



"Building Capacity for Effective Participation in the Biosafety Clearing House (BCH)"

BCH Training workshop for EU

Ljubljana, Slovenia

17-21 September 2007

On 17-18 September and 20-21 September two consecutive training workshops were organised within the framework of the UNEP/GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing House (UNEP/GEF BCH project). The workshops targeted Biosafety Clearing House (BCH) and Cartagena Protocol focal points and were based mainly on case studies, where participants worked online to solve different tasks related to the use of BCH central portal. The report is given in **Annex 1**.

On 19 September the countries participating in the UNEP/GEF BCH project had short meeting the with the project general manager, Jyoti Mathur-Filipp, concerning the national projects. Afterwards representatives of the EU member states focused on input for the Submission according to MOP decision BS III/2. The report is given in **Annex 2**.

Representatives of 13 EU Member States, representatives of the UNEP/GEF BCH project and of the Secretariat of the Convention on Biological Diversity (SCBD) attended the events. Please find the Participants list in **Annex 3**.



"Building Capacity for Effective Participation in the Biosafety Clearing House (BCH)"

Annex 1:

**Training workshops within the framework of the
UNEP/GEF BCH project**

The programme included short presentations combined with online training using case studies prepared under the scope of the UNEP/GEF BCH project (you can find these case studies and other BCH training materials at: (<http://bch.biodiv.org/help/trainingModules/default.shtml> and/or <https://moodle.unep.ch/login/index.php> using username and password: guest).

The UNEP/GEF BCH project regional advisors, Vida Marolt Parabucki and Aleksej Tarasjev, led the workshops.

Short presentations:

- Introduction to the UNEP/GEF BCH Project (Jyoti Mathur-Filipp)
- Summary of the national projects in the EU member states (Prakash Bista)
- Current status of Biosafety and the BCH in Slovenia (Ruth Ruprecht)
- Presentation of introduction to the BCH (Aleksej Tarasjev)
- Using the Central Portal to find information – Browsing and finding information (Aleksej Tarasjev, Vida Marolt Parabucki)
- Improvements to the BCH Central Portal that will be launched within one month (Giovanni Ferraiolo)
- Information sharing obligations of the Parties to the Protocol (Aleksej Tarasjev)
- Four Options for national participation in the BCH (Vida Marolt Parabucki)
- Introduction to the Management Centre (Vida Marolt Parabucki)
- Management of National Authorized Users – Demo (Aleksej Tarasjev, Vida Marolt Parabucki)

Case studies:

1. Searching information on the BCH:

- A regulator wants to determine what genetically modified crops may enter their territory
- A regulator has received a request to import potatoes to be used as food and animal feed
- A medical researcher seeks information about the application of the AIA procedure
- A food company contacts the Competent National Authority (CNA) to import transgenic corn for food use

2. Input of information through the BCH Management Center:

- A country has just become a Party to the Cartagena Protocol and must fulfil its reporting obligations
- Registering data into the BCH Central Portal: Management of Users
- Registering Data into the BCH Central Portal: LMOs and Decisions on LMOs



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- Registering Data into the BCH Central Portal: Risk Assessment and National Laws or Regulations
- Information the CNA must provide to the BCH about a decision

Participants rated the workshop very positively. The UNEP/GEF representative encouraged participants to propose inclusion of Regional Advisors of the UNEP-GEF project onto the Roster of Experts on BCH, in order to ensure sustainability of the BCH regional trainers after the closure of the UNEP/GEF project.



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Annex 2:

Meeting of EU Member States on the Submission according to MOP decision BS III/2

The input for this document came from comments from MS and results from the Meeting of the National Focal Points/National Competent Authorities to the Cartagena Protocol, in Berlin and the Meeting of EU Member States on the submission according to MOP decision BS III/2, in Ljubljana.

AT, BE, BG, CZ, DE, ES, FI, FR, IR, IT, SE contributed written comments.

Written comments on the draft report by JRC were also taken into account.

Member States present at the meeting: AT, CZ, DE, EE, LT, LV, MT, PT, RO, SE, SI, and SK. The representative of the SCBD was also present at the meeting and provided, where possible, technical solutions that could be implemented on the BCH Central Portal.

Member States were asked to:

1. Identify obstacles that, in their practical experience, hinder the adequate use of the BCH central portal or the easy submission of information to the BCH central portal.
2. Describe any experience they have with the development of strategies to overcome such difficulties.

