



CASE STUDY (CSSD03):

Submitting data to the Biosafety Clearing House (BCH): Living Modified Organisms (LMOs) and Decisions on LMOs.

Objective:

- Understand the process of submitting (registering and approving) information to the BCH, specifically the 'LMOs' record and 'Countries Decisions or any other Communications' record.
- Have a general knowledge of the different data input screens.

Scenario

You are working for the Cartagena Protocol Competent National Authority in Germany, 'The Federal Office of Consumer Protection and Food Safety.' The Competent National Authority Record Identification Number (RID) on the BCH is [BCH-CNA-DE-12096-7](#). Today, a decision has been taken on *YieldGard™ maize* (MON-ØØ81Ø-6, transformation event MON810), developed by Monsanto Company (RID: [BCH-CON-SCBD-14925-3](#)). The Insect-resistant maize was produced by inserting the cry1Ab gene from *Bacillus thuringiensis subsp. kurstaki HD-1* into the parenteral maize variety (RID: [BCH-ORGA-SCBD-246-6](#)). The genetic modification affords resistance to attack by the European corn borer (ECB), *Ostrinia nubilalis*. Related organisms on the BCH include ([BCH-LMO-SCBD-14779-7](#) and [BCH-LMO-SCBD-15410-7](#)). The technique used for modification was a Biolistic / Particle gun method, and two vectors were used, namely PV-ZMBK07 and PV-ZMGT10. More information on the introduced genetic elements is as follows: The transgenic maize line MON810 was genetically engineered to resist ECB by producing its insecticide. This line was developed by introducing a synthetic version of the cry1Ab gene, isolated from the soil bacterium *Bacillus thuringiensis* (Bt), modified to enhance the expression of the Cry1Ab protein in plants; however, the resulting amino acid sequence is identical to the native protein.

Molecular studies demonstrated that a single truncated copy of the cry1Ab coding sequence was integrated into the corn genome along with the enhanced cauliflower mosaic virus 35S promoter (P-e35S) and the hsp 70 intron (I-Hsp70). Western analysis confirmed that a truncated Cry1Ab protein of approximately 91 kD (native Cry1Ab had a molecular weight of approximately 131 kD) was inserted into the genome. The nos terminator was not integrated into MON810 due to a truncation of the 3' end of the gene cassette.

Corn event MON 810 was produced by microprojectile bombardment of embryogenic corn tissue with plasmids PVZMBK07 and PV-ZMGT10. However, the plasmid vector PV-ZMGT10 was not integrated into the plant genome.



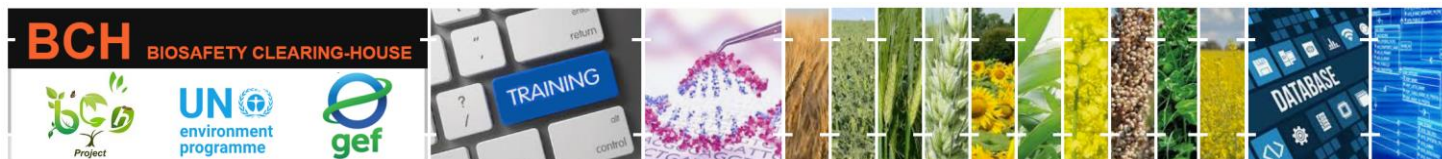


Further Southern blot analysis indicated that the genes for glyphosate tolerance (CP4 EPSPS) and antibiotic resistance (neo) were not transferred to line MON 810, and the absence of the CP4 EPSPS and gox gene products was also confirmed by Western blotting. The CP4 EPSPS and GOX protein-encoding genes were presumed to have been inserted into the initial transformant at separate genetic loci from the cry1Ab gene and then subsequently lost through segregation during the crossing events leading to line MON810.

Southern analysis confirms that the nptII gene (initially present in PVZMBK07 and PVZMGT10) is not present in MON 810. The BCH records containing introduced genetic elements information are [BCH-GENE-SCBD-14985-12](#), [BCH-GENE-SCBD-100359-7](#), and [BCH-GENE-SCBD-100366-6](#). The common use of the LMO is food, feed, and biofuel. The detection and identification methods of the LMO at the EU Reference Laboratory and CropLife International Detection method databases can be accessed at <https://gmo-crl.jrc.ec.europa.eu/gmomethods/query.do?db=gmometh&query=ac:MON-00810-6> and <https://detection-methods.com/product/yieldgard/>, respectively. More information about MON-00810-6 can be accessed at the OECD Biotrack Product database <http://www2.oecd.org/biotech/Product.aspx?id=MON-%C3%98%C3%9881%C3%98-6>.

The title of the decision taken was '6786-01-0169; Decision regarding the deliberate release (field trial) of genetically modified maize (Zea mays) line MON810.' The Federal Office of Consumer Protection and Food Safety received the notification from Monsanto Agrar Deutschland GmbH (RID: [BCH-CON-DE-103566-2](#)) two hundred days ago, and the acknowledgment of receipt was sent to the notifier hundred and ninety days ago. The approval for the field trial was with the following conditions:

- Fertile plant material must be transported and stored in closed, clearly labeled repositories outside the release site and biogas plants. Flowering plants and plant material, including blossoms, must be transported in containers that prevent pollen distribution from the plant material. Genetically modified and wild-type maize must be stored separately at any time.
- Repositories and containers for transport, seed drills, crop choppers, and machines used for inactivation of the germination capacity of corn need to be thoroughly cleaned after usage to prevent accidental transfer of genetically modified seeds.
- The release site of the genetically modified maize has to be within a distance of at least 200 m to other maize cultivation areas, or maize that is cultivated closer to the genetically modified maize has not to be used as food and feed and needs to be destroyed for instance within a biogas plant.
- After completion of the field trial, maize must not be cultivated on the release site for one year. During this period, the release site, where shelter crops were planted, and a further 10 m of the surrounding area must be inspected for transgenic maize volunteers. Volunteers have to be removed and disposed of before the inflorescence.
- Maize plants that are not transported to genetic engineering facilities have to be destroyed by destroying the germination capacity of corn kernels, inactivating plant material of the genetically modified maize, and shelter crops through appropriate land management (chaffing of plant material and subsequent covering with soil) or by disposal in biogas plants (efficient inactivation



needs to be assured) or by composting of all non-fertile plant material (leaves, petioles, cobs, bracts, silage maize) on the release site; this is also permitted for corn kernels that were inactivated through mechanical procedures.

- Inspection of the release site on unexpected biological traits of the LMO and reciprocal effects between LMO and other organisms has to be accomplished weekly during the experiment.

The decision text can be accessed at <https://zag.bvl.bund.de/freisetzung/detail.jsf;jsessionid=xzAjceznV79c0EfBndUWTTILGmm4Gul2utEAUtEH.subs208?dswid=5999&dsrid=24&azLink=6786-01-0169>, and associated LMO identification and risk assessment records are [BCH-LMO-SCBD-14750-19](#), [BCH-RA-DE-103565-4](#).

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 one 'Living Modified Organism' record and one 'Countries' Decisions or any other Communications' record (referencing the previously registered 'LMO') using the fictitious information of the scenario provided above. Finally, 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.