



Bundesministerium
für Ernährung
und Landwirtschaft

Notification of the use of experimental animals

GUIDELINES on filling in the Excel form and further information

Introduction

The Directive on the protection of animals used for scientific purposes (2010/63/EU)¹ and the Implementing Decision (2012/707/EU)² lay down the requirements for the submission of statistical data on the use of animals for scientific purposes in the EU. These requirements were transposed in Germany by the "Ordinance on the reporting of vertebrates or cephalopods used for experimental purposes or of vertebrates used for certain other purposes"³ (hereinafter referred to as the Experimental Animal Reporting Ordinance).

A Microsoft Excel worksheet was provided by the European Commission as an instrument for recording the data. It is intended to make data input more efficient, ensure that the implementation is coherent and minimise errors. It is compatible with the EU database in which the data of all Member States are collated, and serves to ensure the standardised submission of statistical data to the competent authorities.

These guidelines are also based on a draft provided by the European Commission. It explains in detail how to fill in the Excel reporting form and also contains technical references and more extensive information on the data subject to the reporting requirements.

¹ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276 of 20.10.2010, p. 33

² Commission implementing decision of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes, OJ L 320 of 17.11.2012, p. 33

³ Ordinance of 12/12/2013 (Federal Law Gazette I p. 4145)

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1 Purpose of these guidelines

These guidelines explain the steps required to fill in the Excel worksheet with the data on the use of animals that are to be submitted to the national authorities.

The data dictionary (Chapter 4) and the annex contain further information, e.g. "when is an animal deemed to have been reused?" or "how are animals counted when at the larval stage?"

The guidelines are based on Excel 2010 being used to enter the data.

2 Accessing the Excel template

English and German versions of the Excel template can be downloaded by following this link:

- www.bmel.de/Versuchstierzahlen-Leitfaden

3 Entering data in the Excel template

3.1 General

In order to use the Excel template, you need Microsoft Office 2003, 2007 or 2010. Enabling the macros provides additional support regarding data entry. To ensure that the integrated macros remain functional and the template remains compatible with the EU database, it is not possible to change the structure of the Excel template.



N.B.:

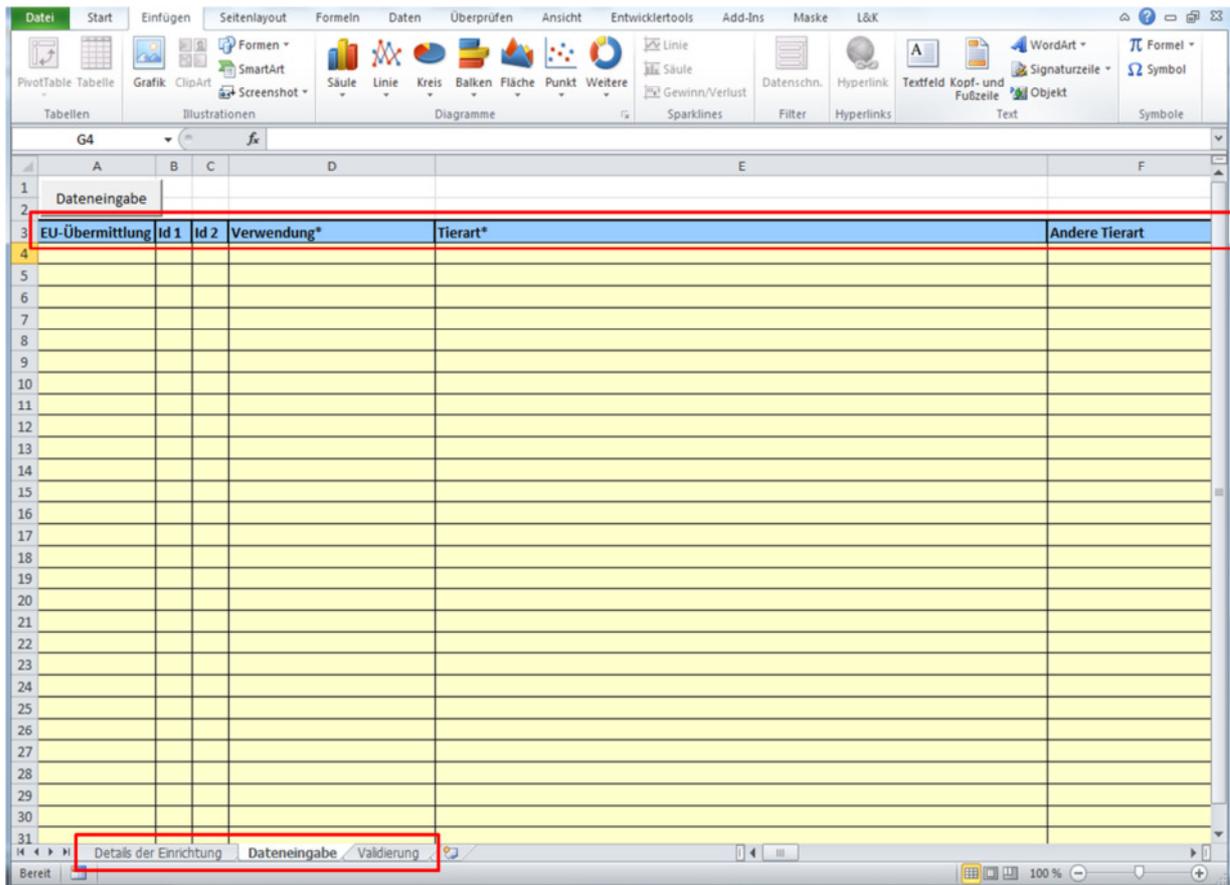
It is recommended that the template is saved under the following name:

State_Establishment_Year.xls(x)

Please use the official abbreviations for the Laender⁴.

