

# **GUIDANCE FOR STATISTICAL REPORTING**

# on the use of animals for scientific purposes - PART 1

# COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE



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# **GUIDANCE FOR STATISTICAL REPORTING**

on the use of animals for scientific purposes – PART 1

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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 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 shall be reported 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 shall report their animals at the end of the procedure.

In 2-step / multi-step procedures it is the last 'user' who shall 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 shall 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 shall 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: <a href="https://leefmilieu.brussels/themas/dierenwelzijn/dierproeven-een-strikt-omlijnde-praktijk">https://leefmilieu.brussels/themas/dierenwelzijn/dierproeven-een-strikt-omlijnde-praktijk</a> in the Documents Guidance section
- In French: <a href="https://environnement.brussels/thematiques/bien-etre-animal/lexperimentation-animale-une-pratique-tres-encadree">https://environnement.brussels/thematiques/bien-etre-animal/lexperimentation-animale-une-pratique-tres-encadree</a> in the Documents Guidance section

#### 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 must have Microsoft Office 2003 or later. The spreadsheet is "locked" to restrict modifications. Other spreadsheet programs (such as Libre Office Calc, Apple Numbers, etc.) will not function properly. 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 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
- Reported year

The "<u>List</u>" sheet contains a total of 32 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

#### 2.3. Prepare data

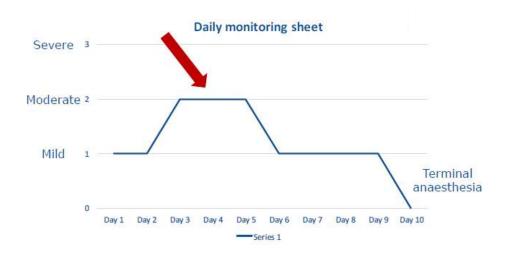
First of all you need to prepare your data for entry in the Excel spreadsheet.



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<u>Actual</u> severity is reported for each <u>individual</u> 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 for the purpose 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.



<u>Prospective</u> severity should <u>never</u> be reported in the yearly statistics. Prospective severities can only be reported in the non-technical summaries (NTS). Prospective severity always reflects the severity estimated for the animal.

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

The <u>actual</u> suffering of the animal could also be influenced by a previous use. However, the severity will not always increase in a subsequent use and in some cases may even decrease as a result (habituation). Therefore, the actual severity to be reported shall always be determined **on a case-by-case basis** taking into account of any impact from previous uses.

## 2.4. 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.



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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 Annex 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)

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.

#### 2.5. 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.

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". It must be a whole positive number.

Step 8: Specify if the animal is re-used or not (for more information on re-use please consult

https://leefmilieu.brussels/sites/default/files/user files/guidance for statistical reporting part 2.pdf Pg.10)

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 V 'Explanation of warnings' why there was a deviation from the legal guidelines.

#### Step 9: Choose the "Place of birth"

Click on the down arrow. A pull-down menu appears, giving you choices. Select the origin that you need. Information on the place of birth and for non-human primates also the generation and information on whether the animal was obtained from a self-sustaining colony shall only be reported for **naïve** animals, that is to say animals used for the first time. For reused animals, this information is therefore not recorded. If for Animal Species, you selected a Non-human primate, then you don't need to complete the "Place of birth", but instead, you need to complete the "NHP Place of birth", NHP Colony type" 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 a new GA Line"

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 2020/569/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 <u>meaningful purpose</u> 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] in purpose you should go to Step 13 and 14. If not go directly to Step 15.

#### Step 13: Complete the legislative instrument "Type of 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"

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 behavioural 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 "Explanation of warnings" and "Comments" fields.

"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" 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 column.

## Step 17: Select the "Method of tissue sampling"

Click on the down arrow. A pull-down menu appears, giving you choices. 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 lines (as for example is done for different severity grades within a project). E.g. if 200 animals are used in a project and 10 are genotyped by blood sampling and 190 by hair sampling you have to enter 2 different lines despite that all other parameters remain the same.

If you select "...other...", then, in the "Specify other method" field, you need to specify what method was used.

#### Step 18: Select the "Severity of genotyping"

#### Step 19: Complete "Field 1 to 6"

In the Brussels-Capital Region, **no additional fields were determined**. Consequently, these columns should be left empty.



Step 20: 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, the severity or method of tissue sampling.

Step 21: 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!".

#### 2.6. 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.

#### 2.7. 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**

the Test File Upon using Quality option at https://webgate.ec.europa.eu/envdataportal/web/resources/public/alures/statistics/validate the system will perform additional validation which will also list any warnings.

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 "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 'Explanation of warnings' iustifies it.



