

GUIDANCE ON THE USER OR BREEDER DATA TEMPLATE **for member state implementation report** (provides a part of the information on the implementation of Directive 2010/63/EU)



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INTRODUCTION

Directive 2010/63/EU on the protection of animals used for scientific purposes and the related Commission Implementing Decision 2020/569/EU lays down the requirements *inter alia* for the provision of information on the implementation of this Directive to the Commission.

Some information for the implementation report is required from users and breeders of animals.

A Microsoft Excel spreadsheet is provided as a tool for capturing part of this information at its source. It is designed to make the process of entering information more efficient and to minimize errors.

PURPOSE OF THE GUIDANCE

The purpose of this guide is to explain the steps required to complete the Excel spreadsheet that will contain a part of the information that you need to submit to your regional authorities **on tissue sampling and animals bred and killed without being used**. It is important that you understand what each column within the Excel spreadsheet represents and what values you may write for each column (Text, Numbers, "Yes", "No").

TARGET AUDIENCE

It is designed to be used **by all users and breeders** to submit information to their respective authorities in line with national instructions.

WHAT TO REPORT AND WHEN

All users and breeders shall report

1. information and numbers regarding species, methods and their related actual severity in respect of **tissue sampling for the purposes of genetic characterisation carried out with or without project authorisation** (Details can be found in Annex II, Section D (Principles of Replacement, reduction and Refinement), point 3 of Commission Implementing Decision 2020/569/EU);
2. efforts made to **refine** tissue sampling methods (See Annex II, Section D (Principles of Replacement, reduction and Refinement), point 3 of Commission Implementing Decision 2020/569/EU);
3. the species and numbers of **animals that were bred** and born (including by Caesarean section) for use in procedures and, having **never been used** in any procedures, **were killed** during the reported year (Details can be found in Annex II, Section C (Operation), point 2 of Commission Implementing Decision 2020/569/EU).

This, to be reported, information must be collected from 01 January to 31 December of each year and sent to Brussels Environment by the 31st of January of the following year (through the Ethical Commission).



TISSUE SAMPLING FOR THE PURPOSES OF GENETIC CHARACTERISATION CARRIED OUT WITH OR WITHOUT PROJECT AUTHORISATION

Tissue sampling for the purposes of genetic characterisation is carried out on animals by users as well as breeders. As some tissue sampling methods require a project authorisation, some information concerning tissue sampling is already included in the annual statistics :

- **included** in the user’s annual statistics (columns X – Z in the Statistical Excel sheet): animals which underwent
 - invasive tissue sampling and were used in other procedures
 - invasive tissue sampling but have not been used in other procedures and have been killed
 - invasive tissue sampling, were found unsuitable for the procedure and will be re-used in another procedure
 - non-invasive tissue sampling and were used in procedures
 - tissue sampling using tissue from marking and were used in procedures
- **not included** in the annual statistics : animals which underwent
 - non-invasive tissue sampling, and tissue sampling using tissue from the marking of the animals by breeders
 - non-invasive tissue sampling, and tissue sampling using tissue from the marking of the animals by users (while the animals have not been used in a procedure)

Therefore, it is important that the missing data (data **not included** in the annual statistics) is collected from **all** authorised users and breeders by means of the “User/breeder data template for MS Implementation Report” which can be found on the website of Brussels Environment. **To collect the data from animals not included in the annual statistics on tissue sampling, please use Record type [IR1] in sheet “List”.**

	A	B	C	D
1	Entry data			
2				
3	Record type *	LA Number	Project Number	Region Code
4	[IR1] Tissue sampling (non-invasive genotyping or from surplus tissue)			
5				
6				

Provide the animal species, numbers of animals and method of tissue sampling.

EFFORTS MADE TO REFINE TISSUE SAMPLING METHODS

The Excel Form contains an additional sheet “Efforts to refine” that allows the user to inform about their efforts to refine tissue sampling methods. This is a free text field of up to 1500 characters.

This allows information to be collected from users so that a national summary of such efforts can be submitted as part of the Member State implementation report.

