
Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 65/2004. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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

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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 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. 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 alphanumeric 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	-
---	---	---	---	---	---	---

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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 comprising 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:

-

or

-

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 alphanumeric digits in the unique identifier. The numerical value of each of the digits is from 0 to 9 for the numerical digits (0 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

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0
1
2
3
4
5
6
7
8
9

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

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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 \emptyset to avoid confusion with the letter O.

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

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Changes and effects yet to be applied to :

- Regulation words omitted by [S.I. 2019/90 reg. 6\(6\)](#)
- Annex Section B words substituted in earlier amending provision S.I. 2019/90, reg. 6(7)(b) by [S.I. 2020/1421 Sch. para. 4\(3\)](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Annex Section A para. 1(1) words omitted by [S.I. 2019/90 reg. 6\(7\)\(a\)](#)
- Annex Section B words substituted by [S.I. 2019/90 reg. 6\(7\)\(b\)](#)
- Art. 12 substituted for Art. 1 by [S.I. 2019/90 reg. 6\(2\)](#)
- Art. 1(d) omitted in earlier amending provision S.I. 2019/90, reg. 8(2) by [S.I. 2020/1421 Sch. para. 5\(2\)](#)
- Art. 1(1)(d) omitted in earlier amending provision S.I. 2019/90, reg. 6(2) by [S.I. 2020/1421 Sch. para. 4\(2\)\(a\)](#)
- Art. 2(2) words inserted by [S.I. 2019/90 reg. 6\(3\)](#)
- Art. 3(b) words substituted by [S.I. 2019/90 reg. 6\(4\)\(a\)](#)
- Art. 3(c) substituted by [S.I. 2019/90 reg. 6\(4\)\(b\)](#)
- Art. 4-6 omitted by [S.I. 2019/90 reg. 6\(5\)](#)