The Excel template contains three worksheets: "Establishment details", "Data entry" and "Validation". The "Data entry" worksheet contains 19 columns for the data to be entered (the order of the columns corresponds to the stipulations in the Laboratory Animal Notification Ordinance).

⁴ BB Brandenburg, BE Berlin, BW Baden-Württemberg, BY Bavaria, HB Bremen, HH Hamburg, HE Hesse, MV Mecklenburg-Western Pomerania, NI Lower Saxony, NW North Rhine-Westphalia, RP Rhineland-Palatinate, SL Saarland, SN Saxony, ST Saxony-Anhalt, SH Schleswig-Holstein, TH Thuringia



N.B.:

All required fields must be filled in. Required fields are denoted with an asterisk (*).
Please do not leave any blank lines.

All data items are described in section 4 of these guidelines.

There are two basic options for entering data:

- a) simple data entry (horizontally) - see 3.5
- b) data entry via the data form (recommended option) - see 3.6

3.2 Macros

To be able to use the functionality of the Excel template, you must enable the macros in the Excel file.

How to enable macros in an Excel file:

Microsoft Excel 2003

1. Select **Macros** from the **Extras** menu, and then click on **Security**.
2. Enable "**Trust all installed add-ins and templates**" in the "**Trusted Sources**" tab.

Microsoft Excel 2007

1. Click on the **Microsoft Office button**  and then on **Excel Options**.
2. Click on **Trust Centre**, then on **Trust Centre Settings** and then on **Macro Settings**.
3. Select **Enable all Macros**.

Microsoft Excel 2010

If you open a file containing macros, the yellow **Message Bar** appears with a shield icon and the **Enable content** button.

1. Click on **Enable content** in the **Message Bar**.

**N.B.:**

Only enable macros if you trust the publisher. This setting makes your computer susceptible to malware. If necessary, check your settings when you have concluded your work on the Excel template for reporting statistical data on experimental animals and open a new file.

3.3 Establishment details

Enter information that will enable your research institution to be identified in the "Establishment details" worksheet. Personal details are voluntary.

		Versuchstiermeldung für 2014
Land:	<input type="text"/>	
Vorname:	<input type="text"/>	
Nachname:	<input type="text"/>	
E-Mail:	<input type="text"/>	
Einrichtung:	<input type="text"/>	
Jahr:	<input type="text" value="2014"/>	
Der empfohlene Speichername für diese Datei lautet: Bundesland_Einrichtung_Meldejahr.xls(x)		
Bitte nutzen Sie die offiziellen Abkürzungen der Bundesländer:		
BW Baden-Württemberg		
BY Bayern		
BE Berlin		
BB Brandenburg		
HB Bremen		
Details der Einrichtung		
Dateneingabe Validierung		

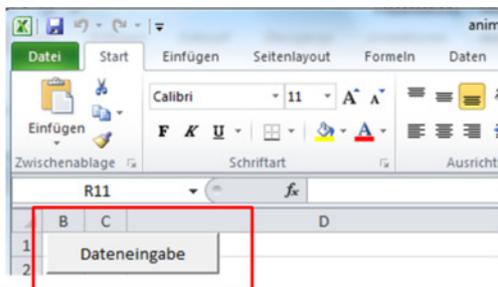
3.4 Prior to data entry

Before you begin to enter data, please note that information on a study may need to be broken down and entered in several different lines. If, for example, you are transferring data on 10 mice from the same study and the mice displayed three levels of severity (e.g. 2 mild, 3 moderate and 5 severe), the data must be entered in 3 different lines. To accelerate the process and reduce the likelihood of errors, the system facilitates the entry of a practically identical set of data (see 3.5 Data entry using the data form).

If you have prepared your report in a different system, it is possible to copy the data from an Excel worksheet and enter them in the Excel template provided. Please ensure you comply with the structure of the target file. Please also note that the columns A-D must not be included in the area to be copied, as they are write-protected.

3.5 Data entry using the data form

The data form enables you to enter all data for a particular line in a dialogue box. Open the form by clicking on the "Data entry" button at the top left of the "Data entry" worksheet.



This form allows you to enter data more quickly. At the end of the form, click on "Save" in order to begin a new line.

Datenformular Versuchstiere

< Vorherige Aktuelle Zeile: 4 Gehe zu: Nächste >

Zelleninhalt

D: Verwendung:

E: Tierart:

F: Andere Tierart: G: Zahl der verwendeten Tiere:

H: Erneut verwendet: [N] Nein I: Geburtsort:

J: Primaten Geburtsort: K: Primaten Generation:

L: Genetischer Status: (GS2) Genetisch verändert ohne pathologischen Phänotyp M: Schaffung einer neuen genetischen Linie: [N] Nein

N: Verwendungszweck: [PR87] (Regulatorischer Zweck, Toxizitäts- und Unbedenlichkeitsprüfungen, nach Prüfungsarten) Toxizität – bei wi

O: Anderer Verwendungszweck:

P: Gesetzlich vorgeschriebene Überprüfung nach: [LT7] Vorschriften für Lebensmittel, einschließlich Materialien, die mit Lebensmitteln in Berührung komm

Q: Andere rechtliche Grundlage:

R: Rechtsquelle: [LO2] Vorschriften, die nur nationale Anforderungen erfü

S: Schweregrad: [SV1] Keine Wiederherstellung dei T: Versuchsvorhaben:

U: Anmerkungen: V: weiterer Versuchszweck (freiwillige Angabe)

W: weiterer Versuchszweck (freiwillige Angabe)

You must carry out the following steps:

Step 1: Go to the "Data entry" worksheet.

*Step 2: Click on cell **D4** (nothing needs to be entered in the columns headed "EU submission", "Id1" and "Id2").*

Step 3: Click on "Data entry".

	B	C	D
1	Dateneingabe		
2			
3	Id 1	Id 2	Verwendung*
4			
5			
6			

Step 4: Choose one of the options from the "Use" list (field D). The dropdown list contains two options: T1 (in accordance with Section 7 (2) Animal Welfare Act) and T2 (in accordance with Section 4 (3) Animal Welfare Act).