ANIMALS BRED AND BORN (INCLUDING BY CAESAREAN SECTION) FOR USE IN PROCEDURES AND KILLED WITHOUT BEING USED IN OTHER PROCEDURES

These include **all other animals bred, killed and not reported** under the annual EU statistics, including animals killed for organs or tissues and animals from the creation and maintenance of genetically altered (GA) animal lines, which are not covered and reported in the annual statistics.



It is important that data on animals bred, killed and not used is collected from all authorised users and breeders by means of the “User/breeder data template for MS Implementation Report” which can be found on the website of Brussels Environment. **To collect the data, please use Record type [IR2] in sheet “List”.**

	A	B	C	D
1	Entry data			
2				
3	Record type *	LA Number	Project Number	Region Code
4	[IR2] Animals bred and killed without being used in other procedures			
5				
6				

Provide the animal species, numbers of animals, genetic status and purpose (creation of a new GA line, maintenance of colonies or collection of organs/tissue).

Subsequently, all the reported information elements allow data then to be grouped in the following categories as required by the implementation report:

- a) genetically normal animals not providing organs and/or tissues: excludes animals as a result of a creation of a new GA line and from the maintenance of a GA line, which are to be reported in the categories referred to in points (d) and (e) respectively;
- b) genetically normal animals providing organs and/or tissues: includes animals as a result of creation of a new GA line and from maintenance of a GA line, when providing organs and/or tissues;
- c) GA animals providing organs and/or tissues: includes animals as a result of creation of a new GA line and from maintenance of a GA line, when providing organs and/or tissues;
- d) genetically normal animals (wild type offspring) as a result of the creation of a new GA line: excludes animals that were genotyped using invasive method and animals from a harmful phenotype line that experienced adverse effect;
- e) animals from the maintenance of a GA line covering all GA and wild type offspring of both harmful and non-harmful phenotype: excludes animals that were genotyped using invasive method and animals from a harmful phenotype line that experienced adverse effect.

USER PROCESS FLOW FOR EXCEL

1. WHERE TO ACCESS THE EXCEL TEMPLATE FILE AND GUIDELINE

You can download the Excel template (User or breeder data template for MS Implementation Report v1.00) for completion and the Guideline on the user or breeder data template for member state implementation report from:

- <https://leefmilieu.brussels/themas/dierenwelzijn/dierproeven-een-strikt-omlijnde-praktijk>
- Or <https://environnement.brussels/thematiques/bien-etre-animal/l'experimentation-animale-une-pratique-tres-encadree>

2. ENTERING DATA IN THE EXCEL TEMPLATE

Once you have downloaded the correct Excel Template, you need to enter your animal data into the spreadsheet.

The template requires/allows only the relevant questions to be entered, based on the record type.

2.1. Generalities

To use the Excel template, you must have Microsoft Office 2003 or later. The spreadsheet is "locked" to restrict modifications. The structure of the spreadsheet should not be modified or it may risk rejection of submission due to an invalid entry.



2.2. The Excel Spreadsheet

The Excel spreadsheet contains four sheets: "Establishment details", "List", "Efforts to refine" and "Validation".

The "Establishment details" sheet contains several fields, which are to be completed by the user and breeder establishments (laboratories, institution):

- Country
- First name
- Last name
- Email
- Establishment
- Reported year

The "List" sheet contains a total of 20 fields (represented by columns in your Excel spreadsheet) that you shall fill out with your information.

All compulsory fields must be filled in. These fields will have an asterisk (*).

You will notice that when you choose a value from a pull down menu that contains the word "**other**", the respective field is highlighted in dark yellow. The Excel spreadsheet highlights these values to remind you that you have to complete the "Specify other"- field placed next to it.

There are two possible options for doing data entry:

- a) simple data entry (horizontal direction) – see 2.3
- b) enter data using the data form (the recommended option) – see 2.4

2.3. Simple Data Entry (horizontal direction)

Do not leave empty rows.

It is important to respect the introduction left-to-right because there are several fields that depend on the information entered in the previous cells in the Excel spreadsheet. However, depending on the value selected in "Record type" list, certain fields shall remain blank. The drop-down menu will remain empty in this case (See for example field "Genetic status" when [IR1] was selected).

