

GUIDANCE FOR STATISTICAL REPORTING
on the use of animals for scientific purposes – PART 1

**COMMISSION
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L'EXPÉRIMENTATION
ANIMALE**



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TABLE OF CONTENTS

INTRODUCTION	3
PURPOSE OF THE GUIDANCE	3
TARGET AUDIENCE.....	3
WHEN TO REPORT	3
USER PROCESS FLOW FOR EXCEL.....	4
1. Where to access the Excel template file and Guideline	4
2. Entering Data in the Excel Template	4
2.1. Generalities	4
2.2. How to enable Macros in an Excel File?	4
2.3. The Excel Spreadsheet	5
2.4. Prepare data.....	5
2.5. Simple Data Entry (horizontal direction).....	6
2.6. Entering Data using the Data Form.....	7
2.7. Reporting a zero-value	9
2.8. Recommended File Name.....	9
3. Check Data in the Excel Template + how to deal with errors	9
4. How to do compulsory(recommended) quality check of the file(s) before submission + how to deal with warnings.....	10
5. How to submit the file to the national Data Provider.....	10
6. Summary.....	11
ADDITIONAL SUGGESTIONS.....	11
ACKNOWLEDGEMENTS.....	12
ANNEXE I: REPORTING DATA DICTIONARY	13



INTRODUCTION

Directive 2010/63/EU on the protection of animals used for scientific purposes and the related Commission Implementing Decision 2012/707/EU lays down the requirements for the provision of statistical data on the use of animals for scientific purposes in the EU.

A Microsoft Excel spreadsheet is provided as a tool for capturing the raw data at its source. It is designed to make the process of entering data more efficient, providing consistent implementation and minimizing errors.

PURPOSE OF THE GUIDANCE

The purpose of this guide is to explain the steps required to complete the Excel spreadsheet that will contain your information that you need to submit to your national authorities on animal use. 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"). The data should be entered on each use of an animal.

TARGET AUDIENCE

It is designed to be used by the **end-users** to submit statistical data to their respective authorities in line with national instructions.

WHEN TO REPORT

All end-users should report their animals **at the end of the procedure**.

In 2-step / multi-step procedures it is the last 'user' who should report at the end of all steps (e.g. when a genetically altered animal is genotyped at the breeder (step 1) and subsequently used in a user establishment (step 2), the user should report the animal at the end of the procedure and includes the severity from the genotyping (step 1)).

If genetically altered animals that were **genotyped** at the breeder (step 1) are killed **as surplus** at that breeder (and NOT subsequently used for a procedure) then the breeder should report that animal with the related actual severity.



USER PROCESS FLOW FOR EXCEL

1. WHERE TO ACCESS THE EXCEL TEMPLATE FILE AND GUIDELINE

You can download the Excel template for completion and the Guideline for statistical reporting from:

- In Dutch: <https://leefmilieu.brussels/themas/dierenwelzijn/dierproeven-eeen-strikt-omlijnde-praktijk>
- In French: <https://environnement.brussels/thematiques/bien-etre-animal/lexperimentation-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 primary aim of data entry is to have the data in a format that allows it to be submitted to the EU database and facilitates data analysis.

2.1. Generalities

To use the Excel template, you need access to Microsoft Office 2003, 2007 or 2010. 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.

The Excel Template file contains macros that will provide you with additional assistance when entering your information. Macros must be enabled in your version of Microsoft Excel.

2.2. How to enable Macros in an Excel File?

Enabling macros will help users to enter the right information. For example, if "Creation of a new genetically altered line" is set to YES, only the purposes under "Basic research studies" or "Translational and applied research" will be allowed. In order for Macros to work, you will have to enable this feature in your Excel software.

Microsoft Excel 2003

To allow unsigned macros to run, the **Trust all installed add-ins and templates** check box must be selected on the **Trusted Publishers** tab of the **Security** dialog box. This option is selected by default. If it is not selected (recommended), Excel allows you to run only macros that have trusted digital signatures.

