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Swiss Biotechnology Update

Approved By:
David Miller
Prepared By:
Christine Strossman

Report Highlights:
Switzerland has an onerous and slow process for approving products of agricultural biotechnology for food and feed use. In addition, there is currently a moratorium on approvals for planting of biotech crops or placing on the market of genetically modified animals. The Federal Council has recently proposed extending the moratorium until 2013. The restrictive regulatory environment, combined with strong anti-biotech public sentiment has dampened interest in the Swiss market for biotech products. It is now possible, however, to set a tolerance for unapproved biotech varieties in food and feed.

Section I. Executive Summary:

Switzerland has an onerous and slow process for approving products of agricultural

biotechnology for food and feed use. In addition, there is currently a moratorium on approvals for planting of biotech crops or placing on the market of genetically modified animals. The Federal Council (the executive branch of the Swiss government) has recently proposed extending the moratorium until 2013. The restrictive regulatory environment, combined with strong anti-biotech public sentiment has dampened interest in the Swiss market for biotech products. It is now possible, however, to set a tolerance for unapproved biotech varieties in food and feed.

Section II. Biotechnology Trade and Production:

No biotech crops are produced commercially in Switzerland, and no request has ever been submitted for approval of a biotech crop for planting in Switzerland. Currently, there is also a moratorium on the production of biotech crops or animals until 2010. The Federal Council recently proposed extending the moratorium until 2013 to allow time for a federal research program on the risks and benefits of biotechnology to be completed. There are no crops under development that will be on the market imminently. Field testing has been controversial and therefore limited.

Biotech imports into Switzerland are limited. Few products are authorized, and public resistance to biotech has reduced demand for authorized products. Biotech products imported for feed use must be declared to Swiss authorities and are therefore tracked statistically. Feed products declared as biotech accounted for only 0.11% of imports of feed in 2005, down from 1.4% in 2001. More recent data is not available. Spot testing is done by the federal authorities to check for biotech content and proper labeling of feed. Spot checking of food for human consumption is carried out by the cantonal (state-level) authorities, with guidance from the Federal Office for Public Health. Statistics on imports of biotech food for human consumption are not tracked.

Section III. New Technologies:

Animal Biotechnology

Currently, the Swiss law on biotechnology prohibits the production and commercialization of genetically-modified animals (vertebrates), except for scientific, medical or veterinary purposes. In addition, the moratorium prevents the importation and distribution of genetically-modified animals intended for the production of food or other agricultural products. Therefore, it is not possible to obtain an authorization in Switzerland for the production or importation of a genetically modified animal, and no such products are currently produced or imported into Switzerland. Imported food or animal feed derived from genetically-modified animals would theoretically be subject to the authorization procedures and regulations described in Section III, although so such request for authorization has been made. As evidenced by the more strict treatment of biotech animals in both Swiss law and the moratorium, public opinion regarding biotech animals is even more negative than that for biotech crops.

Section IV. Biotechnology Policy:

Biotech Approvals

The Swiss Federal Office for Public Health is the competent authority for authorization of biotech products for food use. The Swiss Federal Office for Agriculture is the competent authority for animal feed, plant propagation material for all uses except forestry, as well as plant protection products containing genetically engineered organisms, and

fertilizers. Immunological products for veterinary use are handled by the Swiss Federal Veterinary Office. The Federal Office for the Environment is the competent authority for plant propagation material for use in forests. In addition to these federal authorities, applications for both field trials and commercialization must also be reviewed by the Swiss Expert Committee for Biosafety and the Swiss Ethics Committee on Non-human Gene Technology. Once the application is complete, non-confidential documents are made available for public comment for 30 days.

There is currently a moratorium on the approval of biotech plants and animals for production in Switzerland. The moratorium was the result of a grass-roots movement put to a vote under the Swiss political system, which allows voters themselves to seek changes to the Constitution by referendum as long as at least 100,000 voters sign a petition requesting it. The federal government originally opposed the moratorium, stating that it was unnecessary given the stringent approval process in place. However, the Federal Council recently proposed extending the moratorium until 2013, citing the need for research programs about the risks of biotechnology to be completed. The moratorium does not affect approval of imports for food, feed and processing use. The Swiss farmers' association supports the extension of the moratorium, in order to allow the results of research programs to be assessed and considering the continued strong public rejection of biotech food.