The standard setup in Excel is to press **TAB** to move your active cell to the right by one cell, and press **ENTER** to move your active cell down by one cell.

So when you want to enter data in rows just follow these steps *(detailed information about which data you have to enter can be found in paragraph 2. 4 and Annex I)*:

1. Move to the first cell in your row – **cell A4**
2. Choose a value from "Record type" list.
3. Press **TAB** to move your active cell to the right
4. Choose your *License number* [e.g. LA1230170] from the "LA Number" list
5. Press **TAB** to move your active cell to the right



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6. Enter in Project Number your *Project license number* (*number given by the Ethical committee*), if applicable
 7. Press **TAB** to move your active cell to the right
 8. Choose your *Region code* from the "Region Code" list (**BXL for Brussels Capital Region**, VLA for Flanders Region and WAL for Walloon Region)
 9. Press **TAB** to move your active cell to the right.
 10. Repeat until you get to the last column
 7. Press **ENTER** to move your active cell to the next row (Excel remembers which column you started from and automatically jumps one row down and all the way back to that first column)

Tip: How to use shortcut keys to make data entry faster

- Show pull down list using ALT + Down arrow
- Fill down from above using CTRL + D (copy the contents and format of the topmost cell of a selected range into the cells below)

It is possible to copy and paste rows from one Excel spreadsheet to another.

2.4. Entering Data using the Data Form

A **data form** is a fancy phrase for a dialogue box with the fields for a single row. The form sits on top of your Excel spreadsheet and allows you enter fields per row.

You might think of it as an on screen form. Your columns headers become the form field labels.

Using this form, you can enter data faster and when you are at the end of the form, you can hit "Next" to start another row.

While the Excel data form may not make data entry any more fun, it does significantly reduce the time it takes you to enter the data.

The following steps are the individual items that you need to complete:

Step 1: Navigate to the worksheet "List"

Step 2: Click on cell A4

Step 3: Click "Entry data"

Step 4: Choose a value from "Record type" list.

Click on the down arrow. A pull-down menu appears, giving two choices: [IR1] and [IR2].

Step 5: Complete your national references in the fields LA Number, Project Number, Region Code (for both record types [IR1] and [IR2])

LA Number: *e.g. LA1230170*, no spaces allowed between LA and the number

Project Number: *number given by the Ethical committee*, if applicable. A project number is only available to those animals that were first within a project, however, then excluded from the annual statistical reporting.

Example for [IR1]: A project was submitted in which the animals would first be genotyped using surplus tissue from the marking of the animals and subsequently used (continued use). These animals were,



however, found to be unsuitable after genotyping and were therefore no longer used. Consequently, these animals will not be reported in the annual statistics but should be reported by means of this template.

Example for [IR2] : A project authorization was obtained for the maintenance of a harmful phenotype. In that case, all unused animals that were killed without having exhibited a harmful phenotype and that were not genotyped using an invasive method must be reported under IR2. All unused animals that have been killed and that had exhibited harmful phenotype and/or that have been genotyped using invasive method (not carried out for marking) and also all used animals must be reported in the annual statistics.

Region Code: **BXL** for Brussels Capital Region, VLA for Flanders Region and WAL for Walloon Region

Step 6: Select the "Animal Species" (for both record types [IR1] and [IR2])

Click on the down arrow. A pull-down menu appears, giving you choices. Select the Animal Species that you need.

When in "Animal Species" the user chooses a value that contains the word – other - the user must specify in the "Specify other" field, what species was used exactly. Please use the **scientific name** (Latin) for this. Please specify if **early stages** were used e.g. larval forms (for fish, amphibian) (once they become capable of independent feeding) or foetal forms (offspring shall be reported when they are an integral part of the procedure; only animals that are born, including by Caesarean section, and live are to be counted). This is a conditional field based on "Animal Species" data element.

Step 7: Type the "Number of animals" (for both record types [IR1] and [IR2]). It must be a whole positive number.