Microsoft Excel 2007

1. Click the Microsoft Office Button, and then click Excel Options.
2. Click Trust Center, click Trust Center Settings, and then click Macro Settings.
3. Click the options that you want:
 - **Disable all macros without notification** Click this option if you don't trust macros. All macros in documents and security alerts about macros are disabled. If there are documents with unsigned macros that you do trust, you can put those documents into a trusted location. Documents in trusted locations are allowed to run without being checked by the Trust Center security system.
 - **Disable all macros with notification** This is the default setting. Click this option if you want macros to be disabled, but you want to get security alerts if there are macros present. This way, you can choose when to enable those macros on a case by case basis.
 - **Disable all macros except digitally signed macros** This setting is the same as the **Disable all macros with notification** option, except that if the macro is digitally signed by a trusted publisher, the macro can run if you have already trusted the publisher. If you have not trusted the publisher, you are notified. That way, you can choose to enable those signed macros or trust the publisher. All unsigned macros are disabled without notification.
 - **Enable all macros (not recommended, potentially dangerous code can run)** Click this option to allow all macros to run. This setting makes your computer vulnerable to potentially malicious code and is not recommended.



- **Trust access to the VBA project object model** This setting is for developers and is used to deliberately lock out or allow programmatic access to the VBA object model from any Automation client. In other words, it provides a security option for code that is written to automate an Office program and programmatically manipulate the Microsoft Visual Basic for Applications (VBA) environment and object model. This is a per user and per application setting, and denies access by default. This security option makes it more difficult for unauthorized programs to build "self-replicating" code that can harm end-user systems. For any Automation client to be able to access the VBA object model programmatically, the user running the code must explicitly grant access. To turn on access, select the check box.

Microsoft Excel 2010

When you open a file that has macros, the yellow Message Bar appears with a shield icon and the Enable Content button. If you know the macro, or macros, are from a reliable source, use the following instructions:

- On the Message Bar, click Enable Content.
- The file opens and is a trusted document.

2.3. The Excel Spreadsheet

The Excel spreadsheet contains three sheets: "Establishment details", "List" and "Validation".

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

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

The "List" sheet contains a total of 22 fields (represented by columns in your Excel spreadsheet) that you may 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 contain 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 "Specify other"- field placed next to it.

There are two possible options for doing data entry:

- a) simple data entry (horizontal direction) – see 2.5
- b) enter data using the data form (the recommended option) – see 2.6

2.4. Prepare data

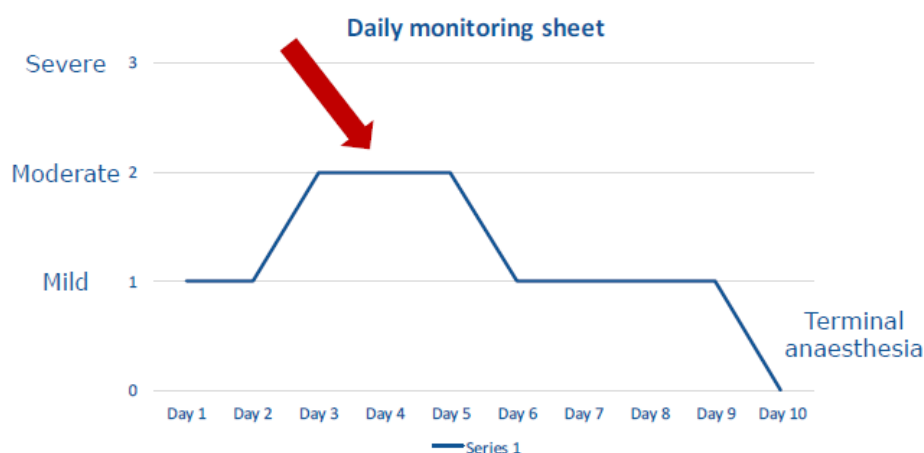
First of all you need to prepare your data for entry in the Excel spreadsheet.

Actual severity is reported **for each individual animal** on the basis of the severity experienced **during the course of the procedure** (as determined by analysis of the effects observed and recorded throughout the procedure) – the actual severity reached by the animal may differ from the prospective severity classification assigned to the whole group of animals for the purposes of project application/evaluation and authorization. I.e. the actual highest severity reached during the procedure may be lower (or may even in some cases be higher) than that assigned prospectively. For example, if you are reporting 10 mice from the same study which have experienced three different severities (for example - 2 Mild, 3 Moderate and 5 Severe), **you will have to input 3 separate rows** one for Mild, another for moderate and the last one



for Severe. However, the entry of an almost identical record is facilitated by the system to speed up the process and reduce errors.