The approval process for biotech products for food, feed and processing use is time-consuming. This, combined with consumer distrust and compounded by retailer anti-biotech polices, has led to few products being submitted for approval. In October, 2008, the regulation governing release of biotech products into the environment was amended to incorporate more strict requirements set out in underlying laws on biotechnology and protection of the environment, as well as to update and harmonize provisions with those of the European Union. The new provisions also relate to (non-biotech) pathogenic organisms and invasive species.

The four main objectives of the regulation and underlying law are as follows:

- Protection of human, animal and environmental health. In particular, the objective is to avoid dangers related to toxic or allergenic substances produced by organisms.
- Conservation and sustainable use of biodiversity. In particular, avoiding propagation of undesirable organisms or the permanent transmission of new transgenic properties to wild flora and fauna.
- Protection of non-biotech production and free consumer choice. Specifically, preventing any contamination of non-biotech production by genetically modified organisms during their production or processing.
- Respect for the dignity of living organisms (animals and plants). Specifically, not allowing use of animals or plants for which the specific properties and functions have been seriously injured as a result of their genetic modification.

The main new elements related to commercialization of biotech organisms are as follows:

- The effects of the commercialization of genetically modified plants on neighboring crops must be taken into consideration.
- A notification requirement has been introduced for the direct spreading of genetically modified organisms in the environment.
- Long-term environmental surveillance has been introduced to determine the spread of biotech products and their possible effects.
- A federal-level register of sites, accessible to the public, indicating where dissemination or direct spreading of biotech products in the environment is taking place.

Animal Feed

The following products have been approved for animal feed:

Name	Raw materials and basic feeds	Approval date
GTS-Soybeans (Monsanto)	All	10 December 1997 (renewal requested)
Bt 11 Corn (Syngenta)	All	14 October 1998 (renewed)
MON 810 Corn (Monsanto)	All	27 July 2000
All products approved in the EU	Corn gluten	
All products approved in the EU	Corn gluten feed	
All products approved in the EU	Corn cob meal	
All products approved in the EU	Soybean meal from extraction	
All products approved in the EU	Soybean meal from pressure	

Bt 176 Corn (Syngenta) was approved in 1998 and therefore the 10-year authorization expired in 2008. As the company has not requested renewal, the event is no longer authorized. However, in line with EU provisions, there is a 0.9% tolerance for adventitious presence of this event in feed products for a five-year period. Imports of feed products made from corn or soy events approved in the EU (as shown in the table above) will continue to be allowed.

In addition to the products listed above, trace amounts (up to 0.5%) of other products authorized in the EU or for which there is a tolerance in the EU, would be allowed as adventitious presence in Swiss feed. In addition, amendments to the animal feed ordinance

which came into force on September 1, 2008 allow the Federal Agriculture Office to approve exceptionally, upon request, the placing on the market of feed containing traces of biotech content not approved in Switzerland or the EU under the following conditions:

1-the traces do not exceed 0.5%

2-these organisms may be legally placed on the market as feedstuffs in Canada or the US

3-adequate detection techniques and reference material are available

4-the applicant may exclude the presence of any impurity in food by means of adequate measures, and

5-the applicant delivers the data required to check whether the conditions in 1-4 are complied with.

In practice, these conditions imply that an application for authorization, including a dossier with the relevant information, would need to already be on file with the Swiss authorities. This may explain why there have recently been some new applications for authorizations, even though no event has been authorized under the Swiss system since the year 2000 and some applications have been pending since 1997.

Food and/or Feed Use

The following products have been approved or are under consideration for food and/or feed use (note that stacked traits must be approved separately):

Event	Name of product/company	Status
MON 40-3-2 Roundup Ready	Soy/Monsanto	Registered on 7/19/1996 Authorized on 12/20/1996 Renewed on 10/31/2002
Bt176	Corn/Syngenta	Registered on 11/1/1996 Authorized on 1/6/1998 Requested renewal on 6/27/2002 Expired
Bt11	Corn/Syngenta	Registered on 7/29/1997 Authorized on 10/14/1998 Requested renewal on 9/7/2003 Under review
T25 Liberty Link	Corn/Bayer Crop Science	Registered on 9/10/1997 Under review
MON810 MaisGard	Corn/Monsanto	Registered 3/16/1998