Eingabemaske Versuchstiere

< Vorherige Aktuelle Zeile: 4 Gehe zu: Nächste >

Zelleninhalt

D: Verwendung:

E: Tierart:

Step 5: Select the species of animal used from field E "Animal species".

E: Tierart:

F: Andere Tierart:

H: Erneut verwendet:

J: Primaten Geburtsort:

L: Genetischer Status:

N: Verwendungszweck:

O: Anderer Verwendungszweck:

[A1] Mäuse (Mus musculus)
[A2] Ratten (Rattus norvegicus)
[A3] Meerschweinchen (Cavia porcellus)
[A4] Goldhamster (Mesocricetus auratus)
[A5] Chinesischer Grauhamster (Cricetulus griseus)
[A6] Mongolische Rennmäuse (Meriones unguiculatus)
[A7] Andere Nager (andere Rodentia)
[A8] Kaninchen (Oryctolagus cuniculus)
[A9] Katzen (Felis catus)
[A10] Hunde (Canis familiaris)
[A11] Frettchen (Mustela putorius furo)
[A12] Andere Fleischfresser (andere Carnivora)
[A13] Pferde, Esel und Kreuzungen (Equidae)
[A14] Schweine (Sus scrofa domesticus)
[A15] Ziegen (Capra aegagrus hircus)
[A16] Schafe (Ovis aries)
[A17] Rinder (Bos primigenius)
[A18] Halbaffen (Prosimia)
[A19] Marmosetten und Tamarine (z.B. Callithrix jacchus)
[A20] Javaneraffen (Macaca fascicularis)

If you select "Other...", you must enter the species used in the adjacent cell "Specify other species".

E: Tierart:

F: Andere Tierart:

G: Zahl der verwendeten Tiere:

Step 7: Enter the "Number of animals" (a whole, positive number) in field G.

Step 8: Enter in field H whether the animal was reused or not (if the research project included animals used for the first time and animals that were reused, the information entered must be broken down and entered in several lines).

E: Tierart:

F: Andere Tierart:

G: Zahl der verwendeten Tiere:

H: Erneut verwendet:

I: Geburtsort:

J: Primaten Geburtsort:

K: Primaten Generation:

L: Genetischer Status:

M: Schaffung einer neuen:

Step 9: Choose the "Place of birth" (field I). The place of birth of animals that have been reused does not need to be entered.

F: Andere Tierart:	<input type="text" value="Stachelratten"/>	G: Zahl der verwendeten Tiere:	<input type="text" value="5"/>
H: Erneut verwendet:	<input type="text" value="[N] Nein"/>	I: Geburtsort:	<input type="text" value="[O2] In der EU, jedoch nicht in einem registrierten Zucht"/>
J: Primaten Geburtsort:	<input type="text"/>	K: Primaten Generation:	<input type="text" value="[O1] In der EU in einem registrierten Zuchtbetrieb geboren"/>
L: Genetischer Status:	<input type="text"/>	M: Schaffung einer neuen genetischen Linie:	<input type="text"/>

If you have entered primates under "Animal species", field I is disabled. If this is the case, enter the primate's place of birth in field J ("NHP place of birth") and the primate's generation in field K ("NHP generation") (if the animals used are not primates, no data needs to be entered in fields J and K).

E: Tierart:	<input type="text" value="[A19] Marmosetten und Tamarine (z.B. Callithrix jacchus)"/>	G: Zahl der verwendeten Tiere:	<input type="text" value="3"/>
F: Andere Tierart:	<input type="text"/>	I: Geburtsort:	<input type="text"/>
H: Erneut verwendet:	<input type="text" value="[N] Nein"/>	K: Primaten Generation:	<input type="text"/>
J: Primaten Geburtsort:	<input type="text"/>	M: Schaffung einer neuen genetischen Linie:	<input type="text"/>
L: Genetischer Status:	<input type="text" value="[NHPO1] In der EU in einem registrierten Zuchtbetrieb geboren"/>	N: Verwendungszweck:	<input type="text"/>
	<input type="text" value="[NHPO2] Im restlichen Europa geborene Tiere"/>		<input type="text" value="Durchsuchen"/>
	<input type="text" value="[NHPO3] In Asien geborene Tiere"/>		
	<input type="text" value="[NHPO4] In Amerika geborene Tiere"/>		
	<input type="text" value="[NHPO5] In Afrika geborene Tiere"/>		
	<input type="text" value="[NHPO6] In anderen Teilen der Welt geborene Tiere"/>		

Step 10: Please enter the "Genetic status" in field L.

Step 11: Please enter in field M whether the animals were used for the creation of a new genetic line (Yes/No).

L: Genetischer Status:	<input type="text" value="(GS1) Genetisch nicht verändert"/>	M: Schaffung einer neuen genetischen Linie:	<input type="text" value="[N] Nein"/>
N: Verwendungszweck:	<input type="text" value="(GS1) Genetisch nicht verändert"/>		<input type="text" value="Durd"/>
	<input type="text" value="(GS2) Genetisch verändert ohne pathologischen Phänotyp"/>		
	<input type="text" value="(GS3) Genetisch verändert mit pathologischem Phänotyp"/>		

Step 12: Enter the "Purpose" (field N).

