



CASE STUDY 26:

A National Focal Point registers biosafety laws.

Objective:

REVIEW: To use the BCH to register several biosafety laws.

References:

BCH Module 6: Registering information

Scenario:

Your government has recently ratified the Protocol and you have been asked to register the relevant laws with the BCH. Your assistant has identified the following laws and regulations as possibly being relevant to the Protocol – your task is to register them with the BCH.

Important note:

Please be sure that you are using the
BCH Training Database
for this exercise!

Summary of laws and regulations that may be relevant to the Protocol

Introduction

The situation governing regulation of GMOs includes a harmonized system of laws, regulations and guidelines. The decisions by different administrative bodies representing different institutional levels are mainly based on a single common science-based biosafety advisory system.

The legal basis of our framework is the " Federal Law on the Release of Organisms into the Environment, governed by the National Competent Authority. The Department of Industry has issued guidelines to cover contained use of all organisms that may impact on biodiversity, including GMOs. The Federal Office of Public Health has issued guidelines for circulation of phytosanitary products and GMO-foodstuffs, GMO-additives and GMO-processing aids. It also maintains a public register of approved GM products for animal feed.

Specific legislation for the release of genetically modified organisms has been drafted and is currently before Parliament.

I. Regulation 137: Approval Procedure for GMO-foodstuffs, GMO-additives and GMO-processing aids

Objective: GMO products as defined below must be approved by the Federal Office of Public Health before being handed over to consumers.

1. GMO foodstuffs, GMO additives and GMO processing aids are GMO products;
2. GMO products are products which:
 - (a) comprise genetically modified organisms;
 - (b) are made or directly derived from genetically modified organisms (1st generation), even if they have been separated from the organism and purified of the genetic material;
 - (c) are mixed with genetically modified organisms;
 - (d) if they derive from hybrids of genetically modified organisms or genetically modified organisms crossed with unmodified organisms.

Entry into force: 01-01-2005

Website reference: www.biosafetylaws.com/reg137EN.html (English);
www.biosafetylaws.com/reg137FR.html (French)

Responsible Authority: Federal Office of Public Health, Tel: 123-456-789

II. Regulation 147: GM Livestock Feed Catalogue

Objective: This document contains a list of genetically modified raw materials and genetically modified feed derived from plants or plant materials that have been authorized as feedstuff for animals.

Entry into force: 01-01-2005

Website: www.biosafetylaws.com/reg147EN.html (English);
www.biosafetylaws.com/reg147FR.html (French)

Responsible Authority: Federal Office of Public Health, Tel: 123-456-789

III. Regulation 157: Circulation of Phytosanitary Products

Objective: To regulate the propagation, circulation and import of phytosanitary products intended to be used in agriculture, in productive horticulture and in private gardens, particularly used as fertilizers.

Entry into force: 01-01-2005

Website: www.biosafetylaws.com/reg157EN.html (English);
www.biosafetylaws.com/reg157FR.html (French)

Responsible Authority: Department of Industry, Tel: 234-567-890

Note: This regulation applies only to Federal States Alpha, Beta and Gamma. Delta has not ratified it as of this date.

IV. Federal Law on the Release of Organisms into the Environment

Objective: The purpose of this law is to protect persons, animals and plants, their biological communities and habitats against harmful effects or nuisances and to maintain the fertility of the soil.

Scope: The law applies to all applications and uses of potentially environmentally hazardous plants including contained use, deliberate release into the environment, marketing as well as import, export and transit.

Entry into force: 01-01-2005

Website: www.biosafetylaws.com/rROE-EN.html (English);
www.biosafetylaws.com/ROE-FR.html (French)

Note: Courtesy copy in Spanish available at: www.biosafetylaws.com/ROE-ES.html

Responsible Authority: Competent National Authority, Tel: 012-345-678

V. Guidelines for the Contained Use of Organisms

Objective: The purpose of these Guidelines is to protect people and the environment, in particular communities of animals and plants and their habitats, against harmful effects or nuisances of the contained use of organisms.

Scope: These Guidelines regulate the contained use of organisms, in particular genetically modified or pathogenic organisms.

Entry into force: 01-01-2005

Website: www.biosafetylaws.com/gcuEN.html (English);
www.biosafetylaws.com/gcuFR.html (French)

Responsible Authority: Department of Industry, Tel: 234-567-890