

Column 3: Field type, Data type, Group ID, Mac. occ., Detail level, Picklist code

The third column contains information that is mainly relevant for IT developers. These include:

1. Field type (e.g. LIST-CLOSED-SUP)
2. Data type (e.g. STRING/255)
3. Group ID (e.g. g286)
4. Max occ. (e.g. 1)
5. Detail level (e.g. 1)
6. Picklist code (e.g. Z08)

Note

In the first version of the OECD Harmonised Templates, separate columns were used for each of the field parameters specified in one column now. Two parameters, i.e. Data type and Group ID, have been added to the updated templates.

In the following subchapters the six field parameters specified in this column are described.

3.1. Field type

The field type determines the kind of data the field should contain. For example, if a field should only contain numbers, the field type Numeric is used. Fields that provide a picklist with predefined items are characterised as LIST fields. TEXT fields are provided for entering free text.

Note

The OECD Harmonised Templates do not prescribe whether the completion of data entry fields should be mandatory. There is always an option to leave a field empty. However, mandatory data input may be set in specific user interfaces as appropriate. Also the display type of data entry fields can vary depending on the design of the user interface. For example, a list field can be implemented as drop-down list box (i.e. closed version of a list box indicated by an arrow), drop-down combo box (i.e. a text box with an arrow next to it) or a checkbox (i.e. a square box to turn on or off an option corresponding to the selection of picklist items "yes" and blank (empty field) in a list field, respectively).

In the OECD templates the following types of fields are proposed, each designed for a specific purpose:

3.1.1. List fields

List fields provide a list of items from which you can select or "pick" one option. Such lists are also called picklists. The following types are distinguished:

LIST-CLOSED

In a closed list field, the picklist contains only distinct items from which to choose. For example, the field "Data protection claimed" comes with a picklist containing the options "yes", "yes, but willing to share" or "yes, but not willing to share". There is no other option available. If none of the picklist items is suitable, the field must be left blank.

Note

Some closed list fields, called **LIST-CLOSED-SUP**, come with an associated text field for optional entry of supplementary free text. In the first version of the OECD templates, such combinations of fields were displayed in one row only and characterised by the field type **LIST-CL-SUP**. In the updated templates, both the list field and the related text field are listed, the latter being indicated by the field type **SUP-TEXT**, as shown in the screenshot below. In addition, the context-sensitive help text of the list field gives instruction as to what kind of information could be entered in the text field.

Note that the XML schema of the supplementary text field slightly differs from that of the related list field by ending with the extension "_TXT" (see chapter [3.7. Column "XML schema"](#)).

LIST-OPEN

In an open list field, the picklist offers the option to choose "other:" or "phrase:" (any phrase ending with a colon, e.g. "other guideline:" or "ASTM method, other:") in case none of any specific item applies.

Depending on the type of the associated text field the following two types are distinguished:

- LIST-OPEN: The text field (type OTHERTEXT) becomes active only, if a distinct item (with an ending colon) is chosen from the picklist, but is otherwise locked.
- LIST-OPEN-SUP: The text field (type SUP-TEXT) is active, if either an item ending with a colon or any other item is chosen. The functionality of types LIST-OPEN-SUP and type LIST-CLOSED-SUP is the same. The distinction is made solely to indicate that a picklist includes the option to choose "other:" or not.

CHECKBOX

In the part ADMINISTRATIVE DATA and in the template ANNOTATIONS, some fields are defined as checkboxes. A checkbox can be considered as a special list field allowing the user to select a given option by clicking the mouse on the box. The value of the checkbox then changes from "false" to "true" (see also data type BOOLEAN).

3.1.2. TEXT fields

Text fields are provided for entering free text. However, only plain text can be entered including letters, numbers and symbols in the character set selected. No formatting such as setting in bold or underline is allowed.

Text fields are the most versatile field type. They are used in cases where no specific control of data entry is required or sensible. In some fields which actually prompt for numeric information, the field type TEXT is used to provide more flexibility in data entry. This has the advantage that several numbers together with explanations can be included in one field. For example the number of animals per sex per dose may be entered as "10 (male); 8 (female)".

The maximum capacity of text fields is defined by the data type. Except for the low-capacity fields (limited to 255 characters), all text fields allow the insertion of line breaks. Some fields allow to upload so-called Freetext templates. Depending on these features, different types of text fields can be distinguished as described in the following subchapters.

