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THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Series on Harmonization of Regulatory Oversight in Biotechnology No. 17

REPORT OF THE OECD WORKSHOP ON UNIQUE IDENTIFICATION SYSTEMS FOR
TRANSGENIC PLANTS

Charmey, Switzerland, 2-4 October 2000

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No. 15, *Consensus Document on the Biology of Glycine max (L.) Merr. (Soybean)* (2000)

No. 16, *Consensus Document on the Biology of Populus L. (Poplars)* (2000)

Consensus Document on the Biology of Beta vulgaris L. (Sugar Beet) (in preparation)

Consensus Document on Information Used in the Assessment of Environmental Applications Involving Bacillus (in preparation)

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Series on Harmonization of Regulatory Oversight in Biotechnology

No. 17

**Report of the OECD Workshop on Unique Identification
Systems for Transgenic Plants**

Charmey, Switzerland, 2-4 October 2000

Environment Directorate

Organisation for Economic Co-operation and Development

Paris 2001

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FOREWORD

This document includes the report of the OECD Workshop on Unique Identification Systems for Transgenic Plants, held under the auspices of OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology, and hosted by the Swiss Government in Charmey, Switzerland 2-4 October 2000. It also makes reference to discussions on the results of the Workshop which were held at the subsequent 9th Meeting of the Working Group (November 2000). In concluding its discussions, the Working Group recommended that the document be forwarded to the Joint Meeting to consider it for declassification.

As part of its work, the Working Group is focusing on outreach activities, particularly through its information system, BioTrack Online. This system includes information on regulatory developments in OECD Member countries, including details of laws, regulations and the contact points of the responsible ministries and agencies. It also has a database of field trials in OECD Member countries, as well as a database of products that have been authorised for commercial purposes (e.g., environmental release, food, feed).

The main objective of this Workshop was to identify ways to improve the product database (<http://www.olis.oecd.org/bioprod.nsf>) which currently includes summary information on those products of modern biotechnology which have been approved for (commercial) use in OECD Member countries. The entries in the database are of particular value where they include links to national safety assessment reports. However, one outstanding issue is the increasing difficulty in ensuring non-duplication of entries in the database, which are dealing with the same product. So a major aim of the Workshop was to identify the most efficient means of establishing a method of unique identifier for transgenic organisms, and to draft conclusions, recommendations and points to consider for OECD's Working Group on how to move forward with this issue. To achieve this aim, the Workshop gathered together 60 participants from 22 countries, as well as representatives of FAO, the CBD Secretariat and UNIDO. There were also representatives from BIAC.

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Section I – Introduction and Follow-up to the Workshop

This document includes the report of the OECD Workshop on Unique Identification Systems for Transgenic Plants that was hosted by the Swiss Government in Charmey, Switzerland 2-4 October 2000. This Workshop was organised by OECD's Working Group on Harmonization of Regulatory Oversight in Biotechnology which is comprised of individuals from government ministries or agencies, who have responsibility for the environmental risk/safety assessment of products of modern biotechnology (including transgenic organisms). Regulatory harmonisation has been the primary goal of the Working Group since it was established in 1995. The Workshop involved 60 participants from 22 countries, as well as representatives of FAO, the CBD Secretariat and UNIDO. There were also representatives from BIAC.

The first objective of this Workshop was to identify the most efficient means of establishing a unique identifier for transgenic organisms, and to draft conclusions, recommendations and points to consider for OECD's Working Group on how to move forward with this issue. In this context, the document identifies two potential options for a unique identifier.

The second objective was to identify ways of improving the product database (<http://www.olis.oecd.org/bioprod.nsf>) which currently includes summary information on those products of modern biotechnology which have been approved for (commercial) use in OECD Member countries. The document makes a number of recommendations on this point, as well as identifying issues which require further discussion.

Development Phase

Following the Workshop, the Working Group discussed the first draft of the Workshop report at its Ninth Meeting (held on 13-15 November 2000), especially the recommendations related to a possible unique identifier and the proposed improvements to the product database. As a result, it was agreed that a number of the recommendations should be implemented as part of a further *development phase* of the product database. The results of this development phase will be reviewed at the Tenth Meeting of the Working Group, which will be held in June 2001. In the meantime, the Working Group recommended that the Workshop report should be declassified as soon as possible.