Step 8: Select "Genetic status" (only for record type [IR2])

Click on the down arrow. A pull-down menu appears only when you selected [IR2]. Select the appropriate Genetic Status.

Step 9: Select "Creation of a new GA Line" (only for record type [IR2])

Click on the down arrow. A pull-down menu appears only when you selected [IR2], giving two choices: Yes and No.

Step 10: Select "Maintenance of colonies" (only for record type [IR2])

Click on the down arrow. A pull-down menu appears only when you selected [IR2], giving two choices: Yes and No. However, if "Yes" was already indicated in the previous entry (creation of a new GA line), only "No" will be possible as an option.

Step 11: Select "Collection of organs/tissue" (only for record type [IR2])

Click on the down arrow. A pull-down menu appears only when you selected [IR2], giving two choices: Yes and No.

Step 12: Select "Method of tissue sampling" (only for record type [IR1])

Click on the down arrow. A pull-down menu appears only when you selected [IR1], giving you choices (e.g. *[ST1] Surplus from the marking of an animal via ear punch*). Select the method of tissue sampling that you need. If different methods of genotyping have been carried out within the same project, these different methods should be mentioned in different lines¹ (as for example is done for different severity grades within a project in the annual statistics). E.g. if 200 animals are used in a project and 10 are genotyped by observation under special lighting and 190 by hair sampling you have to enter 2 different lines despite that all other parameters remain the same. If out of these 200 animals 10 have been genotyped by blood sampling (**invasive** genotyping for which a project authorisation is required), these 10 animals can under no circumstances be recorded using this template, as they, should have been included in the annual statistical report.

If you select a [NG4 code] in method of tissue sampling you should go to Step 13. If not go directly to Step 14.

¹ Please note also that for animals whose tissue sampling is carried out with an invasive method, the severity related ONLY to the tissue sampling has to be entered (Severity of genotyping).



Step 13: Select "Specify other method" (only for record type [IR1])

If you select "[NG4] Non-invasive genotyping: other", then, in the "Specify other method" field, you need to specify what method was used. In 'Specify other method', a specific method shall be described by which the tissue samples were taken from the animal, e.g. a new technique applied to the animal.

Please note that any method that is invasive can only be carried out under project authorisation and subsequently reported using annual statistical reporting template.

Step 14: Complete "Comments" field (for both record types [IR1] and [IR2])

"Comments" allows a data entry of additional relevant information. It can be used for justification of input data, etc.

Step 15: Complete "Field 1 to 6" (for both record types [IR1] and [IR2])

These additional national fields (columns Z to AE) are used for various national reporting interests. In the Brussels-Capital Region, **no additional fields were determined**. Consequently, these columns should be left empty.

Step 16: Click Save to **save** the row data you just entered or **Save & Duplicate** to save the row data and to create a new row below to facilitate entry of rows containing very similar data, for example varying only in the numbers of animals or the method of tissue sampling.

Step 17: Click Next > to pass to the next row (row 5)

Tip: If you want to jump to a specific row, then you need to type the number of row in the "Current Row" field and after click "Go!".

2.5. Reporting no data

Reporting "No data" is possible. This allows a user or breeder to report that no tissue sampling (non-invasive genotyping or from surplus tissue) was carried out or that no animals were bred and killed without being used in other procedures.

The "Establishment details" sheet therefore contains a checkbox with "NO [IR1] OR [IR2] DATA TO REPORT ". This will give the authority the opportunity to control that all establishments have fulfilled their reporting obligation.

2.6. Recommended File Name

When you finish entering your data, don't forget to "Save"/"Save as" your file.

Recommended file name: IR_"year"_"Licence number" (e.g. **IR_2022_LA1230170**)

3. CHECK DATA IN THE EXCEL TEMPLATE + HOW TO DEAL WITH ERRORS

Prior to saving your Excel spreadsheet, we strongly suggest using the "**Validate**" utility to check your entered data.

If you have finished data entry, or at any stage when you want to check if your introduced data are correct, you can go to "Validation" worksheet and click "Validate". Excel will advise you if your data structure is correct or not, and which rows have **errors or warnings**. Additionally, all fields with errors are filled in red and all fields with warnings are filled in orange. This is the data you need to check and correct. Entering a value that is not in the list provided, will also cause an error message.