Note

The field types **TEXT-MEDIUM**, **TEXT-INTMED**, **TEXT-LONG** used in the first version of OECD Harmonised Templates are now called **TEXT**. The maximum capacity is indicated by the data type.

3.1.2.1. TEXT fields designed as single-line text fields

Field type **TEXT** with data type "STRING / 255" means that the maximum capacity is limited to 255 characters and no line breaks can be inserted, that is, text entered cannot be broken explicitly and no empty lines can be added to structure the text. This field type is normally used in cases where only brief text is expected to be entered. Typical single-line fields are:

- Text fields associated with list fields. Such fields are then indicated as OTHERTEXT or SUP-TEXT as described above.
- Subfields of type TEXT in (repeatable) blocks of fields

3.1.2.2. TEXT fields designed as multi-line text fields

Field type **TEXT** with data type "STRING / 2000" means that the maximum capacity is limited to 2000 characters. Line breaks can be inserted, which can make long text easier to read. This field type is normally used in cases where reasonably long text may have to be entered.

3.1.2.3. TEXTAREA

Field type **TEXT** with data type "STRING / 32768" means that the maximum capacity is limited to 32768 characters. Line breaks can be inserted, but no other formatting is possible. This field type is used in cases where the entry of rather long text may be necessary.

3.1.2.4. TEXT-TEMPL: Fields featuring optional upload of freetext templates

Field type TEXT-TEMPL means that a text field, in most cases designed as TEXTAREA, offers the option to upload so-called Freetext templates chosen from a drop-down list. These are predefined texts consisting of headings and subheadings which are intended to serve as prompts for the type of information expected. For example the field "Details on test material" provides a freetext template with the following items:

Table 1.1. Freetext template for field "Details on test material"

- Name of test material (as cited in study report):
- Molecular formula (if other than submission substance):
- Molecular weight (if other than submission substance):
- Smiles notation (if other than submission substance):
- InChI (if other than submission substance):
- Structural formula attached as image file (if other than submission substance): see Fig.
- Substance type:
- Physical state:
- Analytical purity:
- Impurities (identity and concentrations):
- Composition of test material, percentage of components:
- Isomers composition:
- Purity test date:
- Lot/batch No.:
- Expiration date of the lot/batch:
- Radiochemical purity (if radiolabelling):
- Specific activity (if radiolabelling):
- Locations of the label (if radiolabelling):
- Expiration date of radiochemical substance (if radiolabelling):
- Stability under test conditions:
- Storage condition of test material:
- Other:

The concept of Freetext templates follows the needs of a relatively high degree of complexity in robust study summaries. . The advantages are as follows:

- They help reduce the number of distinct input fields considering the already high number of fields in many endpoint study records
- They help standardising the entry of additional information for which no distinct input fields are available, where requested by the regulatory programme.
- They provide on the other hand a great deal of flexibility as their use is completely optional and flexible in such a way that the predefined items provided as quasi fields can be adopted, modified or deleted as appropriate. In general, the prompts provided with the freetext templates comprise a maximum of detail. Their use is not mandatory, but may be requested depending on the regulatory programme.
- They can also be supplemented with additional structured elements (i.e. (sub)headings) if necessary.
- Different freetext templates may be provided for the same field in cases where different study types are covered by one endpoint section. For example, for field "Details on exposure" of template no. 72 *Carcinogenicity*, a freetext template each is provided for oral, inhalation and dermal exposure.

3.1.3. NUM (numeric) fields

Field type **NUM** means that only numeric characters can be entered. The format as specified by the data type determines whether whole and decimal, positive and negative numbers and how many digits are allowed.

3.1.4. Numeric range fields

In the first version of OECD Harmonised Templates, the field type **NUM-RANGE** was used to group the following four subfields in one field description: Qualifier (lower value), Numeric field (lower value), Qualifier (upper value) and Numeric field (upper value). In the updated OECD templates, this field type has become obsolete. Instead, each of these subfields is listed together with the respective field types LIST-CLOSED (for Qualifier fields) and NUM (for Numeric fields) and the field-specific XML schema.

3.1.5. DATE fields

Field type DATE means that a date can be entered in the format YYYY-MM-DD, e.g., "2004-08-12" for August 12, 2004. In the OECD templates, there is currently only one field for which this type is used, i.e. field "Report date" in field block "Reference".

3.1.6. YEAR field

Field type YEAR is used to specify the entry of four-digit numbers.