The key issues to be included as part of the development phase include the recommendations that the product database should include the fields referred to in Section IV, with a number of adjustments. During the development phase, the unique identifier (Section IV) will not be one of the options identified in Section IV, but will be a 9-digit alphanumeric code, with an extra verification digit (total 10 digits). The unique identifier will be based on the transformation event. The applicant will have the responsibility of generating it. In order to demonstrate how the unique identifier might work, five examples will be selected from the existing product database. The Working Group invited applicants to explore possibilities for developing coherent rules for the generation of a unique identifier based on the use of a shortened form of the name of the plant and the name of the applicant.

A central register (a web site) will also be developed by the OECD Secretariat to allow applicants to verify whether or not, a unique identifier is already in use. The central register will also include tools to assist applicants in generating an identifier.

The Working Group also discussed the items for further consideration identified in Section IV. As regards detection and identification methods, Member countries agreed to consider how best this should be addressed during the development phase, perhaps by including links to existing information in the public domain. Member countries will clarify during the development phase whether additional information on regulatory elements (promoters, terminators) and marker genes should be included in the database. Finally, as regards methods for safe handling, storage and transport, Member countries will also consider during the development phase whether and how these issues should be addressed in the database.

Section II – The Charmey Workshop - Setting the Scene

At the start of the Workshop, a number of presentations were made to set the work in context. Eric Schoonejans (EU) and Phil Macdonald (Canada) both spoke about the need for a unique identifier from the perspective of regulators. Eric Schoonejans characterised a unique identifier as being a key attributed unambiguously to a biotech product, which could unlock information from a range of databases, as well as an harmonised unique entry point enabling information management related to that product. After touching on the “what”, “why” and “how” issues, including the foreseeable regulatory requirements for a unique identifier, he emphasised the criteria of user friendliness, efficiency and outreaching requirements of the unique identifier, of relevance to the OECD and to other international initiatives. He also emphasised the importance of the variety of stakeholders and potential users of a unique identification system. Phil Macdonald spoke about the value of a unique identifier to facilitate information flow through the regulatory community and in communicating to the public, growers and the scientific community. He noted that currently, regulators communicated with one another using terms based on the transformation event designation. He stressed the need for a simple numeric system with an identifier that should be provided by applicants, which does not encode extensive information.

Cyrie Sendashonga (CBD Secretariat) spoke about the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, highlighting its provisions which make specific reference to unique identification (i.e. Article 18.2(a) and Annex II of the Protocol). She noted that a unique identifier could facilitate search and retrieval of information relating to LMOs through the Biosafety Clearing-House (BCH) established under Article 20 of the Protocol, especially if a centralised approach to storage and management of information relating to procedures for LMOs-FFPs (Article 11.1 of the Protocol) was going to be implemented, as recommended by the meeting of technical experts on the BCH that took place in Montreal from 11 to 13 September 2000.

Tetsuya Maekawa (OECD Secretariat) gave an overview of OECD’s field trials database as well as its product database as they exist today. The information in the product database is organised into two categories: information about the product (organism, trait, applicant, etc.); and information about the product approval process. On this latter point, the key information includes details of the agencies which have approved a product. Where possible, there are links to national decision documents.

Pierre Miauton (Switzerland) and Monica Pequeno-Araujo (Argentina) gave an overview of the need for a unique identifier in the context of the OECD Seeds Schemes. The purpose of the OECD Schemes for Seed Moving in International Trade is to encourage the use of seed of consistently superior quality in participating countries. There are a number of means to achieve this including internationally harmonised labels and certificates. The issue of designating GM cultivars on the OECD list of varieties, as well as on labels that are placed on bags of certified seed has been raised in the Seeds Schemes. If the Seeds Schemes move forward in this direction in the future, and for several other points, a unique identification system would constitute a major advantage in the work of the international seed network.

Willy de Greef (BIAC) gave an overview of the experiences of industry and, in supporting the concept of a harmonised unique identifier, made a specific proposal. This comprised a simple numerical code which corresponds to a single transformation event and all the products derived from it. This code

would not need to contain any information that identifies, for example, crop, company, first year of commercialisation, etc. This information would be included in a database. He emphasised the need to take into account the particular situations of all practitioners.

