



CASE STUDY (CSSD11):

Submitting data to the Biosafety Clearing House (BCH): A BCH National Focal Point submits biosafety laws.

Objective:

Learn how to use the BCH to submit national biosafety-related laws or regulations.

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 relevant to the Protocol – your task is to submit them to the BCH.

Summary of laws and regulations relevant to the Protocol

Introduction

The situation governing the 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 the contained use of all organisms that may impact biodiversity, including GMOs. The Federal Office of Public Health has issued guidelines for circulating phytosanitary products, GMO foodstuffs, GMO additives, and GMO-processing aids. It also maintains a public register of approved GM products for animal feed.

Specific legislation for releasing 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 that:
 - (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 authorized as animal feedstuff.

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, productive horticulture, and private gardens, particularly 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 soil fertility.

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

Mechanics:

Participants should be divided into groups of three to four members. Each group will be assigned a given country. Participants in each group will take turns assuming the BCH National Focal Point role while the rest can observe what he is doing.

Groups and log-in details for the BCH National Focal points are summarized below:

Group	Country	NFP User name	Password
1	Cape Verde	caboverde.nfp@gmail.com	BCH2021!!!
2	Pakistan	pakistan.nfp@gmail.com	BCH2021!!!
3	Jamaica	jamaica.nfp@gmail.com	BCH2021!!!
4	Mauritania	mauritania.nfp@gmail.com	BCH2021!!!
5	Mozambique	mozambique.nfp@gmail.com	Bchworkshop
6	Rwanda	rwanda.nfp@gmail.com	Bchworkshop
7	Gabon	gabon.nfp@gmail.com	Bchworkshop
8	Greece	greece.nfp@gmail.com	Abdef1234\$
9	Angola	angola.nfp@gmail.com	Abdef1234\$
10	Andorra	andorra.nfp@hotmail.com	Abdef1234\$
11	Comoros	comoros.nfp@hotmail.com	Abdef1234\$

Participants should visit the BCH' Training Site' (<https://bch.cbd.int>> Help> Training Site). Then log in using the assigned country NFP user name and password.



Participants should practice creating a 'Biosafety Laws, Regulations, Guidelines and Agreements (LAW)' record using the fictitious scenario information above.

During this exercise, participants can also explore the following functions:

- Submitting the record in multiple languages by selecting the languages in the 'Please select in which language(s) you wish to submit this record' drop-down menu and including translation in the newly added fields.
- Use the 'Review' tab to check entered data and if any mandatory data is missing quickly.
- Use the 'Save Draft' functionality to save your data and make changes later.