



CASE STUDY (CSSD04):

Submitting data to the Biosafety Clearing House (BCH): National Laws or Regulations and Risk Assessment.

Objective:

- To understand the process of submitting (registering and approving) information to the BCH, specifically 'Biosafety Laws, Regulations, Guidelines, and Agreements' and 'Risk Assessment' records.
- To have a general knowledge of the different data input screens.

Scenario

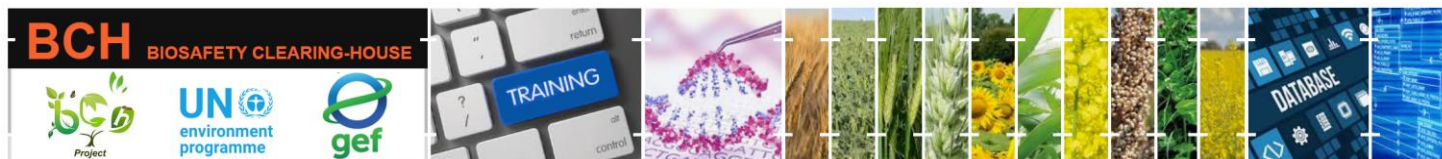
'Biosafety Laws, Regulations, Guidelines, and Agreements' Record

You work for the National Biosafety Authority in Kenya (Record Identification Number (RID) [BCH-CNA-KE-8339-15](#)), and the National Biosafety Law 'The Biosafety Act No.4 of 2023' was just approved. The new law covers all functions under the Cartagena Protocol on Biosafety and all types of Living Modified Organisms. The objectives of the law are: 1) To facilitate responsible research into and minimize the risks that genetically modified organisms may pose; 2) To ensure an adequate level of protection for the safe transfer, handling, and use of genetically modified organisms that may harm the health of the people and the environment; and (c) to establish a transparent, science-based, and predictable process for reviewing and making decisions on transferring, handling, and using genetically modified organisms and related activities. The law enters into force immediately and can be accessed at the National Biosafety Authority website <https://www.biosafetykenya.go.ke/>.

'Risk Assessment Generated by a Regulatory Process' record

You work for the Norwegian Environment Agency (RID: [BCH-CNA-NO-5451-8](#)), and a risk assessment of genetically modified carnation line 26407-2 Moonvelvet (RID: [BCH-LMO-SCBD-104609-3](#)) was conducted on January 5th, 2023. The scope of risk assessment is for the import, distribution, and sales as cut ornamental flowers. The risk assessment summary report can be downloaded at <https://bch.cbd.int/api/v2013/documents/0d94a106-905f-4cae-98ff-ec3bedca2885/attachments/19179/Risk%20assessment%20of%20genetically%20modified%20carnation%20line%2026407-2%20Moonvelvet.pdf>. The risk assessment is carried out by the Norwegian Scientific Committee for food and environment (VKM), on behalf of the Norwegian Environment Agency. The LMO is approved for import, distribution, and sale as a cut, ornamental flower in the European Economic Area (EEA), which includes Norway.





Mechanics:

Participants should be divided into four groups of four members each. 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 are National Authorized Users.

Groups and log-in details are summarized below:

Group	Country	Role	User name	Password
1	Greece	NFP	greece.nfp@gmail.com	Abdef1234\$
		NAU	greece.nau1@gmail.com	Abdef1234\$
		NAU	greece.nau1@gmail.com	Abdef1234\$
		NAU	greece.nau1@gmail.com	Abdef1234\$
2	Angola	NFP	angola.nfp@gmail.com	Abdef1234\$
		NAU	angola.nau1@gmail.com	Abdef1234\$
		NAU	angola.nau2@gmail.com	Abdef1234\$
		NAU	angola.nau3@gmail.com	Abdef1234\$
3	Andorra	NFP	andorra.nfp@hotmail.com	Abdef1234\$
		NAU	andorra.nau1@hotmail.com	Abdef1234\$
		NAU	andorra.nau2@hotmail.com	Abdef1234\$
		NAU	andorra.nau3@hotmail.com	Abdef1234\$
4	Comoros	NFP	comoros.nfp@hotmail.com	Abdef1234\$
		NAU	comoros.nau1@hotmail.com	Abdef1234\$
		NAU	comoros.nau2@hotmail.com	Abdef1234\$
		NAU	comoros.nau3@hotmail.com	Abdef1234\$

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

Following the assigned role (NAU1, NAU2, etc.), each participant should submit 'Biosafety Laws, Regulations, Guidelines, and Agreements' and 'Risk Assessment Generated by a regulatory Process' records referencing existing records for an LMO and a CNA using the fictitious information of the scenario provided above. After that, S/He will see its status as 'Pending BCH-NFP Approval.'

The BCH-NFP can also submit some records (note that, in this case, it will be automatically published with a need to be validated).

When the group's participants have entered at least one record, the BCH-NFP can practice the 'Approve,' 'Edit,' or 'Reject' functionalities. The NAUs could watch the process on BCH-NFP's



computer. Practice 'reject' for at least one submission. Participants should exchange roles between them so that each participant in the group can play the role of a BCH-NFP.

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.