		Authorized on 7/27/2000 Requested renewal on 7/1/2005 Under review
GT73 Roundup Ready	Colza/Monsanto	Registered 11/30/1998 Under review
T25 X MON 810	Corn/Pioneer Hi-Bred	Registered on 6/22/2000 Withdrawn
1507 Herculex I	Corn/Pioneer Hi-Bred	Registered on 4/9/2001 Under review
GA21 Roundup Ready	Corn/Monsanto	Registered on 4/26/2001 Under review
NK603 Roundup Ready	Corn/Monsanto	Registered on 8/8/2001 Under review
NK603 X MON810	Corn/Monsanto	Registered on 5/8/2002 Under review
59122	Corn/Pioneer Hi-Bred	Registered on 4/19/2005 Under review
MIR604	Corn/Syngenta	Registered on 7/1/2005 Under review
GA21	Corn/Syngenta	Registered on 10/28/2005 Under review
3272	Corn/Syngenta	Registered 6/23/2006 Under review
MON89788	Soy/Monsanto	Request on 4/3/2007 Under review
356043 "Optimum GAT"	Soy/Pioneer Hi-Bred	Request on 6/28/2007 Under review
A2704-12 "Liberty Link"	Soy/Bayer CropScience	Request on 8/2/2007 Under review

Although not yet listed by the Swiss Federal Office for Public Health, applications were received in 2008 for DP305423 (Soy/Pioneer/DuPont) and crosses of Bt11, MIR 604 and GA21 (Corn/Syngenta). Applications reportedly have been received in 2009 for a cross of Bt11, MIR604, and GA21 with MIR162 as well as oilseed rape MS8, RF3 and a cross of MS8xRF3 and cotton LLCotton25.

The approval status of enzymes, vitamins and other products is as follows:

Enzymes, vitamins and other products	Name of product/company	Status
Vitamin B12	Sanofi Aventis	Registered on 7/10/1996

		Authorized on 12/20/1996 Renewed on 10/31/2002 Requested renewal on 12/8/2006
Vitamin B2 (riboflavin)	DSM	Registered on 7/24/1997 Authorized on 5/9/2001 Requested renewal on 8/31/2006
Enzyme chymosine "Maxiren"	DSM	Registered on 3/30/1987 Authorized on 8/1/1988 Requested renewal on 6/25/1998 Under review
Enzyme chymosine "Chy-Max"	Christian Hansen	Registered on 12/7/1989 Authorized on 4/1/1993 Requested renewal on 6/24/1998 Under review
Lipase "Lipopan F BG"	Novozymes	Registered on 11/26/2004 Under review
Lipase "Lipopan 50 BG"	Novozymes	Registered 11/26/2004 Under review
Amylase "Novamyl 10000 BG"	Novozymes	Registered 11/26/2004 Under review
Xylanase "Pentopan Mono BG"	Novozymes	Registered 11/26/2004 Under review
Pectinesterase, Pectintranseliminase, Polygalacturonase I + II	Rohm	Registered 2/10/19997 Request withdrawn
Amaylases "Novamyl" and "Termamyl"	Novo Nordisk	Registered 7/15/1996 Request withdrawn
Asparaginase "PreventASe"	DSM	Requested 7/16/2007 Decision 6/2/2008 Authorization not required

Authorizations are for 10 years and companies must apply for renewal of the authorization before it expires. As long as they do so, the product may continue to be commercialized while the application for renewal is under review.

In April, 2008, a new amendment was introduced in the Swiss Regulation on Biotech Food which provides the possibility for a tolerance for unapproved varieties in food. Small quantities of foods, additives, or technological auxiliaries that are genetically modified plants or contain or are derived from them may be tolerated without authorization under the following conditions:

A. If they are considered appropriate for use in food by a foreign authority, through a

procedure comparable to that set by the Swiss law, and

B.

1-the amounts are not more than 0.5% by mass related to the ingredient,

2-any danger to public health can be excluded by the Federal Office for Public Health on the basis of an evaluation in conformity with the latest technical and scientific advances

3-the public has access to the appropriate methods of detection and reference materials

For small quantities of foods, additives, or technological auxiliaries that are genetically modified plants or contain them, the tolerance assumes that an evaluation by the Federal Office for the Environment shows, on the basis of current science, that any danger to the environment can be excluded.

Within 30 days, the Federal Office for Public Health submits its report for the opinion of the Federal Office for the Environment, the Federal Veterinary Service and the Federal Office for Agriculture. The Federal Office for Public Health may also limit or set conditions for the commercialization of such products.

The unapproved genetically modified materials that are tolerated in food, additives or technological auxiliaries will be listed in an annex of the regulation. As this amendment is relatively new, no products are listed yet in the annex.