N: Verwendungszweck:	<input type="text"/>	<input type="button" value="Durchsuchen"/>
O: Anderer Verwendungszweck:	[PB1] (Grundlagenforschung) Onkologie	↑
P: Gesetzlich vorgeschriebene Überprüfung nach:	[PB2] (Grundlagenforschung) Kardiovaskuläres System (Blut- und Lymphgefäße)	
Q: Andere rechtliche Grundlage:	[PB3] (Grundlagenforschung) Nervensystem	
R: Rechtsquelle:	[PB4] (Grundlagenforschung) Atmungssystem	
S: Schweregrad:	[PB5] (Grundlagenforschung) Gastrointestinales System, einschließlich Leber	
U: Anmerkungen:	[PB6] (Grundlagenforschung) Muskuloskelettales System	
	[PB7] (Grundlagenforschung) Immunsystem	
	[PB8] (Grundlagenforschung) Urogenitales System/ Fortpflanzungssystem	
	[PB9] (Grundlagenforschung) Sinnesorgane (Haut, Augen, Ohren)	
	[PB10] (Grundlagenforschung) Endokrines System/ Stoffwechsel	
	[PB11] (Grundlagenforschung) Multisystemisch	
	[PB12] (Grundlagenforschung) Ethologie, Tierverhalten, Tierbiologie	
	[PB13] (Grundlagenforschung) Andere	
	[PT21] (Translationale und angewandte Forschung) Krebserkrankungen des Menschen	
	[PT22] (Translationale und angewandte Forschung) Infektionskrankheiten des Menschen	
	[PT23] (Translationale und angewandte Forschung) Kardiovaskuläre Erkrankungen des Menschen	
	[PT24] (Translationale und angewandte Forschung) Nerven- und Geisteserkrankungen des Menschen	
	[PT25] (Translationale und angewandte Forschung) Atemwegserkrankungen des Menschen	
	[PT26] (Translationale und angewandte Forschung) Gastrointestinale Erkrankungen des Menschen, einschließlich der	
	[PT27] (Translationale und angewandte Forschung) Muskuloskelettales Erkrankungen des Menschen	

Next to the "Purpose" field you will find the "Search" button. Clicking on this button opens a window which takes you through all the different categories until the selection of the final purpose. The purpose may need to be broken down into several levels. The structure corresponds to the format laid down in Commission implementing decision 2012/707/EU.

Auswahl Versuchszweck		<input type="button" value="X"/>
Übergeordneter Zweck (Ebene 1):	<input type="text" value="Verwendung zu regulatorischen Zwecken und Routineproduktion"/>	
Zweck (Ebene 2):	<input type="text" value="Toxizitäts- und andere Unbedenklichkeitsprüfungen, einschließlich pharmakologischer Tests"/>	
Zweck (Ebene 3):	<input type="text" value="Toxizität bei wiederholter Applikation"/>	
Zweck (Ebene 4):	<input type="text" value="[PR87] < und 28 Tage"/>	
<input type="button" value="Ok"/>		<input type="button" value="Abbrechen"/>

If you select "Other...", you must specify what the other purpose was in field O (other purpose”).

Step 13: Enter in field P the relevant legislation (only to be completed if one of the options PR51 - PR 106 - regulatory purpose was entered under "Purpose"; if this is not the case, no options are listed in field P).

P: Gesetzlich vorgeschriebene Überprüfung nach:	<input type="text"/>
Q: Andere rechtliche Grundlage:	[LT1] Vorschriften für Humanarzneimittel
R: Rechtsquelle:	[LT2] Vorschriften für Tierarzneimittel und ihre Rückstände
	[LT3] Vorschriften für Medizinprodukte
	[LT4] Vorschriften für Industriechemikalien
	[LT5] Vorschriften für Pflanzenschutzmittel
	[LT6] Vorschriften für Biozidprodukte
	[LT7] Vorschriften für Lebensmittel, einschließlich Materialien, die mit Lebensmitteln in Berührung komm
	[LT8] Vorschriften für Futtermittel, einschließlich Vorschriften für die Sicherheit von Zieltieren, Arbeitne

If you select "Other...", you must specify the other legislation in field Q to show what specific legislation the use was based on.

Step 14: Select field R "Legislative requirements" (only to be completed if the experiment served a regulatory purpose).

Step 15: Enter the "Severity" in field S (in case of a use in accordance with "T2: Section 4 (3) Animal Welfare Act", please enter "[SV1] non-recovery". This serves to avoid error reports in the validation).

Step 16: Enter in field T ("Project number") the information providing clear identification of the research project, i.e. the code number or reference number that was supplied by the authorities during the approval or notification procedure.

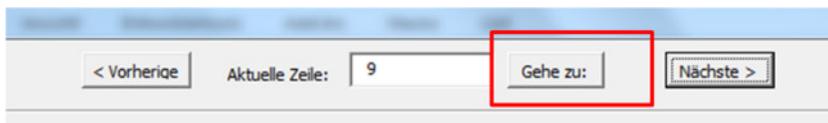
Step 17: Complete field U ("Comments") as required. In case of Section 25 (2) of the Experimental Animal Welfare Ordinance, you must enter in column U any information on an exemption, on details of the use and the respective reasons.

The "Comments" field serves, for example, to inform authorities about the reasons why warnings (recognised during the validation) occur but can be ignored.

Step 18: Complete, as required, fields V and W ('Purpose 2' and 'Purpose 3' (this information is voluntary and gives you the option, for Section 4 animals, for stating further possible uses of the organs / tissue in addition to the primary purpose [column N]. The information should be given in order of importance).

Step 19: Click on "Save" to save the data you have entered, or on "Save and Copy" to save the data and create a new line underneath with the same data. The latter option facilitates the entry of lines containing very similar data which, for instance, only differ in the number of animals or the severity.

If you would like to **jump to a particular line**, enter the line number in the "Current line" field and then click on "Go to".



After you have finished entering data, close the data form by clicking on the red "Close" button at the top left.

3.6 Simple data entry (horizontally)

Under the standard Excel settings, you press the **TAB** key to move one cell to the right and the **ENTER** key to move down a line. The data are to be entered from left to right, as the Excel worksheet contains **several cells that are dependent on others**.

Please, therefore, follow the steps below to enter the data:

1. Go to cell D4 (nothing needs to be entered in the columns headed "EU submission", "Id1" and "Id2").
2. Choose one of the options from the "Use" list.