Simone Jung (Germany) made a second specific proposal for a unique identifier. This proposal did include a number of components, possibly the species, the trait, the event, the applicant, the year and the country of the first approval and an individual number (an open field). The unique identifier consists of administrative reference and descriptive components. The central component is the transformation event as it is named by the applicant. Therefore, it is necessary to include further information in the unique identifier, e.g., the applicant.

Robert Schubnel (EAN, Switzerland) gave a presentation on the activities of the EAN-UCC Organisations which are non-profit, Non Governmental Organisations, controlled by more than 800,000 members in over 90 countries. The main objective is to guarantee uniqueness for products via the barcode symbols and EDI messages.

Section III – Two Break-out Groups

The Workshop organised its work in two breakout groups.

The first group discussed the purpose of a unique identifier, the users who should be served by the unique identifier, the information or elements which should be included in the identifier and how the information should be encoded. They went on to identify options as to who should generate the identifier (for example, the applicant and/or competent authorities) and the system of quality control.

The second group discussed the information or data elements which should be included in the product database. The starting point was to identify whether the current fields in the database are sufficient. Who owns and updates the database? Who provides the information and how? It also discussed the relationship between the product database and other related initiatives (e.g., national databases, the Biosafety Clearing House, BINAS, culture collection databases).

Section IV – Conclusions, Recommendations, Points to Consider

The Unique Identifier

There was a consensus that there was a need for a unique identifier. Different proposals relevant to this unique identifier and the product database were made. The Workshop answered the following questions. In addition, although it did not come to a consensus on a specific proposal it identified two options for a unique identifier for consideration by OECD's Working Group at its next meeting.

What should be the purpose of a unique identifier in the database? Which users should be served by the unique identifier?

The primary purpose of the unique identifier should be to provide a key to a database. However, some participants considered that the identifier should also have some descriptive elements. The database contains information about the transformation events in transgenic plants which are reviewed for regulatory approvals necessary for commercial purposes. The unique identifier should facilitate the ability to cross reference information in different databases, and improve access to and management of information by regulators and other interested stakeholders.

Currently most regulators identify a particular transgenic plant line by the transformation event assigned by the applicant. However, across applicants, there is a lack of standardisation in naming these events, creating some confusion in the regulatory process, and therefore harmonisation in this area is encouraged. This harmonisation would also facilitate the comparison of review information for approvals of transgenic plants by different regulatory authorities responsible for risk assessments.

Most participants felt that the unique identifier should be assigned at the time of the first application for regulatory approval necessary for commercial purposes (but this is an issue the Working Group may wish to discuss further). Subsequent applications for the same transgenic plant line will use the same identifier. A related issue, which may need clarification, is how to address the situation when an applicant is seeking simultaneous approval in several countries.

Finally, the unique identifier should be suitable for those products that have already been approved. The preliminary indication shows that both options below can be applied to existing products.

What information should be included in the unique identifier? How should the information be encoded?

The unique identifier should at least contain a prefix, information related to a transformation event, and a system for verification. There was consensus that it should be kept short, simple and user friendly. It should also have built in flexibility because it might potentially serve as a core unique identifier for related purposes. For example, certain countries or relevant international bodies may add a suffix (outside the code) for other purposes.

Two options were developed on the creation of a unique identifier. Both options identified core information consisting of a prefix plus approximately 10 digits or spaces for appropriate use and therefore ensuring brevity. Suggestions for a prefix included B = biotech, BK = BioTrack, UID = Unique Identifier, and UITP = Unique Identifier for Transgenic Plants. The system for verification was proposed as a single digit at the end of the code (the 10th digit) and should be built on existing mechanisms.

Option 1:

The approximate 9-digit code should be numerical to ensure practicality and simplicity. The initial 6 numerical digits should represent the transformation event. The remaining 3 digits would be zeroes and open for future assignment. This would satisfy the simplicity criteria as well as future flexibility. All the relevant information such as the plant species, transformation, traits, applicant, etc, would be contained in the database. To satisfy the uniqueness, the single 6-digit number assigned to any transformation event would have to be generated or managed by an appropriate single body.

For example: X123456000#
(X= prefix, # = verification)

Option 2:

The approximate 9-digit code should include the following information describing and related to the transformation event: the applicant, the plant species or other relevant information, and the event number. Each of these criteria could be represented by a flexible number of alphanumerical codes. The applicant and plant species could be represented by letters or numbers and the event could be numerical. The 9-digit code would be generated by the applicant based upon a common set of criteria, yet to be determined. For the purposes of future flexibility, the approximate 10-digit code would have to be extended for this option.