Field Trials

In contrast to the approval process for commercialization, there are specific timeframes set out for the approval process for field trials. Once a complete application has been received by the Federal Office for the Environment, the non-confidential documents are made available for public comment for 30 days. Then the application is forwarded to the Swiss Federal Office for Public Health, the Federal Veterinary Office, the Swiss Federal Office for Agriculture, the Swiss Expert Committee for Biosafety and the Swiss Ethics Committee on Non-human Gene Technology and the competent authority in the canton where the proposed field test will take place. These entities must state their position within 50 days, although the clock stops if any entity requests further information from the applicant. Public meetings in the locality where the test will take place may also be organized.

The Federal Office for the Environment should then issue a permit within 90 days of opening public comment, as long as it is determined that there is no danger to the environment or people and each of the entities outlined above has given its consent. The approval may be linked to conditions related to monitoring and security of the site. Applicants must also provide a liability guarantee of up to 20 million Swiss Francs (approx. $16.6 million). The federal government, its public corporations and institutions and the cantons are exempt from the liability guarantee requirement.

The following requests for field trials have been approved by the Swiss Federal Office for the

Environment:

Applicant	Organism	Trait	Proposed dates of trial
University of Zürich	Hybrid of Aegilops cylindrica and Triticum aestivum	Fungus resistance	2008-2010
University of Zürich	Wheat	Oidium resistance	2008-2010
EPFZ*	Wheat	Fungus resistance	2008-2010

*Swiss Federal Institute of Technology Zürich

According to the Federal Office for the Environment, 29 comments from citizens and 10 opinions of associations were submitted in opposition to the field trials. The majority of the comments (27 out of 29) were submitted about the field trial proposed by the EPFZ to take place in Pully, near Lausanne. All opponents signaled their intention to appeal any approval of a permit.

In June 2008, the field trials (wheat) under these requests which were planted in May 2008 in Zurich were vandalized by a group of 35 masked individuals. The field testing was part of a research program designed to gain more knowledge of the environmental benefits and risks of biotech crops while the moratorium is in place. The Swiss Farmer's Union condemned the attack, having supported the moratorium in order to allow the time for scientific research into the questions of concern to the Swiss public. In July 2009, the only other approved request for experimental planting, in Pully, was also vandalized.

In June, 2008, the Swiss government reported on the results of a previous program of research which took place from 2004 – 2007. One of the projects consisted of a survey of the current debate on the ethics of risk, which showed that, in addition to cost/benefit analysis and the precautionary principle, there should be a "duty of care," meaning that all possible security measures must be taken to ensure that any chance of harm from the release of biotech organisms into the environment is "extremely low."

Three other projects focused on the impacts of biotech crops on non-target organisms. A study on biotech scab-resistant apples found no negative impact on the development of harmful insects. It was also shown that transgenic plants resistant to harmful fungi retain their symbiosis with useful soil fungi.

Two projects focused on the impacts of biotech crops on soil ecosystems. This research showed that there was no difference in terms of impact on the soil (including soil organisms such as worms, snails, etc) between insect-resistant Bt corn plants and conventional varieties of corn.

Two projects focused on early detection of unexpected environmental impacts. The first project identified suitable indicator organisms and survey methods for detecting unexpected impacts from the cultivation of biotech corn and potatoes. The second project showed the difficulties of detecting harmful environmental impacts of genetically modified plants and proposed solutions to be considered when setting up a monitoring program.

In spite of public resistance and administrative hurdles to testing and commercialization of agricultural biotechnology products, the overall Swiss biotech industry (including medical and industrial applications) is relatively dynamic. In 2005 there were 229 biotech companies in Switzerland of which 91 were biotech suppliers and 138 were core biotech companies. On a per capita basis, Switzerland has the world's highest density of biotech companies.

Coexistence

Although no crops are currently produced and a moratorium is in place, Switzerland has proposed draft coexistence rules for comment. Work on this draft legislation has been put on hold as a result of the moratorium and while awaiting the results of the Swiss National Science Foundation's National Research Program on the "Benefits and Risk of the Deliberate Release of Genetically Modified Plants." This research program includes projects to evaluate the impacts of biotech crops on wild relatives, soil fertility and non-target insects as well as coexistence and ethical issues.

Labeling

The Swiss biotech labeling regime is closely aligned with that of the EU. Labeling is for consumer information purposes. All food and feed products (including pet food) containing/consisting of biotech products and/or produced from biotech products, including products that no longer contain detectable traces, must be labeled. If a product contains 0.9 percent or lower biotech (or biotech derived) content and the content is "adventitious" (ie. not intentional), the product need not be labeled as containing or being derived from biotech. This tolerance is for approved biotech products only - there is no tolerance for unapproved varieties (except as noted previously), although there is an exception (up to 0.5% adventitious presence) for feed products that are approved in the EU, even if they are not approved in Switzerland. Imports of food and feed (including pet food) are spot-checked to ensure that they are properly labeled if they have biotech content.