Actual severity is always based on the **highest reached severity**.



Prospective severity should **never** be reported in the yearly statistics. Prospective severities can only be reported in the non-technical summaries (NTS). Prospective severity always reflects the highest level of severity encountered by the animals, even if it only represents a small fraction of the total number of animals likely to be used in the ethical project (e.g., for a project using 300 animals, if 280 of these will undergo a moderate procedure and 20 of them will undergo a severe procedure, the prospective severity for this project will be severe).

Prospective Severity	Actual Severity
> Non-technical Project Summaries	> Statistical Reporting
E.g. 300 animals likely to be used	280 animals used
300 animals in a 'severe' procedure	15 animals as 'severe' 243 animals as 'moderate' 22 animals as 'mild and up to mild' => three entries in the stats

2.5. Simple Data Entry (horizontal direction)

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 2.6 and Annexe I:*

1. Move to the first cell in your row – cell **A4**
2. Choose a value from "EU submission" list. This should be "yes" for yearly statistics reporting.
3. Press **TAB** to move your active cell to the right
4. Choose your *License number* (e.g. LA1230170) from the "ID1" list
5. Press **TAB** to move your active cell to the right
6. Enter in Id2 your *Project license number* (number given by the Ethical committee)



7. Press **TAB** to move your active cell to the right
8. Choose your *Region code* from the "ID3" 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)

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.

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.

2.6. 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 "EU submission" list. (This should be "yes" for yearly statistics reporting)
Click on the down arrow. A pull-down menu appears, giving two choices: Yes and No.

Step 5: Complete your national references in the fields Id 1, Id 2, Id 3 [as per national instructions]

Id1: License number (e.g. LA1230170, *no spaces allowed between LA and the number*)

Id2: Project licensee number (number given by the Ethical committee)

Id3: Region code (BXL for Brussels Capital Region, VLA for Flanders Region and WAL for Walloon Region)



Step 6: Select the "Animal Species"

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

If you select "...other...", then, in the "Specify other" field, you need to specify what other species was used. Please use the **scientific name** (Latin) for this. Please specify if **early stages** were used e.g. larval forms (for fish, amphibian) or fetal forms.

Step 7: Type the "Number of animals". It must be a whole positive number.

Step 8: Specify if the animal is re-used or not.

Click on the down arrow. A pull-down menu appears, giving two choices: Yes and No. **If in column H 'Reuse [Y] Yes' is selected in combination with Severity '[SV4] Severe' in column S, it should be clearly stated in column U 'Comment 1 / Explanation of warnings' why there was a deviation from the legal guidelines.**

Step 9: Choose the "Place of birth (origin)"

Click on the down arrow. A pull-down menu appears, giving you choices. Select the origin that you need. If for Animal Species, you selected a Non-human primate, then you don't need to complete the "Place of birth (origin)", but instead, you need to complete the "NHP Source (origin)" and "NHP Generation".

Step 10: Select "Genetic status"

Click on the down arrow. A pull-down menu appears, giving you choices. Select the appropriate Genetic Status.

Step 11: Select "Creation of new GL"

Click on the down arrow. A pull-down menu appears, giving two choices: Yes and No

Step 12: Define the "Purpose"

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

Near the field "Purpose", you will see a "Browse". Click on it.

A pop-up window will appear, having a tree-like structure, showing you the path until choosing the final purpose through the all the various categories of purposes. Level 1 represents the upper level of purposes. The level 2 breaks down further into Level 3 and then Level 4. The structure follows the format established by the Commission Implementing Decision 2012/707/EU.

Depending on your choice, the path might stop at the level 1, 2, 3 or 4.

Alternatively choosing the Purpose from the pull down menu, you can use this pop-up window to select your purpose.

If you select "...other...", then, in the "Specify other" field, you need to specify what the other Purpose was. 'Specify other' describes a meaningful purpose for which the animal was used, not e.g. a technique that was carried out on the animal such as "MRI scan", "immunization", "antibody production", "superovulation", "donor" – these examples do not explain for which purpose the technique was carried out.

