COMMISSION REGULATION (EC) No 65/2004

of 14 January 2004

establishing a system for the development and assignment of unique identifiers for genetically modified organisms

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1830/2003, of the European Parliament and of the Council, of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1], and in particular Article 8 thereof,

Whereas:

(1) Regulation (EC) No 1830/2003 lays down a harmonised framework for the traceability of genetically modified organisms, hereinafter 'GMOs', and of food and feed products produced from GMOs through the transmission and holding of relevant information by operators for such products at each stage of their placing on the market.

(2) Under that Regulation, an operator placing on the market products containing or consisting of GMOs is required to include, as part of that relevant information, the unique identifier assigned to each GMO as a means of indicating its presence and reflecting the specific transformation event covered by the consent or authorisation for placing that GMO on the market.

(3) Unique identifiers should be developed in accordance with a particular format in order to ensure consistency both at Community and international level.

(4) The consent or authorisation granted for the placing on the market of a given GMO under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2] or other Community legislation should specify the unique identifier for that GMO. Moreover, the person applying for such consent should ensure that the application specifies the appropriate unique identifier.

(5) Where, prior to the entry into force of this Regulation, consents have been granted for the placing on the market of GMOs under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [3], it is necessary to ensure that a unique identifier is or has been developed, assigned and appropriately recorded for each GMO covered by those consents.

(6) In order to take account of and maintain consistency with developments in international fora, it is appropriate to have regard to the formats for unique identifiers established by the Organisation for Economic Cooperation and Development (OECD), for use in the context of its BioTrack product database and in the context of the Biosafety clearing house established by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

(7) For the purposes of the full application of Regulation (EC) No 1830/2003, it is essential that this Regulation apply as a matter of urgency.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SCOPE

Article 1

1. This Regulation shall apply to genetically modified organisms, hereinafter 'GMOs', authorised for the placing on the market in accordance with Directive 2001/18/EC or other Community legislation, and applications for placing on the market under such legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Council Regulation (EEC) No 2309/93 [4], or applications for authorisation under that Regulation.

CHAPTER II

APPLICATIONS FOR THE PLACING ON THE MARKET OF GMOs

Article 2

1. Applications for the placing on the market of GMOs shall include a unique identifier for each GMO concerned.

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003.
[3] OJ L 117, 8.5.1990, p. 15. Directive as last amended by Directive 2001/18/EC.
[4] OJ L 214, 24.8.1993, p. 1.

2. Applicants shall, in accordance with the formats set out in the Annex, develop the unique identifier for each GMO concerned, following consultation of the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with these formats.

Article 3

Where consent or authorisation is granted for the placing on the market of a GMO:

(a) the consent or authorisation shall specify the unique identifier for that GMO;

(b) the Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house;

(c) The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

CHAPTER III

GMOs FOR WHICH CONSENT FOR THEIR PLACING ON THE MARKET HAS BEEN GRANTED PRIOR TO THE ENTRY INTO FORCE OF THIS REGULATION

Article 4

1. Unique identifiers shall be assigned to all GMOs in respect of which, prior to the entry into force of this Regulation, consent has been granted under Directive 90/220/EEC for their placing on the market.

2. Relevant consent holders or where appropriate the competent authority that has taken the final decision on the original application shall consult the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with the formats set out in the Annex.

Article 5

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO and where a unique identifier has been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3 and 4 shall apply.

2. Each consent holder, or where appropriate the competent authority that has taken the final decision on the original application, shall within 90 days following the date of entry into force of this Regulation, communicate the following, in writing, to the Commission:

(a) the fact that the unique identifier has already been developed in accordance with the formats set out in the Annex;

(b) the details of the unique identifier.

3. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

4. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

Article 6

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO but where a unique identifier has not been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3, 4 and 5 shall apply.

2. Each consent holder or, where appropriate, the competent authority that has taken the final decision on the original application, shall develop a unique identifier for the GMO concerned in accordance with the formats set out in the Annex.

3. The consent holder shall, within 90 days following the date of entry into force of this Regulation, communicate the details of the unique identifier, in writing, to the competent authority granting consent, which in turn shall immediately transmit these details to the Commission.

4. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

5. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

CHAPTER IV

FINAL PROVISION

Article 7

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 January 2004.

For the Commission
Margot WALLSTRÖM
Member of the Commission

ANNEX

FORMATS FOR UNIQUE IDENTIFIERS

The Annex below defines the format for the unique identifier for plants in Section A and for micro-organisms and animals in Section B.

SECTION A

1. **Overall format**

This Annex provides details as to the format to be used for unique identifiers for GMOs pending or authorised for the placing on the market under Community legislation. The format consists of three components comprising a number of alphanumeric digits and providing reference to the applicant/consent holder, transformation event and a means for verification.

The format comprises nine alphanumeric digits in total. The first component represents the applicant/consent holder and comprises two or three alphanumeric digits. The second component comprises five or six alphanumeric digits and represents the transformation event. The third component provides for verification and is represented by a final numerical digit.

The following provides an example of a unique identifier developed using this format.

C	E	D	-	A	B	8	9	1	-	6

or

C	E	-	A	B	C	8	9	1	-	5

The following sections provide guidance as to how the three individual components of the unique identifier should be developed.

2. **Applicant/consent holder component**

The first two or three alphanumeric digits represent the applicant/consent holder (for example, the first two or three letters of the applicant/consent holder organisation name), followed by a dash, such;

C	E	D	-

or

C	E	-

Applicants may already have assigned alphanumeric digits to indicate their identity and these appear in the applicant's code table within the OECD BioTrack product database. These applicants should continue to use these digits.

Any new applicant that is not identified within the database will not be permitted to use the existing codes listed in the applicant's code table within the database. The new applicant Should inform the national authorities, which should update the OECD BioTrack product database by including a new code (digits) that will be designed to identify the new applicant in the code table.

3. **Transformation event component**

The second set of five or six alphanumerical digits should represent the specific transformation event(s), which is the subject of the application for the placing on the market and/or consent, such as:

A	B	8	9	1	-

or

A	B	C	8	9	1	-

Clearly, an individual transformation event may occur in different organisms, species and varieties and the digits should be representative of the specific event in question. Again, applicants should, prior to formulating unique identifiers, consult the OECD BioTrack product database in terms of the unique identifiers that have been assigned to similar transformation events of the same organism/species in order to provide consistency and to avoid duplication.

Applicants should develop their own internal mechanism to avoid applying the same designation (digits) to a 'transformation event' if used in a different organism. Where similar transformation events are developed by two or more organisations, the 'applicant information' (see section 2) should enable applicants to generate a unique identifier for their own product, while at the same time ensuring its uniqueness from those generated by other applicants.

As regards new GMOs compromising more than one transformation event (often referred to as stacked-gene transformation events), applicants or consent holders should generate a novel unique identifier for such GMOs.

4. **Verification component**

The final digit of the unique identifier is for verification, which shall be separated from the rest of the unique identifier digits by a dash, such as:

- 6

or

- 5

The verification digit is intended to reduce errors by ensuring the integrity of the alphanumeric identifier, 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 sections 5 and 6). 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, the final unique identifier then becomes — CED-AB891-6.

5. **Form of digits to be used in the unique identifier**

∅
1
2
3
4
5
6
7
8
9

6. **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=10
K=11
L=12
M=13
N=14
O=15
P=16
Q=17
R=18
S=19
T=20
U=21
V=22
W=23
X=24
Y=25
Z=26

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

SECTION B

The provisions of section A of this Annex shall apply to micro-organisms and animals unless another format for a unique identifier is adopted internationally and endorsed at Community level.