3	EU-Übermittlung	Id 1	Id 2	Verwendung*	Tierart*
4				T1: nach § 7 Absatz 2 TierSchG	2] Ratten (Rattus norvegicus)
				T1: nach § 7 Absatz 2 TierSchG	
				T2: nach § 4 Absatz 3 TierSchG	
6					
7					

3. Press the TAB key to move one cell along to the right and make the corresponding entry.
4. Repeat this until you reach the last column.
5. Press the ENTER key to move one line further down (Excel remembers the column which you began with and jumps automatically to column D in the next line down).

You can use the following keyboard shortcuts to speed up data entry:

- Show the dropdown list by pressing ALT + down arrow
- Press CTRL + D to copy the content and format of the top cell of a selected area into the following cells

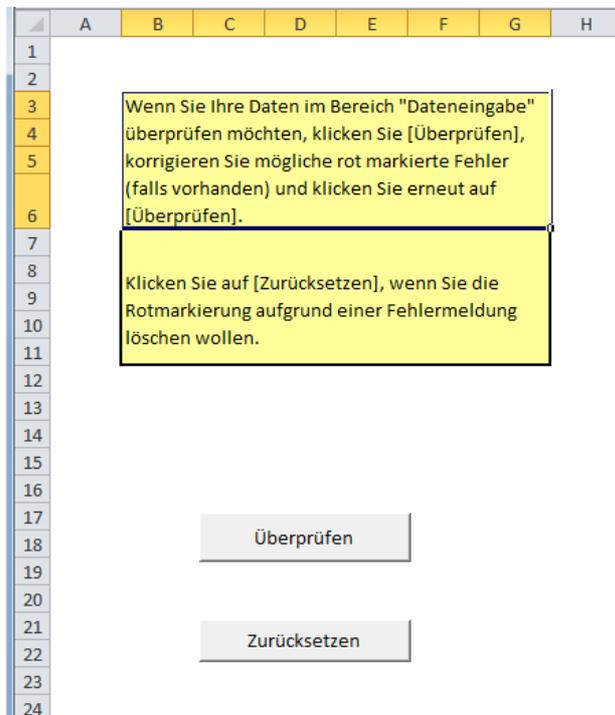


N.B.:

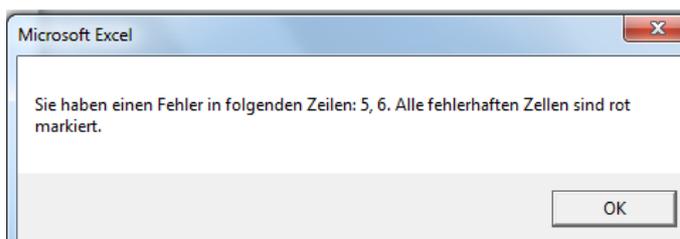
Make sure you **enter the data from left to right**, as the Excel worksheet **contains several cells that are dependent on others**. If you do not, the dropdown lists may not be enabled.
Please do not leave any blank lines.

3.7 Data validation

When you have finished the data entry, or if at any point you wish to check whether the data structure you have used is correct, go to the "Validation" worksheet and click on "Validate".

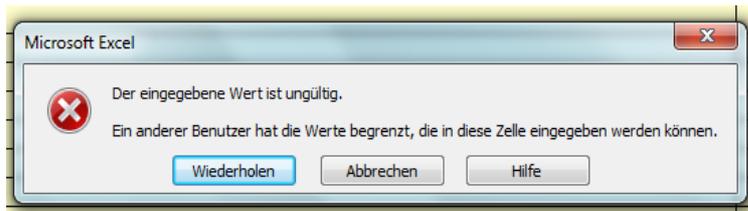


Excel tells you whether your data structure is correct or not, and what lines contain errors. Blank lines and all fields that contain errors are shown in red.



	B	C	D	E	F	G
1	Dateneingabe					
2						
3	Id 1	Id 2	Verwendung*	Tierart*	Andere Tierart	Zahl der verwendeten Tiere*
4						
5						
6						
7						
8			TI: nach § 7 Absatz 2 TierSchG	[A1] Mäuse (Mus musculus)		4
9						
10						

Entering data that does not correspond to data in a dropdown list also leads to an error message.



If errors are shown, please correct your data.

If you have corrected the errors in the corresponding lines of the worksheet, you can click on "Validate" again. The validation process will then be initiated and all fields in which the errors were corrected will be shown in normal format.

If you do not validate your data again, but instead wish to return to having the fields displayed in the normal format, click on "Clean validation".

If warnings continue to be shown after the data have been corrected, enter in the "Comments" field the reasons why the warnings for this set of data can be ignored.



N.B.:

When using "**T2: Section 4 (3) Animal Welfare Act**" animals, enter in column S "Severity" "[SV1] **Non-recovery**" to avoid error messages during validation.

4 Data dictionary

The data dictionary describes the data items that are to be reported.

Table 1 - Data dictionary for the Member States' reports

Data items	Yellow - User entry field (there are no restrictions on the length of the entry)
	Blue - Field with a fixed list from the Excel data sheet
	Green - to be completed by the authority

Data item	Requirement	Regulation(s) and comments
A: EU submission	to be left blank	
B: Id 1	to be left blank	
C: Id 2	to be left blank	
D: Use	Fixed list, mandatory field	Users must enter whether the animal testing consisted of a use under Section 7(2) or under Section 4(3) of the Animal Welfare Act.
E: Animal species	Fixed list, mandatory field	The following species are "Non-human primates": <ul style="list-style-type: none"> - [A18] Prosimians (Prosimia); - [A19] Marmosets und tamarins (e. g. Callithrix jacchus) - [A20] Cynomolgus monkeys (Macaca fascicularis) - [A21] Rhesus monkeys (Macaca mulatta) - [A22] Vervets (Chlorocebus spp. usually pygerythrus or sabaesus) - [A23] Baboons (Papio spp.) - [A24] Squirrel monkeys (e. g. Saimiri sciureus) - [A25-1] Other species of Catarrhines (Cercopithecoidea) - [A25-2] Other species of Platyrrhines (Ceboidea)
F: Other animal species	A field that is dependent on the data item "Animal species"	If you select an option from "Animal species" that includes the word "other", you must now enter what other species was used. Example: Spiny rats