If you select a [PR code] or [PN code] in purpose you should go to Step 13 and 14. If not go directly to Step 15.

Step 13: Complete the legislative instrument "Testing by legislation"

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

If you select "...other...", then, in the "Specify other" field, you need to specify what legislation was required to be satisfied by the use. 'Specify other' describes the type of legislation that required the use of the animal, not e.g. "national", "ISO norm", "OECD", "internal control", "method development", "positive control" – none of which describes a type of legislation. Furthermore, **check this in combination with the origin of the legislative requirement**: if EU-legislation is stated as the legislative requirement, the name/number of the piece of EU legislation should be entered in the field 'specify other'. Same should apply for national legislation.

Step 14: Select the origin of legislation "Legislative requirements"



Click on the down arrow. A pull-down menu appears, giving you choices. Select the origin of legislation that you need.

Step 15: Next complete the "Severity"

Click on the down arrow. A pull-down menu appears, giving you choices. Select the severity type that you need. Only the **actual** severity is reported here (see 2.4 for more detailed information).

Note: "mild" severity actually means "up to mild". If the animal goes through a short behavioral test that would ensure very little stress for example, the severity level will be mild.

Correct use of "non-recovery" i.e. nothing (no procedure is applied) is done to that animal before it is put under a general anaesthesia and the animal is not allowed to recover but instead is killed without regaining consciousness. If the procedure contains several steps and the last step is done under general anaesthesia, the actual severity is not non-recovery but reflects the highest actual severity that the animal has experienced during the course of the procedure, taking into account all the steps of the procedure.

"Custom severity" is an optional field that is intended for those member states which require further breakdown of the 4 standard "Severity" types. These categories have not yet been defined in the Brussels Capital Region and this field should therefore not be filled in.

Step 16: Complete "Comment 1/Explanation of warnings" and "Comments 2" fields.

"Comments 1/Explanation of warnings" is reserved to notify the authorities of the reasons why warnings (identified at the Test Submission) appear but can be ignored.

"Comments 2" allows a data entry of additional relevant information. It can be used for justification of input data, etc. For example if actual severity is higher than the prospective severity due to unforeseen circumstances (e.g. an animal was used but gets an infection during the procedure and ends up in a higher severity category) this should be explained in the comments 2 column.

Step 17: 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 severity.

Step 18: 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!".

2.7. Reporting a zero-value

Reporting a zero-value is possible. This allows a user to report that no animals were used in a given reporting period.

The "Establishment details" sheet therefore contains a checkbox with "NO ANIMALS USED IN THE REPORTED YEAR". This will give the authority the opportunity to control that all establishments have fulfilled their reporting obligation.

2.8. Recommended File Name

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

Recommended file name: STAT_"year"_"Licence number" (e.g. **STAT_2018_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**. Additionally, all fields with errors are filled in red. This is the data you need to correct. Entering a value that is not in the list provided, will cause also 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 format.

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 format.

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

4. HOW TO DO COMPULSORY(RECOMMENDED) QUALITY CHECK OF THE FILE(S) BEFORE SUBMISSION + HOW TO DEAL WITH WARNINGS

Upon using the Test File Quality option at <https://webgate.ec.europa.eu/alures/web/resources/submission/test> the system will perform additional validation **which will also list any warnings**.

10

End users are strongly advised to send the file to the Test File Quality to identify any **warnings**. If any warnings remain after corrections have been made to the data, explain in the "Comment 1/Explanation of warnings" column why the warning on that record can be ignored. The explanation should be a detailed enough so that justifications can be given to the European Commission why this warning is present.

Possible warnings can be for example:

- Explain why re-use resulted in actual severity of 'severe' (as this will be higher than estimated prospectively)
- Exceptional use of 'severe' procedure for this purpose. Please ensure that the field 'Comments1/Explanation of warnings' justifies it.
- Exceptional use of non-human primates for this purpose. Please ensure that the field 'Comments1/Explanation of warnings' justifies it.
- Exceptional use of non-human primates in 'severe' procedure. Please ensure that the field 'Comments1/Explanation of warnings' justifies it.
- The use of Great Apes is only allowed with a specific exemption by the Member State. Please ensure that the field 'Comments1/Explanation of warnings' justifies it.

