21; and the Ordinance on Protection against Major Accidents, SR 814.012.

(2) In particular, the Federal Act on Agriculture, SR 910.1; the Ordinance on Seeds, SR 916.151; the

Plant Protection Ordinance, SR 916.20; the Plant Protection Products Ordinance, SR 916.161; and the Ordinance on Genetically Modified Feed Lists, SR 916.307.11.

(3) In particular, the Federal Act on Foodstuffs and Utility Articles, SR 817.0; the Ordinance on Food, SR 817.02; and the Ordinance on Genetically Modified Food, SR 817.022.51.

(4) In particular, the Federal Act on Accident Insurance, SR 832.20; the Ordinance on Protection of Employees from the Danger through Microorganisms, SR 832.321; the Ordinance on the Prevention of Professional Accidents and Illnesses, SR 832.30; and the Labour Act, SR 822.11.

(5) The Convention on Biological Diversity, SR 0.451.43; and the Cartagena Protocol on Biosafety, SR 0.451.431.

(6) The Federal Constitution of the Swiss Confederation, SR 101.

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