Data item	Requirement	Regulation(s) and comments
G: Number of animals used	Mandatory field	A whole positive number must be given.
H: Reused	Fixed list, mandatory field You must enter whether the same animal was used previously in another experiment (Yes/No).	If the research project included animals used for the first time and animals that were reused, the data entered is to be broken down and entered in several lines.
I: Place of birth	Fixed list, Field dependent on the data items "Reused" and "Animal species"	The place of birth of the animals used must be given, except in the case of primates. The place of birth of animals that have been reused does not need to be entered.
J: Place of birth of primates	Fixed list, Field dependent on the data items "Reused" and "Animal species"	This column must be completed if you have selected "No" for "Reuse" and a "non-human primate" for "Animal species".
K: Primates' generation	Fixed list, Field dependent on the data items "Reuse" and "Animal species"	This column must be completed if you have selected "No" for "Reused" and a "non-human primate" for "Animal species". As long as the colony is not self-sustained, animals born in that colony are to be reported under F0, F1, F2 or greater according to their generation derived from the maternal line.
L: Genetic status	Fixed list, mandatory field Enter whether the animals were genetically altered or not, and the type of alteration.	The genetic status of the used animals is to be entered in accordance with the explanatory comments in Annex II (B) No. 6 of Implementing Decision 2012/707/EU (see also 5.2).
M: Creation of a new genetically altered line	Fixed list, mandatory field Enter whether a new genetic line was created or not.	
N: Purpose	Fixed list, field that is dependent on the data item "Creation of a new genetically altered line"	If you enter "Yes" in "Creation of a new genetically altered line", you can only select one purpose from the purpose category "Basic research" or "Translational and applied research".

Data item	Requirement	Regulation(s) and comments
O: Specify other purpose	A field that is dependent on the data item "Purpose"	If your entry in "Purpose" includes the word "Other", you must now enter what purpose the animal was used for.
P: Testing by legislation under...	Fixed list, A field that is dependent on the data item "Purpose" Enter the regulation on which the use of the animals was based.	This field is only to be completed if one of the options PR51 - PR106 was entered in column N. Example: [PR93] Regulatory use, toxicity and safety testing by test type/developmental toxicity
Q: Other legal foundation	Field that is dependent on the data item "Legally prescribed test pursuant to ..."	If your entry for "Legally prescribed test pursuant to..." includes the word "Other", you must now enter what legal instrument was used. Example: Spanish legal provisions
R: Legal source	Fixed list, A field that is dependent on the data item "Purpose" Enter the origin of the legal provisions on which the use of the animals was based.	This field need only be completed if the experiment served a regulatory purpose. Example: [PR93] Regulatory use, toxicity and safety testing by test type/developmental toxicity The determining factor is not who requests the test to be carried out but which legislation is satisfied, giving priority to the widest level of harmonisation.
S: Severity	Fixed list, mandatory field Enter the actual severity that occurred.	You must enter the severity of pain, suffering or damage that actually occurred, not the severity given in the application for authorisation or in the notification. If animals display different degrees of severity in a research project, the data are to be broken down and entered <u>in several lines</u> . If the use falls under Section 4 (3) Animal Welfare Act, the following should be entered in this column: "SV1 Non-recovery". In case of Section 25(2) Experimental Animal Welfare Ordinance, which deals with particularly onerous animal experiments which involve significant pain or suffering that lasts for longer periods and cannot be alleviated, data on exemption, on details of the use and on the reasons are to be made in column U.

Data item	Requirement	Regulation(s) and comments
T: Project number	Mandatory field Identification of the research project	Give the officially allocated data for the clear identification of the research project, e.g. the code number or reference number.
U: Comments	Optional field This enables you to explain, for example, any warnings.	The comments are not automatically processed by the application, but are visible to the user who processes the submitted file. The comment can then be used for all meaningful purposes. Rationale for entered data etc. Example: This animal experiment requires a very large number of -, because:
V: Purpose 2 (optional)	Optional field, fixed list or free text	This field allows other purposes to be entered for removal of organs / tissue under Section 4 (3) Animal Welfare Act. The entries are to be made in order of importance. The primary purpose is to be entered in column N.
W: Purpose 3 (optional)	Optional field, fixed list or free text	See column V

5 Annex/FAQs:

The following information is based on Implementing Decision 2012/707/EU of the European Commission of 20 December 2013 and on the Experimental Animal Reporting Ordinance

5.1 Which animals must be reported? How are the animals counted? When are the animals reported?

Sentinels are not reported unless they are used in an animal experiment.

Cephalopods, used under Section 4 (3) of the Animal Welfare Act, are not reported.

Larval forms of animals are to be reported once they become capable of independent feeding.

All cephalopod species are to be reported under the heading 'Cephalopods' from the stage at which the animal becomes capable of independent feeding i.e. immediately post-hatching for octopus and squid; and around seven days after hatching for cuttlefish.

Fish are to be reported from the stage of being capable of independent feeding onward. Zebrafish kept in optimal breeding conditions (approximately + 28C) are counted 5 days post fertilisation.

Due to the small size of some fish and cephalopod species, the count may, insofar as not otherwise possible, be done on the basis of estimation.

Foetal and embryonic forms of mammalian species are not counted; only animals that are born, including by Caesarean section, and live, are to be counted.