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

Once the Quality Control has been carried out, each user shall provide the statistical data (relating to the use of laboratory animals in his establishment during the past calendar year) **to the Ethical Committee** to which the institution is affiliated.

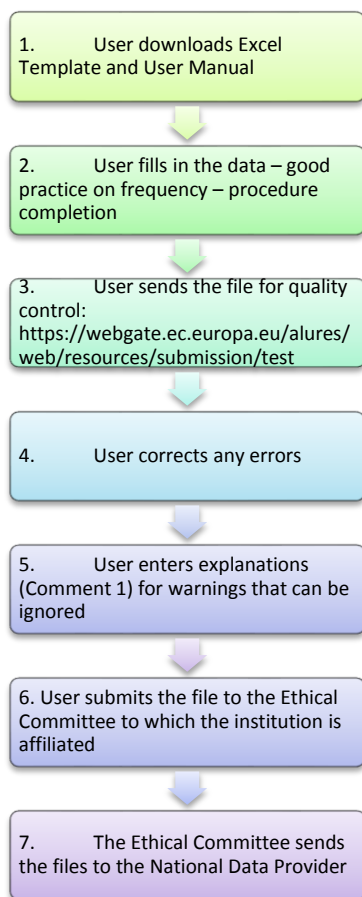
Afterwards, the Ethical Committee sends the Excel Files by email to:

Labo.bea.dwz@leefmilieu.brussels

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



6. SUMMARY



ADDITIONAL SUGGESTIONS

- **Applied research for dentistry** should be reported under "[PT27] Musculo-skeletal disorders". It would be beneficial to add "dentistry" in the "specify other (purposes)" field for future identification.
- Pay specific attention to entries under "Basic Research/Multisystemic": this category should **only** include research where **more than one system is the primary interest**, such as on some infectious diseases. Otherwise, the entry should be made **under the category of the primary purpose**.
- **Use of cephalopods**: it would be beneficial to add the type of species e.g. using Latin name in the "specify other (species)" for future analysis.
- **Specify other** field for **species**, may also be used for further specification of the types of animals e.g. using 'specify other' for a 'mouse' to identify the specific mouse line.
- **Specify other** field for **purposes**, may also be used for further specification of the purposes e.g. see above for 'dentistry'.



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- Mrs. Inge Decorte
- Mrs. Audrey Veldeman

For further information please contact:

*Brusselse Commissie voor dierproeven
Departement Dierenwelzijn
Havenlaan 86C bus 3000
B-1000 Brussel*

Email: comexpan_comdierpr@leefmilieu.brussels



ANNEXE 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)
EU Submission	Indicate if the line should be processed for EU statistics	Yes	This should be “yes” for yearly statistics reporting	This is a required field, fixed list
Id 1	Field to be completed for national further reference	LA1230170	Choose your License number (e.g. LA1230170) from the “ID1” list.	This field is required.
Id 2	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.
Id 3	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 in the research/experiment. 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) - [A22] Vervets (Chlorocebus spp. usually either pygerythrus or sabaesus) - [A23] Baboons (Papio spp.) - [A24] Squirrel monkey (eg. Saimiri sciureus)	This is a required field, fixed list.



			- [A25] Other species of non-human primates (other species of Ceboidea and Cercopithecoidea)	
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 fetal 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.
Re-use	Use of the same animal previously in other research/or another experiment.	No		This is a required field, fixed list
Place of birth (origin)	Origin of species Indicate where animals were born.	[O1] Animals born in the EU at a registered breeder	In cases where an animal has been reused, this field is not completed	Fixed list. This a conditional field based on "Re-use" and "Animal Species" data elements. "Place of birth (origin)" must be completed if "Re-use" is set "No" and, in "Animal Species", is selected any species apart of Non-human primates.
NHP Source (origin)	Origin of Non-human primates Indicate where Non-human primates were born.	[NHPO2] Animals born in rest of Europe		Fixed list. This a conditional field based on "Re-use" and "Animal Species" data elements. "NHP Source (origin)" must be completed if "Re-use" is set "No" and, in "Animal Species", is selected a Non-human primate.
NHP Generation	Types of generation for Non-human primates	[NHPG2] F1		Fixed list. This a conditional field based on "Re-use" and "Animal Species" data elements. "NHP Generation" must be