3.1.7. RICHTEXT (HTML) area fields and predefined tables / executive summaries

This is a large text area where fonts, colours, bullets, and other text attributes can be specified. Also (predefined) tables or text templates can be inserted and edited. Currently the following types of predefined documents are provided:

- In Annex 2, a number of predefined tables are provided for individual templates for optional upload into rich text fields. The overview list in Annex 2 denotes the target field, file name, title of table, the field to which the table refers to, and the source of the table.
- In Annex 3, a number of predefined executive summaries are provided for individual templates for optional upload into the rich text field "Executive summary" (in part Applicant's summary and conclusion). The overview list in Annex 3 indicates for which OECD template a document is available. Currently, only text for executive summaries that are used within the Canada and US pesticides programmes are available as samples. Additional sample text, developed for other programmes, may be available in the future.

Note

The storage capacity for each HTML area is limited to 256 KB of HTML code including text. Excessive formatting (e.g. bold, italics, colours, different fonts, underlining, complex tables) will produce a lot of (invisible) styling HTML code, which may reduce the capacity left for entering the actual text. The handling of this field type may depend on the HTML editor used in the database system. In any case, care must be taken when copying and pasting data from a word processing or spreadsheet document. Instructions given for the respective user interface should be followed. For instance, it may be necessary to save a word processing document as filtered HTML document before it or part of its content is uploaded or copied into a rich text area.

3.1.8. Headings (HEAD and HEAD BLOCK)

If the field type is specified as HEAD-x (x = 1, 2 or 3), this means that the piece of information defined is no data entry field, but a heading. The number is an indication for the heading style and can be used to format headings and subheadings differently in the user interface.

HEAD BLOCK identifies the heading of a (repeatable) block of fields, which is further specified by the group ID.

3.2. Data type

The data type specifies the format of a field and determines how the content of a field will be handled, stored, and displayed in a database.

The following data types are used:

- **STRING / <no.>**: A string is a sequence of characters such as letters, numbers, and punctuation marks. The number (<no.>) after the slash specifies the fixed maximum length of a string, i.e. 255, 2000, 32768 or 256000.

- **NUMBER/<precision>/<scale>**: This data type determines a numeric value including the total number of digits and the format. For example, "NUMBER/13/#####0.#####" stands for a numeric value with the total number of digits being 13, a decimal point and six number of digits in the fractional part. The former field type YEAR is now specified by the data type "NUMBER/4/###0".
- **BOOLEAN**: The Boolean data type is a logical data type having one of two values: non-zero and zero, which are equivalent to true and false, respectively. This data type is used for field type Checkbox.
- **DATE/<no.>**: Determines the data format YYYY-MM-DD.
- **Block label**: Redundant with the corresponding field type, i.e. identifies the heading of a (repeatable) block of fields.
- **Heading level x (x = 1, 2 or 3)**: Redundant with the corresponding field type, i.e. identifies a heading or subheading.

3.3. Group ID

If a Group ID is indicated, the field is part of a (repeatable) block of fields. All subfields of that block have an identical group identification number.

[N/A] means that the field is not grouped to a block of fields.

3.4. Max. occ. (Maximum occurrence)

The maximum occurrence is an indicator specifying if a field or block of fields can be copied or repeated to allow multiple entries, i.e.: 1 = only once (no repeatability of the field); 0 = unlimited repeatability; any number (e.g. 5) = maximum number of repetitions allowed. Subfields within a block of fields are not repeatable. However, the block itself can be repeated depending on the Max. occ. setting.

3.5. Detail level

The detail level is an indicator of whether a field is relevant for all study summaries (Level 1) or, as additional information, for Robust Study Summaries (Level 2). If implemented in a user interface of a database, it will allow to switch between display type "basic fields" (detail level 1) and "all fields" (detail level 2). For instance, detail level 2 fields can be hidden or locked if the user chooses the level 1 mode.

Note

In some blocks of fields, both detail levels occur. When implementing the detail levels in a user interface, it may be necessary for technical reasons to assign all subfields grouped in a block of fields to a given detail level, i.e. either 1 or 2. If this is done, the context-sensitive online Help text still gives guidance as to whether a subfield is actually considered as additional field and hence, only relevant for robust study summaries.

In addition to the Level 1/2 system, a Level 3 is used, but currently only for the field "Confidential details on test material". If implemented in a user interface, it can be used for filtering out this kind of confidential information.

3.6. Picklist Code

The picklist code is an internal code given to each picklist allowing to refer to any picklist in the complete list of picklists in Annex 1.

[N/A] is indicated if the field is no list field.