Each use of an animal is to be reported at the end of each research project. For research projects running longer than two calendar years, the data on the animals are to be reported in the year in which they are killed or die or in which they are no longer used in the animal experiment.

5.2 Data on genetically altered animals

'Genetically altered animals' include genetically modified (transgenic, knock-out and other forms of genetic alteration) animals and naturally occurring or induced mutant animals if the animals were used in the animal experiment due to this mutation.

Genetically altered animals are to be reported:

- when used for the creation of a new line;
- when used for the maintenance of an established line with an intended and exhibited adverse phenotype; or
- when used in other animal experiments (i.e. not for the creation or for the maintenance of a line).

All animals carrying the genetic alteration are to be reported during the creation of a new line. In addition, those animals used for superovulation, vasectomy or embryo implantation should equally be reported (these may or may not be genetically altered themselves). Genetically normal animals (wild type offspring) produced as a result of creation of a new genetically altered line are not reported.

In the category 'Purpose', the animals used for the creation of a new genetically altered line are reported under 'basic research' or 'translational and applied research' in the respective category the line is being created for.

'Not genetically altered' covers all animals that have not been genetically altered, including genetically normal parent animals used for the creation of a new genetically altered animal line/strain.

'Genetically altered without an adverse phenotype' includes animals used for the creation of a new line, carrying the genetic alteration but exhibiting no adverse phenotype, and genetically altered animals used in other animal experiments (not for creation or maintenance) but exhibiting no adverse phenotype.

'Genetically altered with an adverse phenotype' includes:

- animals used for the creation of a new line and exhibiting an adverse phenotype;
- animals used for maintaining an established line with an intended adverse phenotype and exhibiting an adverse phenotype; and
- genetically altered animals used in other animal experiments (not for creation or maintenance) and exhibiting an adverse phenotype.

5.3 From what point is a new line regarded as established? Which animals must be reported in respect of maintenance breeding?

A new strain or line of genetically altered animals is considered to be "established" when transmission of the genetic alteration is stable, which is a minimum of two generations, and a welfare assessment has been completed.

The welfare assessment determines if the newly created line is expected to have an intended adverse phenotype; if this is the case, the animals from this point onwards are to be reported under the category 'Maintenance of colonies of established genetically altered animals, not used in other procedures' – or, if appropriate, in the other animal experiments they are being used for.

If the welfare assessment concludes that the line is not expected to have an adverse phenotype, its breeding falls outside the scope of an animal experiment and no longer needs to be reported.

'Maintenance of colonies of established genetically altered animals, not used in other procedures' contains the animals required for the maintenance of colonies of genetically altered animals of established lines with an intended adverse phenotype and which have exhibited pain, suffering or lasting harm as a consequence of the adverse genotype. The intended purpose for which the line is being maintained for is not recorded. This excludes all animals needed for the creation of a new genetically altered line and those used in other animal experiments (other than creation/breeding).

5.4 How are animals which have a phenotype with effects, and which are used either for the removal of organs / tissue or in an animal experiment, reported?

All genetically altered animals which are used in other animal experiments (not for the creation or maintenance of a genetically altered line) should be reported under their respective purposes (the same way as any non-genetically altered animal). These animals may or may not exhibit an adverse phenotype.

Genetically altered animals, expressing an adverse phenotype, and killed for their organs and tissue, are to be reported as Section 7 (2) Animal Welfare Act animals under the respective primary purposes for which the organs/tissue were used. Columns V and W offer the possibility of breaking down the purpose further.

5.5 Data on reused animals

Each use of the animal is reported at the end of each animal experiment. For research projects running longer than two calendar years, the data on the animals are to be reported in the year in which they are killed or die or in which they are no longer used in the animal experiment.

The data on the place of birth are only required for naïve animals. For reused animals, their place of birth is therefore not recorded.

If a research project both uses animals for the first time and reuses animals, the data are to be broken down and entered in several lines.

The use after breeding (either creation or maintenance) does not constitute reuse. The following rule applies: the duty to report "accompanies" the animal that is used. The final user must report the entire animal experiment, taking into consideration the severity associated with the phenotype.

Later, the exact number of reused animals can no longer be deduced from the data, as some animals may be reused several times.

5.6 What is the difference between a first use and a reuse?

An animal experiment uses an animal for a single scientific/experimental/educational/ training purpose. A single use extends from the time when the first technique is applied to the animal until the completion of data collection, observations or achievement of educational objective.

A single animal experiment may contain a number of steps (techniques) all related to achieve a single outcome and which require the use of the same animal. The user reports the entire animal experiment including any preparation (regardless of the location this has taken place) and takes into account the severity associated with the preparation.

Examples of preparation include surgical procedures (such as cannulation, implantation of telemetry, ovariectomy, castration, hypophysectomy etc) and non-surgical procedures (such as feeding modified diets, induction of diabetes etc).

The same applies to the breeding of genetically altered animals i.e. when the animal is used in its intended animal experiment, the end user reports the entire animal experiment taking into account the severity associated with the phenotype. The following rule applies: the duty to report "accompanies" the animal that is used.

Should, for exceptional reasons, a prepared animal not be used for a scientific purpose, the establishment that has prepared the animal, must report the details of the preparation in the statistics as per the intended purpose, provided the preparation of the animal has been above the threshold of minimum pain, suffering, distress and lasting harm. This also applies, for example, to tail-tip biopsies (cf. > 7 Helpful links, Guidance Document of the European Commission "Question and Answer").

5.7 What is to be taken into account when assessing the severity?

The severity actually suffered by the animal in the animal experiment is to be given, not the severity predicted in the application for authorisation or the notification. If the severities differ within a research project, they are to be broken down and entered in several lines.

In certain cases, the suffering could be influenced by a previous use. However, the severity of suffering does not automatically increase in a subsequent use; and in some cases, it may even decrease due to habituation. Therefore there should be no attempt to automatically add up the severities from previous uses. The severity of suffering should always be judged on a case-by-case basis.