Once you have fixed the errors in your spreadsheet rows you can click again "Validate". The validation process will start again and every cell that had an error, which has been corrected, would be back to its normal colour.

If you do not want to check your data again but you want to return the cell format to normal, click "Clean Validation" and every cell will recover its original colour.

The validation option within the Excel file is only suitable to confirm initial structure completeness.



4. HOW TO SUBMIT THE FILE TO THE NATIONAL DATA PROVIDER

Once the Quality Control has been carried out, each user shall provide the implementation report data (relating to tissue sampling and animals bred and killed without being used in other procedures in his establishment during the past calendar year) **to the Ethical Committee** to which the institution is affiliated.

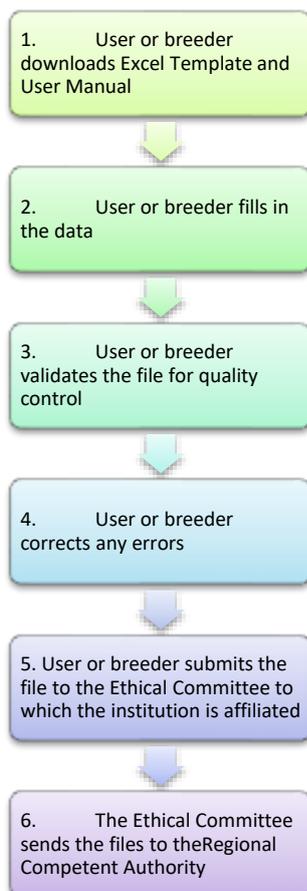
Afterwards, the Ethical Committee sends the Excel Files by email to:

Labo.bea.dwz@leefmilieu.brussels

The Excel File should arrive in the mailbox on **the 31st of January of each year at the latest.**

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5. SUMMARY



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From Leefmilieu Brussel / Bruxelles Environnement

- Mr. Fabrice Peeters (head of the Department Animal Welfare)
- Mrs. Inge Decorte
- Mrs. Sylvie Straetmans

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ANNEX I: REPORTING DATA DICTIONARY

The data dictionary describes the data elements specifically required for Member States reporting under the Directive 2010/63/EU.

Data Element	Definition	Example	Comments	Validation and Business Rule(s)
Record type	Provision of information on the implementation of Directive 2010/63/EU	[IR1]		This is a required field, fixed list
LA number	Field to be completed for national further reference	LA1230170	Choose your License number (e.g. LA1230170) from the "ID1" list.	This field is required.
Project number	Field to be completed for national further reference	586N, 2017-44, 18-212-01, ...	Enter the Project license number (number given by the Ethical committee).	This field is required. Please note : not all records will have project licence number e.g., breeders of non-GA animals when recording animals bred, killed and not used.
Region Code	Field to be completed for national further reference	BXL	Choose your Region code from the "ID3" list (BXL for Brussels Capital Region, VLA for Flanders Region and WAL for Walloon Region).	This field is required.
Animal Species	The species of animal used during breeding/sampling. Both the common name and scientific names are presented.	[A1] Mice (Mus musculus)	The following species are considered "Non-human primates": - [A18] Prosimians (Prosimia) - [A19] Marmosets and tamarins (eg. Callithrix jacchus) - [A20] Cynomolgus monkey (Macaca fascicularis) - [A21] Rhesus monkey (Macaca mulatta)	This is a required field, fixed list.



