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REVISED 2006: OECD GUIDANCE FOR THE DESIGNATION OF A UNIQUE IDENTIFIER FOR TRANSGENIC PLANTS

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Series on Harmonisation of Regulatory Oversight in Biotechnology

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REVISED 2006: OECD GUIDANCE FOR THE DESIGNATION OF A UNIQUE IDENTIFIER FOR TRANSGENIC PLANTS

Environment Directorate

Organisation for Economic Co-operation and Development

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ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups composed of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in nine different series: Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; and Emission Scenario Documents. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (http://www.oecd.org/ehs/).

This publication is available electronically, at no charge.

For the complete text of this and many other Biosafety publications, consult the OECD's World Wide Web site (http://www.oecd.org/biotrack)

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FOREWORD TO THE REVISED VERSION

Since the first publication of this guidance document in 2002, the OECD's unique identification system for transgenic plants has been utilised without any major problems as "keys" to access information of each transgenic product in the Product Database (http://www.oecd.org/biotrack/productdatabase). In addition, it has been recognised as an appropriate identification system of products included in the Biosafety Clearing-house of the Cartagena Protocol on Biosafety.

With the recent increases of commercialisation of plant products having one or more traits obtained through the use of recombinant DNA techniques and stacked by conventional crosses in the backdrop, it was proposed at the 17th meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology to standardise the way to designate a unique identifier for such plant products. Up to that time, this guidance document had allowed two different options for such product in item 8.

After it was agreed to revise the Item 8 of this document at the 18th meeting of the Working Group and the revised paragraph was agreed by the Working Group subsequently, this revised document was forwarded to the Joint Meeting and its declassification was endorsed.

FOREWORD

This guidance for a unique identifier for transgenic plants was developed by OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology. The purpose is for use as a "key" to unlock or access information in OECD's database of products of modern biotechnology which have been approved for commercial application, as well as interoperable systems (such as the Biosafety Clearing-House of the CBD).

One of the first major steps in the development of this guidance was an OECD Workshop on Unique Identification Systems for Transgenic Plants, which was hosted by Switzerland in Charmey in October 2000. The report of the Workshop was declassified and published during 2001 [ENV/JM/MONO(2001)5].

At the time of the Charmey Workshop, a number of options for developing a unique identifier were under consideration. Subsequently, these options (and related issues) were discussed in detail at the 9th and 10th meetings of the Working Group (November 2000 and June 2001). The final step in the process was at the 11th meeting of the Working Group (14-16 January 2002) when delegations drafted and agreed the attached guidance. It includes an introductory section, a section on how to develop and generate unique identifiers, as well as a section on future developments. OECD's Business and Industry Advisory Committee (BIAC) have played an important part at all stages in the discussion through their Expert Group on Biotechnology. This is important because according to the guidance, it is the developers of transgenic products who will generate the unique identifier.

At the 33rd Joint Meeting of OECD's Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology, it was agreed that this guidance be declassified so that it could be widely disseminated in a short time.

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OECD GUIDANCE FOR THE DESIGNATION OF A UNIQUE IDENTIFIER FOR TRANSGENIC PLANTS

Introduction

The purpose of the unique identifier is for its use as a key to accessing information in the OECD product database and interoperable systems for the products of modern biotechnology which have been approved for commercial application. This guidance addresses the development of a unique identifier for use in the product database. It was developed from plant products in the OECD BioTrack Product Database and its use is directly applicable to plant products entered into the database. While the concepts and principal components were developed for plants they may be considered for their potential applicability to other products.

OECD has been working on a "unique identifier for transgenic plants" since 2000. This was initiated with an OECD Workshop on Unique Identification Systems for Transgenic Plants, which was hosted by Switzerland in October of that year (Charmey, Switzerland, 2-4 October 2000).

A major objective was to identify the most efficient means of establishing a unique identifier for transgenic plants, and to draft conclusions, recommendations and points to consider within the context of OECD's Product Database. In this context, the Workshop proposed several options for a unique identifier. (See the "Report of the OECD Workshop on Unique Identification Systems for Transgenic Plants" http://www.oecd.org/biotrack)

There was a consensus that there is a need for a unique identifier: a simple alphanumeric code based on the transformation event (rather than other options such as a new variety), with a single digit for verification. The unique identifier should be a "key" to unlocking more detailed information in the product database and interoperable systems (for example, the Biosafety Clearing-House). As such, it should be kept short, simple and user friendly. It should also be built in a flexible way and might potentially serve as a core unique identifier for future developments. It should also take into account experience with, and be applicable to, existing products.