No major obstacles were identified by: BG, ES, FI, FR, IR, IT and SE.

Some of the member states also reported limited experiences with the BCH, mainly due to the low number of data that exists in their countries, which must be provided to the BCH (AT, FI, IR, SE).

Main conclusions of the meeting:

Participants consider the BCH as a core element of the Cartagena Protocol that supports the AIA and FFP procedures, and also importantly serves as a platform where Parties can share their experiences in decision making, risk assessment and other biosafety related issues. Thus the BCH also represents an important capacity building tool and the EU has a responsibility to provide all available information in a transparent manner.

Participants have concluded that MS and the EC provide the majority of the required information to the BCH. Some types of information are still missing, and MS and the EC should submit it as soon as possible.

With reference to MOP decision BS III/2, many obstacles were discussed and organised in groups based upon who has the competence over them (EU, SCBD, MOP).



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1. Obstacles / solutions to be addressed at the EU level:

a) Finding reliable information on genetically modified organisms (GMO) products on the EU market

It was observed by the participants that finding reliable information on GMO products on the EU market is rather difficult for anyone not aware of the EU legislative system.

- Decisions taken at the EU level are not found during a European Union member states (this search option is provided on BCH and allows searching all MS together) or individual MS search.

At the Berlin workshop we discussed the responsibilities of MS and the EC to submit information of the decisions to the BCH. Pursuant to the Regulation (EC) No. 1946/2003 and the Cartagena Protocol, EU Member States are responsible for the submission of documents regarding decisions based on Directive 2001/18/EC, and the EU-Commission is responsible for the submission of the relevant documents regarding decisions based on Regulation (EC) No. 1829/2003. These decisions are valid for all MS, however, they are only shown in search results of the authority that submitted the decisions (the MS or the EC)

Solution: The EU should ask the SCBD to provide a selection button (e.g. -valid for MS or EC, -valid for all MS) for submission of the decisions/RAs of MS and EC, where the authority submitting information could select whether this input is valid only for them or for all MS. It is to be discussed if we also need a validation step in all MS (by BCH NFP), before this information would be shown under each MS on the BCH. This technical solution would preserve the ownership of the information to the authority submitting the information.

- There is no time limitation for decisions (to be marked "expired")
Solution: the EU should ask the SCBD to provide this feature for EC and MS decisions.

b) Finding information on GMO laws and regulations for EU/MS is difficult

- Because of the double layer legislation (EU/ MS) it is difficult to retrieve all relevant legislation under individual MS search. Regulations, Commission and Council decisions which are relevant for MS are not retrieved under MS search.

Solution: The technical solution could be similar to the solution proposal for the EU level decisions under point 1.a). the EU should ask the SCBD to provide a selection button (-valid for all MS) for submission of the Regulations, Commission and Council decisions, where the Commission submitting information could select whether this input is valid for all MS. It is to be discussed if we also need a validation step in all MS (by BCH NFP), before this information would be shown under each MS on the BCH. This technical



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solution would preserve the ownership of the information to the authority submitting the information.

- European Commission is providing all legislation and guidance under bilateral, multilateral and regional agreement on BCH, thus it is not retrievable under search on Laws, regulations and guidelines which is the most intuitive way of searching legislation. *Solution: The EC is to provide a solution. EC is invited to consider providing the disclaimer on Laws, regulations and guidelines which would explain that due to regional nature of EU Laws, regulations and guidelines are provided under bilateral, multilateral and regional agreement. At the same time it should be discussed with SCBD to make also that searchable under Laws, regulations and guidelines search.*
- Commission recommendations are posted under bilateral, multilateral and regional agreement *Solution: Commission recommendations are not bilateral, multilateral and regional agreement. The EC is to provide a solution.*

c) Avoiding re-entering information

One of the obstacles mentioned by many MS is the extra burden of duplication of information requirements. Responsible authority has to submit the information in accordance with the requirements of the EU legislation and after taking decisions also to the BCH in different formats. Identified obstacles:

- There is no structured format available at the EC level for the dossier that is completely comparable with the Common Formats. However GMOREGEX is flexible in that the structure of the dossier can be redefined according to the requirements. The structures already provided can be considered as an initial proposal which could be revised if necessary. However, it must be understood that in order to comply with the information submission requirements with a copy and paste function, there must be a one to one mapping of all the required field and a common understanding of their meaning (semantic interoperability). *Solution: During the development of the GMOREGEX and the EU BCH this was most probably addressed by the EC (JRC) for the documentations derived from Directive 2001/18/EC. The EC is invited to share this process and outcomes with MS. Comment from JRC: GMOREGEX supports the workflow and lifecycle of the authorisation (including the dossier management) for 2001/18. However, since the structure of the dossier is flexible and new structures can be defined, and since the system can be used also without the workflow, it is not a major issue to include the documentation required under 1829/2003. However this has never been discussed. This flexibility is also explained in the documentation/training on GMOREGEX.*