			<ul style="list-style-type: none"> - [A22] Vervets (Chlorocebus spp. usually either pygerythrus or sabaesus) - [A23] Baboons (Papio spp.) - [A24] Squirrel monkey (eg. Saimiri sciureus) - [A25-1] Other species of New World monkeys (other species of Ceboidea) - [A25-2] Other species of Old World monkeys (other species of Cercopithecoidea) - [A26] Apes (Hominoidea) 	
Specify other	Other Animal Species	Lissotriton helveticus	Please use the scientific name (Latin). Please specify if early stages were used e.g. larval forms (for fish, amphibian) or foetal forms.	Optional field. This is a conditional field based on "Animal Species" data element. When in "Animal Species" the user chooses a value that contains the word – other - the user must specify what species was used exactly.
Number of Animals	Indicate how many animals are used in the research/experiment.	6	It must be a whole positive number.	This is a required field.
Genetic status	Types of genetic alterations. Indicate if animals were genetically altered or not in the research/experiment and alteration type.	[GS1] Genetically altered		This is a required field for 'Record type' 'Animals bred and killed without being used in other procedures', fixed list. Genetic status must be empty for 'Tissue sampling (non-invasive genotyping or from surplus tissue)' record type.
Creation of new GA line	Creation of new genetically altered (GA) animals.	No		This is a required field for 'Record type' 'Animals bred and killed



	Choose whether a new genetic line was created in the research/experiment or not.			without being used in other procedures', fixed list. Genetic status must be empty for 'Tissue sampling (non-invasive genotyping or from surplus tissue)' record type.
Maintenance of colonies	Choose whether colonies were maintained in the research/experiment or not.	No		This is a required field for 'Record type' 'Animals bred and killed without being used in other procedures', fixed list. Genetic status must be empty for 'Tissue sampling (non-invasive genotyping or from surplus tissue)' record type.
Collection of organs/tissue	Choose whether organs or tissue were/was collected in the research/experiment or not.	No		This is a required field for 'Record type' 'Animals bred and killed without being used in other procedures', fixed list. Genetic status must be empty for 'Tissue sampling (non-invasive genotyping or from surplus tissue)' record type.
Method of tissue sampling	Select the method of tissue sampling	[IG3] Invasive genotyping: tail biopsy		This is a required field for 'Tissue sampling (non-invasive genotyping or from surplus tissue)' record type. Fixed list. Dropdown: user can select between (non) invasive genotyping and surplus.



				Method of tissue sampling must be empty for 'Animals bred and killed without being used in other procedures' record type.
Specify other method	Other Method		If you select "...other...", then, in the "Specify other" field, you need to specify what the other Method was.	<p>Optional field.</p> <p>This is a conditional field based on "Method of tissue sampling" data element.</p> <p>When in "Method of tissue sampling" the user chooses a value that contains the word – other - the user can specify what method was used exactly.</p> <p>Please note: invasive tissue sampling methods should never be recorded under this category as invasive tissue sampling always requires a project authorisation. As a result it will be recorded in the annual statistics.</p>
Comments	Allow a data entry of additional relevant information		This field allows a data entry of additional relevant information. It can be used for justification of input data, etc.	This field is optional.
Field 1	Allow data entry of additional relevant information as per MS instructions.		The comments will not be automatically processed by the application, but are visible to a user handling the submission file. The comment can be used for whatever purpose they can be judged useful: justification of input data, etc.	This field is not required by Brussels Environment.



Field 2	Allow data entry of additional relevant information as per MS instructions.		The comments will not be automatically processed by the application, but are visible to a user handling the submission file. The comment can be used for whatever purpose they can be judged useful: justification of input data, etc.	This field is not required by Brussels Environment.
Field 3	Allow data entry of additional relevant information as per MS instructions.		The comments will not be automatically processed by the application, but are visible to a user handling the submission file. The comment can be used for whatever purpose they can be judged useful: justification of input data, etc.	This field is not required by Brussels Environment.
Field 4	Allow data entry of additional relevant information as per MS instructions.		The comments will not be automatically processed by the application, but are visible to a user handling the submission file. The comment can be used for whatever purpose they can be judged useful: justification of input data, etc.	This field is not required by Brussels Environment.
Field 5	Allow data entry of additional relevant information as per MS instructions.		The comments will not be automatically processed by the application, but are visible to a user handling the submission file. The comment can be used for whatever purpose they can be judged useful: justification of input data, etc.	This field is not required by Brussels Environment.
Field 6	Allow data entry of additional relevant information as per MS instructions.			This field is not required by Brussels Environment.