				completed if "Re-use" is set "No" and, in "Animal Species", is selected a Non-human primate.
Genetic status	Types of genetic alterations. Indicate if animals were genetically altered or not in the research/experiment and alteration type.	[GS2] Genetically altered without a harmful phenotype		This is a required field, fixed list.
Creation of new GA	Creation of new genetically altered (GA) animals. Choose whether a new genetic line was created in the research/experiment or not.	No		This is a required field, fixed list.
Purpose	Purpose of animal experiment. Indicate the reason for the research/experiment and the area of investigation.	[PB3] (Basic Research) Nervous System	In cases where a Member State chooses to use the same Excel spreadsheet for the submission of additional national reporting requirements which go beyond that of the EU reporting, these purpose fields will be added in comment columns at the end.	Fixed list. This is a required, conditional field based on the "Creation of new GL" data element. If you choose "Yes" in "Creation of a new GA" you can only choose a purpose from "Basic research purposes" or "Translational and applied research purposes" category of purposes.
Specify other	Other Purpose	Other System	If you select "...other...", then, in the "Specify other" field, you need to specify what the other Purpose was. 'Specify other' describes a meaningful purpose for which the animal was used, not e.g. a technique that was carried out on the animal such as "MRI scan", "immunization", "antibody production", "superovulation", "donor" – these examples do not explain for which purpose the technique was carried out.	Optional field. This is a conditional field based on "Purpose" data element. When in "Purpose" the user chooses a value that contains the word – other - the user can specify what purpose was used exactly.



Testing by legislation	Different legislative instruments. Indicate under which specific legislation the use of animals is included.	[LT3] Medical devices legislation		Fixed list. This is a conditional field based on the "Purpose" data element. "Testing by legislation" must be completed if in "Purpose" is selected any purpose that has the code "PR". Example of purpose having the code PR: "[PR93] (Regulatory use/Toxicity and..) Developmental toxicity"
Specify other	Other legislative instruments	Spanish legislation	If you select "...other...", then, in the "Specify other" field, you need to specify what legislation was required to be satisfied by the use. 'Specify other' describes the type of legislation that required the use of the animal, not e.g. "national", "ISO norm", "OECD", "internal control", "method development", "positive control" – none of which describes a type of legislation.	Optional field. This is a conditional field based on "Testing by legislation" data element. When in "Testing by legislation" the user chooses a value that contains the word – other - the user can specify what legislative instrument was used exactly.
Legislative Requirements (origin of legislation)	Legislative sources. Indicate on the basis of which legislation the use of animals is carried out by origin of the legislation.	[LO1] Legislation satisfying EU requirements		Fixed list. This is a conditional field based on the "Purpose" data element. "Legislative Requirements (origin of legislation)" must be completed if in "Purpose" is selected any purpose that has the code "PR". Example of purpose having the code PR: "[PR93] (Regulatory use/Toxicity and..) Developmental toxicity"
Severity	Research/experiment degree of severity. Indicate the actual severity that the animal experienced during the research/experiment.	[SV3] Severe		This is a required field, fixed list. Dropdown: user can select from four (4) types of Severity.



Custom Severity	Optional field for those MS which require further breakdown of the 4 standard "Severity" types	Below Mild	These categories have not yet been defined in the Brussels Capital Region and this field should therefore not be filled in.	This field is optional.
Comments 1/Explanation of warnings	Allow a data entry of explanation of warnings, if any	This project used an exceptionally high number of - authorised.	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 optional.
Comments 2	Allow a data entry of additional relevant information as per MS instructions.	Behavioral study, severity below EU minimum threshold	This field allows a data entry of additional relevant information. It can be used for justification of input data, etc. For example if actual severity is higher than the prospective severity due to unforeseen circumstances (e.g. an animal was used but gets an infection during the procedure and ends up in a higher severity category) this should be explained in the comments 2 column.	This field is optional.