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- Some MS expect improvements when the EU-BCH will become operational.
Comment from JRC: As explained in the documentation and training on GMOREGEX and related BCH module, if this system is used to manage the dossier, then information can be submitted automatically to the central portal using the MS account. However, usage (and interest?) of MS so far on the pilot portal has been very limited. We see very few accesses and most of them are one-time access only or accesses where only a password change has been requested.
Solution: MS are invited to test the pilot GMOREGEX and related BCH module.
- Using part B-SNIFs directly via the EU-BCH was considered as a possible solution to avoid re-entering information for part B release (field trials) under *Directive 2001/18/EC*.
Comment from JRC: The EC is not responsible for submission of part B information to the BCH, therefore this functionality has never been foreseen for GMOREGEX. However, MS can copy and paste from the WebSNIF information to be submitted for the BCH.

d) Missing information :

- **Summaries of risk assessments** or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof, namely processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology: (Article 20 paragraph 3 (c)).
There are currently only 16 risk assessments submitted by MS and the EC (5 on market release and 11 for field trials). Most of them only contain title, contact and link to the original RA.
Many EU Member States have gained broad experience in risk assessment and decision making processes regarding genetically modified organisms to be used for deliberate releases and placing on the market. This experience is of high value for many other parties to the Protocol and thus should be made available through the BCH-CP.
Solution: Member States and the Commission are urged to submit RAs to the BCH.
- Information on the **application of domestic regulations** to specific imports of LMOs (article 14 paragraph 4.)
Only the EU and not the MS is reporting that: Legislative framework for intentional movements of GMOs within the EC and for imports of GMOs into the EC (The EC relies on its existing legislative framework for intentional movements of GMOs within the Community and for imports of GMOs into the EC.).
Clearly also MS relies on the existing legislative framework for intentional movements of GMOs within the Community and for imports of GMOs into the EC and should report that to the BCH.



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Solution: Member States are urged to submit statements on the application of domestic regulations to intentional movements of GMOs within the EC and for imports of GMOs into their territory.

- Contact details for **emergency contact point** for receiving notifications of unintentional transboundary movements of LMOs (Article 17 paragraph 2)
Solution: Member States, that have not yet done so, are urged to submit contact details for emergency contact point.
- **Illegal transboundary movements** of LMOs (Article 25 Paragraph 3)
Solution: Member States are urged to submit cases of illegal transboundary movements.
- For the EU decisions posted by the OECD there could be up to triple postings (one for each approved use).
Solution: the SCBD has presented new improvements on the BCH where the search of decisions will provide results in a table showing countries on one side and approved use on the other. The EU should check with the SCBD if this would solve the multiple entries for the same decision.

2. Technical obstacles to be addressed to the SCBD:

a) Finding information

- Using the **BCH requires a certain level of expertise**
It was observed that one should be an expert to be able to find information quickly and efficiently and thus the BCH is not a suitable application for general public.
Solution: the SCBD has explained that on the basis of the recommendations from IAC-BCH they made a lot of improvements towards an user-friendliest and intuitively usable BCH. The launch of new pages is expected in one month time. It remains to asses these new changes and provides further comments to the SCBD if needed.
- **Search based on approved use** is not possible (field trials, feed, food, processing, cultivation).
Solution: Technically solved by SCBD in the new version of BCH
- **Field trials** posted under the AIA should be differentiated from commercial cultivations (the same is true when searching RAs)
Solution: Technically solved by the SCBD in the new version of BCH.
- Each **decision/RA search result** should be described and sorted by:
 - LMO: scientific name, common name, I.U., event
 - Trait



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- Approved usage
- Country:

Solution: Should be addressed to the SCBD.

- Not all information on the BCH is **regularly updated** and a reliability of ‘old’ information poses an obstacle.

Solution: Parties and other authorised users are responsible for managing the information on the BCH including updating. The SCBD regularly sends reminders for updating information. The only mechanism that would also include mandatory updating of information was suggested by Capacity Building Lesson Group for managing the information on Roster of Experts, but it is up to MOP to decide on that. In view of this it was suggested to the SCBD to implement a ‘time button’ in a search options that would allow to search only information that was updated within certain time period.