For example: XAAPS12345#000
(AA = applicant, PS = Plant species)

Both options focus on identifying a transformation event in a plant line. It was recognised that certain countries may require additional approvals for stacked products (conventional cross between plants with different transformation events). In such cases, some participants consider that the identifier would simply be a combination of the same identifiers related to the transgenic plant lines used in the conventional cross, while others felt a new unique identifier should be assigned.

Who should generate the identifier and what would be the system of quality control?

In Option 1 above, an appropriate single body would be responsible for administering numbers for the identifier, and in Option 2, the applicant would generate the identifier and no need for a single body to design the unique identifier. The system of quality control is built in, consisting of the last check digit for verification as well as validation by the regulatory authorities.

The Product Database

With respect to the product database, the Workshop considered a number of questions as outlined below.

Who should provide the information?

In principle, it should be the authorities of the Member countries who provide the information. For that purpose, Member countries should nominate contact points with responsibility for the product database ("BioTrack Co-ordinators").

Quality assurance of the data is important in order to check the accuracy of the information. The OECD Secretariat and competent authorities should ensure that information entered into the database is accurate. In this context, it is preferable to make links to applicant-supplied data (e.g., on the commercial status of the product, any varieties) where possible.

When should the information be provided?

Information should be provided to the OECD Product Database whenever a product is approved. The time limit of the Biosafety Protocol (15 days) should be observed. This information should include the unique identifier at the time when the first country approves the product. Subsequent applications and approvals will then refer to this unique identifier.

For future consideration by the Working Group:

- Should data on products in the approval process be addressed or should the database only address approved products?

What should be the key features of the Product Database?

The product database should have the following features:

- it should be an entry point for further information (via the unique identifier);
- it should include a basic set of data (including genetic components of the insert);
- there should be links to the OECD Consensus Documents;
- there should be links to further information (applicant, authority, risk assessment);
- date of last update;
- summaries of approvals;
- glossaries (e.g., for the public);
- link to other databases;
- automatic notification of any updates to the database;
- the information in the product database should be information in the public domain.

For future consideration by the Working Group:

- exploring the possibility for a commitment for providing information;
- taxonomy experts, build on, for instance, experts of the Germplasm Resources Information Network (GRIN), ARS, USDA; UPOV; ISTA; CBD Global Taxonomy Initiative;
- explore the possibility for compatibility in both structure and substance between the product database and other databases including the BCH; and
- language related issues (also in the case of links).
- explore whether there should be links to molecular detection and identification tools, including any unique sequence, where they exist; and
- explore whether there should be links to varieties (if possible, OECD Seeds Schemes).

Are the current fields in the database sufficient?

We should build on what we have in the product database but there is the need for some adjustment. The following recommendations are based on an analysis of the Product Database in its existing format. An additional attempt will have to be made to undertake a comparison with the BCH and to examine if any additional points should be included in the Product Database.

Recommendations for an order of the entries on the Product Database

Information about the product:

- a) Unique Identifier (*replacing the OECD record number*),
- b) transformation event as designated by the applicant, if different from the unique identifier
- c) organism common name (*harmonised, one name, searchable by synonyms*)
- d) organism scientific name
- e) trade name, if any
- f) trait(s) (*insect resistance, herbicide tolerance etc.*)
- g) gene(s): inserted gene(s) encoding/expressing in the host organism *option for further consideration: information about additional genetic elements (other encoding genes, promoter, terminator, non-coding elements, etc.) further suggestion: standardisation of nomenclature for the description of genes (e.g., Bt-toxins)*
- h) applicant (*name of the institution at the time of the approval, link to the applicant's contact points, BIAC will come up with a proposal*)

Information about the product approval process:

- a) first country where approved
- b) date of approval
- c) specific approvals:

Countries	Date	Type of use	Decision (Link)	Risk Assessment (Link)
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Any other relevant information:

Options for further discussion:

- *detection and identification methods*
- *suggested methods for safe handling*
- *status of the product (is it actually commercialised, under which conditions?), information to be given by the applicants*

Appendix I

List of Workshop Participants

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