Each applicant has their own internal mechanism to avoid applying the same designation of the "transformation event" to different products. Consequently, incorporating the applicant information into the unique identifier is the only way to enable applicants to generate the unique identifier for their own product, while at the same time ensuring its uniqueness from those generated by other applicants. Furthermore, this provides applicants with the flexibility to generate the unique identifier at the time they believe appropriate or necessary.

DEVELOPMENT AND DESIGNATION OF THE UNIQUE IDENTIFIER

Item 1

The purpose of the unique identifier is for its use as a key to accessing information in the OECD product database and interoperable systems for the products of modern biotechnology which have been approved for commercial application. This guidance addresses the development of a unique identifier for use in the product database. It was developed from plant products in the OECD BioTrack Product Database and its use is directly applicable to plant products entered into the database. While the concepts and principal components were developed for plants they may be considered for their potential applicability to other products.

Item 2

Applicants should designate to the national authority a unique identifier for their product, at the latest, at the time of application for the first commercial approval.

Item 3

The national authority should, at the time of the first approval for commercialisation, notify the OECD BioTrack Product Database of the designated unique identifier, in order to enable access to the relevant information in the database for all subsequent applications for commercialisation in other countries.

Item 4

The unique identifier is a code of a fixed length of 9 alphanumeric digits for a transformation event derived from modern biotechnology.[1] It should be unique to that transformation event.

Item 5

The unique identifier is composed of three elements that must be separated by dashes (-). The total length is 9 digits, the last of which is a verification digit. The transformation event and the applicant designation should total 8 alphanumeric digits.

- 2 or 3 alphanumerical digits to designate the applicant;
- 5 or 6 alphanumerical digits to designate the "transformation event"[2];
- One numerical digit as a verification, as foreseen in item 7.

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1 Zero should be reflected by the symbol ∅ to avoid confusion with the letter O.

2 When the transformation event of an existing plant product, prior to the adoption of this guidance, is shorter or longer than 5 or 6 digits, the applicant should select 5 or 6 digits within the transformation event in order to fit it into this limit.

For example,

C	E	D	–	A	B	8	9	1	–	6

or

C	E	–	A	B	C	8	9	1	–	5

Item 6

The unique identifier should include the "applicant information" of 2 or 3 alphanumeric digits (for example, the first 2 or 3 digits of the applicant organisation name), followed by a dash. Any new applicant that is not identified within the database shall not be permitted to use the existing codes listed in the applicant's code table within the database. The applicant shall inform the national authorities who will update the BioTrack Product Database, by including a new code that will be designed to identify the new applicant in the code table.

Item 7

The unique identifier should include one verification digit, which shall be separated from the rest of the unique identifier digits by a dash. The verification digit is intended to reduce errors by ensuring the integrity of the alphanumeric code, entered by the users of the database.

The rule to calculate the verification digit is as follows. The verification digit is made up of a single numerical digit. It is calculated by adding together the numerical values of each of the alphanumerical digits in the unique identifier. The numerical value of each of the digits is from ∅ to 9 for the numerical digits (∅ to 9) and 1 to 26 for the alphabetical digits (A to Z) (see annex). The total sum, if made up of several numerical digits, will be further calculated by adding the remaining digits together using the same rule, in an iterative process, until the final sum is a single numerical digit.

For example, the verification digit for the code CED-AB891 is calculated as follows:

Step one : 3+5+4+1+2+8+9+1 = 33;

Step two: 3+3 = 6; therefore the verification digit is 6;

Therefore, this unique identifier then becomes

CED-AB891-6

Item 8

The above guidance is sufficient to generate unique identifiers for the majority of existing plant products. Regarding plant products having two or more traits obtained through the use of recombinant DNA techniques and stacked by conventional crosses, the unique identifier should consist of the unique identifiers from each parental transgenic plant (*e.g.,* MON-15985-7 x MON-∅1445-2).

FUTURE DEVELOPMENT

It was recognised that it may be necessary to revisit in the future the potential use of prefixes or suffixes if there is a need to incorporate further information fields. The use of prefixes or suffixes, on an ad hoc or voluntary basis, to incorporate further information fields for use in the BioTrack Product Database, as appropriate or requested by a country, will continue to be discussed and should be made public by national authorities.

This guidance for the development and designation of the unique identifier may be reassessed in the light of experience gained.

ANNEX

Form of digits to be used in the unique identifier

∅
1
2
3
4
5
6
7
8
9

Form of alphabetic characters to be used, plus numerical equivalents for calculating verification digit.

A=1
B=2
C=3
D=4
E=5
F=6
G=7
H=8
I=9
J=1∅
K=11
L=12
M=13
N=14
O=15
P=16
Q=17
R=18
S=19
T=2∅
U=21
V=22
W=23
X=24
Y=25
Z=26