- **Language problem**

The BCH only allow submitting information in one of the six UN languages. Many Parties do not have documents in those languages which also present problem for them.

Solution: SCBD informed the participants that in new version of BCH central portal (Management centre) there will be possibility to enter country data in two languages – in one of the six UN official languages and another of country’s choice. Two new applications developed by SCBD (HERMES and AJAX) support multilingual national BCH.

Parties are encouraged to provide courtesy translations if possible (could be unofficial).

- For using the search option “**multiple choice**”, where available, should be written a comment that <CTRL> has to be pressed simultaneously – since this is not self explanatory for non IT (information technology) users.
- **Work with several search results:** When you have to work with several search results it would be helpful to have an option to export the result sheets to another program for data processing e.g. Excel.

b) Entering information

- Risk assessment
 - On Page 2 of the common format provided at the Management Centre should be search mechanism to find adequate LMOs.
 - Support in the form of metadata/ Controlled vocabulary would be welcomed
 - Summary – Annex III has to be used
 - Attaching original Risk Assessments should be promoted



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- Creating new LMO
 - Page 2 of LMO creation: Description of a gene modification – left to the author to fill
 - Page 3 of LMO creation:
 - Recipient organism – list of organisms should be provided
 - Parental organism – only one is possible at the moment
 - Point of collection can be left for SCBD
 - Page 4 of LMO creation
 - LMO commercial status - Agbios database could be used as a reference
 - Page 5 of LMO creation
 - Reference – scientific papers, suggested to provide as much as possible information
 - Notes – by the owner

- Create new gene
 - There is no create button.
Solution: Only the SCBD can create new gene, for submitting gene SCBD should be contacted. Still create button should exist to prepare draft and submit it to the SCBD for creation.

c) Interoperability

The SCBD explained, that this is not considered as a major technical problem, as frequent changes in the BCH appearance do not influence the interoperability. **The SCBD** expects, that each time that the changes that do influence the interoperability occur, they would still maintain the old version at least two years.

3. Obstacles to be addressed at MOP

Participants have discussed thoroughly different issues concerning risk assessments. It was recognised that information is largely missing on BCH and many obstacles were identified. With regards to which RA is concerned, participants agreed that only RA connected to AIA (cultivation) and FFP decisions are mandatory, anything else is voluntary, including field trials. With regards of whose RA should be submitted it was concluded, that all submissions of the Parties are considered as theirs, including RA.

- Key question to be addressed is ‘What does "summary of risk assessments or environmental reviews" exactly mean?’ Lack of certainty of meaning of this expression is surely one of the obstacles for submitting RAs.



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Solution: Since this wording is in the Protocol it is up to MOP to further discuss it. EU should form an opinion whether we want to open this issue in the future MOPs.

- Is the common format (based on Annex III) currently used in the BCH adequate?

Solution: The comment to the previous bullet point applies.

- RA on BCH were seen as one of the valuable capacity building resources in implementation of the Protocol where exchange of experiences is of utmost importance. Thus even in the absence of further MOP guidance on the RA common formats and Annex III improvements to this part of BCH is necessary.

Participants have suggested some improvements to promote the input and search of RAs. These improvements should focus on the technical possibilities of the BCH and could be made through improvements to metadata of the common format. SCBD could provide for option to differentiation according to intended use, scope and between the RA which are connected to the decisions and others for example. This could be achieved by another field with controlled vocabulary for usage, scope and cross linking with the decisions. SCBD could also provide some metadata under RA summary that would allow the authorities to click which issues were considered under RA. This would at least enable somebody that is searching the information to conduct more targeted search. Even if one should then download the original documents and possibly even translate them this targeted search would ensure that he would indeed find the relevant information there.



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Annex 3: Lists of participants

BCH Training for EU Members States

Ljubljana, Slovenia

17-18 September 2007

Name	Organisation	
Abela Medici Joseph, MSc	Malta Environment and Planning Authority, St. Francis Revelin, Floriana, CMR01, Malta	
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"Building Capacity for Effective Participation in the Biosafety Clearing House (BCH)"

**Meeting of EU Member States on the Submission according to MOP
decision BS III/2
Ljubljana, Slovenia
19 September 2007**

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BCH Training for EU Members States

Ljubljana, Slovenia

20-21 September 2007

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