Meat, milk, eggs or other livestock products made from animals fed biotech feed need not be labeled. Products produced using genetically modified microorganisms as processing aids (such as yeasts in the production of wine or beer, or enzymes in the production of cheese) do not have to be labeled if the biotech processing aid is not present in the final product.

Biosafety Protocol

Switzerland has signed and ratified the Biosafety Protocol. It was implemented with an ordinance complementing existing rules that were already in place. The ordinance integrated new elements regarding notification and documentation requirements for exports of biotech products intended for use in the environment. It also set up the national focal point in the Swiss Federal Office for the Environment and provided for Swiss participation in the Biosafety Clearing-House and a mutual alert system with neighboring countries in the event of unintentional transboundary movement of biotech products. No changes were required regarding imports since they were already covered by existing legislation.

LL601 Rice

In August, 2006, trace amounts of regulated biotech rice were found in samples taken from commercial long grain rice. The line in question, LL601 "Liberty Link" rice was not considered to present a danger to human health, food safety, or the environment, but it presented a regulatory and trade issue since it was unapproved in the US and Switzerland. The US traditionally exports approximately 18,000 metric tons of rice to Switzerland annually, mainly husked (brown) rice, valued at approximately $7 million.

The Swiss Federal Office for Public Health issued a recommendation for importers to obtain certificates on imports of US long grain rice showing them to be free of LL601 contamination. Certificates issued at origin were acceptable. If imports are accompanied by a certificate based on the EU sampling and testing methodology, re-testing at destination would not be required, although there would be spot-checking. Spot checks by cantonal control bodies use the EU sampling and testing methodology. The two main retailers, Migros and Coop conducted their own testing of their rice supplies and temporarily removed all US long-grain rice from their shelves.

While some US rice brands were eventually returned to the shelves, shifting to non-US suppliers (including suppliers of milled, vs. husked rice) has taken place and the market for US rice in Switzerland has not yet recovered. Trade statistics show no imports of husked rice from the US in 2007 and 2008. A small amount of US husked rice (19 tons) was imported into Switzerland from January to May 2009, the most recent period for which import statistics are available. The new amendment to the Swiss regulation on biotech food, providing the possibility for a tolerance for unapproved varieties in food, may help address similar situations in the future. Due to the strong anti-biotech public opinion in Switzerland however, there would still be a commercial issue in such a situation, even if the regulatory concerns were addressed.

Section V. Marketing:

The main retailers in Switzerland have taken a generally anti-biotech stance, reflecting their perception of market reality in Switzerland. Coop, with 35% of the market, is the second-largest food retailer in Switzerland and has its biotech policy outlined on its website and promotional material. Coop prohibits any biotech ingredients or additives in its store-brand products, and

endeavors to keep other products containing biotech off its shelves, including meat which may have been fed biotech feed. Migros, the largest food retailer with 37% of the market, has a similar anti-biotech policy, citing the need to be responsive to consumer demands. Migros's policy states that it does not sell any genetically-modified foods of plant origin and guarantees that any Swiss origin meat products have not been produced using biotech feed. For imported meat, dairy products and eggs, Migros endeavors to ensure that biotech feed has not been used. Both Migros and Coop state that if any product were to contain biotech ingredients, it would be properly labeled, but that for the time being, no such products are sold in their stores. The retail market is highly concentrated and controlled by these two retail giants. In addition, they are large players in the importation and distribution of food in Switzerland.

In a 2007 press release, Coop published the results of an in-house survey, which showed that 85% of Swiss people do not want biotech food. This opposition was noted to be slightly more pronounced among women (88%) than men (81%). The strongest opposition was in the 35-54 age group. 83% of the respondents opposed the use of biotech feed as well. 54% of respondents requested that Coop not stock biotech products, a 10% increase compared to the results of a similar survey in 2004. In spite of the fact that biotech products are generally not available on the market in Switzerland, 75% of respondents believed that these products were on the market.

Animal products produced from animals fed biotech feed are not required to be labeled in Switzerland. However, due to retailer policies and the fact that the Swiss import tariff regime results in the same price level for biotech and non-biotech feed, Swiss livestock producers have no incentive to use biotech feed. As Switzerland gradually liberalizes agricultural trade with the EU, this situation could change.