- Exceptional use of non-human primates for this purpose. Please ensure that the field 'Explanation of warnings'
  justifies it.
- Exceptional use of non-human primates in 'severe' procedure. Please ensure that the field '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 '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

- User downloads Excel
   Template and User Manual
- 2. User fills in the data good practice on frequency procedure completion
- 3. User sends the file for quality control: https://webgate.ec.europa.eu/alures/web/resources/submission/test
- 4. User corrects any errors
- 5. User enters explanations (Comment 1) for warnings that can be ignored
- 6. User submits the file to the Ethical Committee to which the institution is affiliated
- 7. The Ethical Committee sends the files to the National Data Provider



#### **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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#### From the Brussels Committee for animal experimentation

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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)
EU Submission	Indicate if the line should be process for EU statistics	Yes	This should be " <b>yes</b> " 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 sabaeus) - [A23] Baboons (Papio spp.) - [A24] Squirrel monkey (eg. Saimiri sciureus) - [A25-1] Other species of New World monkeys (other species of Old World monkeys (other species of Ceboidea) - [A25-2] Other species of Ceccopithecoidea)	This is a required field, fixed list.



			- [A26] Apes (Hominoidea)	
			[A20] Apc3 (Horrimolaca)	
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.
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 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 "Reuse" 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 Place of birth	Origin of Non-human primates Indicate where Non-human primates were born.	[NHPO2] Animals born in the Union but not at an authorised breeder, and NHP born in rest of Europe		Fixed list. This a conditional field based on "Reuse" and "Animal Species" data elements. "NHP Source (origin)" must be completed if "Re-use" is set "No" and, in "Animal Species", is selected a Nonhuman primate.
NHP Colony type	Colony type Indicate whether NHP come from Self-sustaining colony or not.	[Y] Yes		Fixed list. This a conditional field based on "Reuse" and "Animal Species" data elements. "NHP Colony type" 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 "Reuse" 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 line	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.



T f     -   -   -   -	Different legislation in terms	[1.72]		minus di libra
Type of legislation	Different legislative instruments.	[LT3] Medical		Fixed list.
	Indicate under which specific	devices legislation		This is a conditional field based on the
	legislation the use of animals is			"Purpose" data element.
	included.			"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	Optional field.
			"Specify other" field, you need to specify	This is a conditional field based on
			what legislation was required to be	"Testing by legislation" data element.
			satisfied by the use. 'Specify other'	When in "Testing by legislation" the
			describes the type of legislation that	user chooses a value that contains the
			required the use of the animal, not e.g.	word – other - the user can specify
			"national", "ISO norm", "OECD", "internal	what legislative instrument was used
			control", "method development",	exactly.
			"positive control" – none of which	
			describes a type of legislation.	
Origin of legislation	Legislative sources.	[LO1] Legislation		Fixed list.
	Indicate on the basis of which	satisfying EU		This is a conditional field based on the
	legislation the use of animals is	requirements		"Purpose" data element.
	carried out by origin of the legislation.			"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	[SV3] Severe		This is a required field, fixed list.
	severity.			Dropdown: user can select from four
	Indicate the actual severity that the			(4) types of Severity.
	animal experienced during the			
	research/experiment.			
Custom Severity	Optional field for those MS which	Below Mild	These categories have not yet been	This field is optional.
	require further breakdown of the 4		defined in the Brussels Capital Region and	
	standard "Severity" types		this field should therefore <b>not be filled in.</b>	



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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	Allow a data entry of additional relevant information as per MS instructions.	Behavioural 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 column.	This field is optional.
Method of tissue sampling	Select the method of tissue sampling	[IG3] Invasive genotyping: tail biopsy		This is a required field, fixed list. Dropdown: user can select between (non) invasive genotyping and surplus.
Specify other method	Other Method		If you select "other", then, in the "Specify other" field, you need to specify what the other Method was.	Optional field.  This is a conditional field based on "Method of tissue sampling" data element.  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.
Severity of genotyping	Select the severity of the genotyping. Indicate the actual severity that the animal experienced during the genotyping.	[SV2] Mild [up to and including]		This is a required field, fixed list. Dropdown: user can select from four (4) types of Severity.
Field 1	Allow a 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.



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Field 2	Allow a data entry of additional	The comments will not be automatically	This field is not required by Brussels
	relevant information as per MS	processed by the application, but are	Environment.
	instructions.	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.	
Field 3	Allow a data entry of additional	The comments will not be automatically	This field is not required by Brussels
	relevant information as per MS	processed by the application, but are	Environment.
	instructions.	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.	
Field 4	Allow a data entry of additional	The comments will not be automatically	This field is not required by Brussels
11010	relevant information as per MS	processed by the application, but are	Environment.
	instructions.	visible to a user handling the submission	Livironinent.
	mstractions.	file. The comment can be used for	
		whatever purpose they can be judged	
E: 11E	All I C Live I	useful: justification of input data, etc.	TI C II II D
Field 5	Allow a data entry of additional	The comments will not be automatically	This field is not required by Brussels
	relevant information as per MS	processed by the application, but are	Environment.
	instructions.	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.	
Field 6	Allow a data entry of additional		This field is not required by Brussels
	relevant information as per MS		Environment.
	instructions.		