Whenever the "severe" classification is exceeded, whether pre-authorised or not, these animals and their use are to be reported under the "severe" category. Commentary is to be added covering the species and number of the animals, on whether prior exemption was authorised, on the details of the use and on the reasons why "severe" classification was exceeded.

If the use falls within Section 4(3) Animal Welfare Act, "Non-recovery" is to be entered as the severity, in order to avoid error messages in the validation.

Categories:

Non-recovery – Animals which have undergone an animal experiment that has been performed entirely under general anaesthesia from which the animal has not recovered consciousness are to be reported as non-recovery. If the use of animals falls within Section 4 (3) Animal Welfare Act, you should also enter 'Non-recovery'.

Mild (up to and including) - Animals which have undergone an animal experiment as a result of which the animals have experienced up to, and including, short-term mild pain, suffering or distress, but there was no significant impairment of the well-being or general condition of the animals, are to be reported as 'Mild'.

Note: This also includes any animals used in an authorised animal experiment which have ultimately not been observed to have experienced a level of pain, suffering, distress or lasting harm equivalent to that caused by the introduction of a needle in accordance with good veterinary practice.

It does not include animals required for the maintenance of colonies of genetically altered animals of established lines with an intended adverse phenotype and which have not exhibited pain, suffering, distress or lasting harm as a consequence of the adverse genotype (not reportable).

Moderate - Animals which have undergone an animal experiment as a result of which the animals have experienced short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as animals which have undergone animal experiments that have caused moderate impairment of the well-being or general condition of the animals are to be reported as 'Moderate'.

Severe - Animals which have undergone animal experiments as a result of which the animals have experienced severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as animals which have undergone animal experiments that have caused severe impairment of the well-being or general condition of the animals are to be reported as 'Severe'.

If the 'severe' classification pursuant to Section 25 (2) Experimental Animal Welfare Ordinance is exceeded, these animals and their use are to be reported under 'Severe'. Commentary is to be added covering the species and number of the animals, on whether prior exemption was authorised, on the details of the use and on the reasons why the 'severe' classification was exceeded. If this particularly severe exposure was unforeseen, this is also to be explained.

Please refer to Annex VIII of Directive 2010/63/EU for further information.

5.8 Data on the place of birth

The origin of the animal is based on its place of birth i.e. the place it was 'born in' and not according to the place which the animal was supplied from.

Animals born in the EU at a registered breeder covers animals born at breeders as authorised and registered under Section 11 (1) Animal Welfare Act (or according to the respective legal situation in other Member States).

Animals born in the EU but not at a registered breeder include animals born outside a registered breeder, such as wild animals, farm animals (unless the breeder is authorised and registered), as well as any exemptions granted under Section 19 (1) Experimental Animal Welfare Ordinance (see Article 10(3) of Directive 2010/63/EU).

Animals born 'in the rest of Europe' and animals born 'in the rest of the world' covers all animals regardless of whether they have been bred in registered breeding establishments or other establishments and includes animals that have been captured in the wild.

5.9 Data on the place of birth of primates

For the purposes of this reporting:

- 'Animals born at a registered breeder in the EU' covers animals born in the Member States;
- 'Animals born in the rest of Europe' includes animals born in Turkey, Russia and Israel;
- 'Animals born in Asia' includes animals born in China;
- 'Animals born in America' includes animals born in North, Central and South America;
- 'Animals born in Africa' includes animals born in Mauritius;
- 'Animals born elsewhere' includes animals born in Australasia.

The origins of animals recorded under 'Animals born elsewhere' are to be detailed to the competent authority with the data submission.

5.10 Data on the generation of primates

As long as the colony is not self-sustained, animals born in that colony are to be reported under F0, F1, F2 or greater according to their generation derived from the maternal line.

Once the colony is self-sustained, all animals born in that colony are to be reported under 'Self-sustaining colony' regardless of their generation derived from the maternal line.

5.11 Data on the purpose

The primary purpose is to be given. If necessary, the purpose can be specified in greater detail in columns V and W.

Basic research

Basic research includes studies of a fundamental nature including physiology, studies that are designed to add knowledge about normal and abnormal structure, functioning and behaviour of living organisms and environment (this includes fundamental studies in toxicology) as well as investigation and analysis focused on a better or fuller understanding of a subject, phenomenon, or a basic law of nature instead of on a specific practical application of the results.

When animals are used for the creation of a new genetically altered animal line (including crossing of two lines) for the purposes of basic research (e.g. developmental biology, immunology), they are to be recorded according to the purpose they are being created for. In addition they are to be reported in 'Creation of a new genetic line'.

Oncology

- This covers any research studying oncology, regardless of the target system.

Nervous system

- This category includes neuroscience, peripheral or central nervous system and psychology.

Sensory organs (skin, eyes and ears)

- Studies on the nose are to be reported under 'Respiratory system' and those on the tongue are to be reported under 'Gastrointestinal system including liver'.

Multisystemic

- This only covers research where more than one system is the primary interest, such as on some infectious diseases, and excluding oncology.

Ethology/Animal Behaviour/Animal Biology

- This category covers both animals in the wild and in captivity, with the primary goal of learning more about that specific species.

Other

- This category covers research that is not related to an organ/system listed above or is not organ/system specific. The exact purpose is to be entered in the following column.

Translational and applied research

Translational and applied research uses animals for the following purposes (any regulatory use of animals is excluded):

- prevention, detection or treatment of diseases, suffering, physical harm or physical discomfort in humans and animals;
- detection of or influence on the physiological condition of humans or animals; or
- promotion of the welfare of animals or improvement of production conditions for animals reared for agricultural purposes.

This also includes discovery toxicology and investigations to prepare for the regulatory submission and method development. This does not include studies required for regulatory submissions.

Animals which are used for the creation of a new genetically altered animal line (including crossing of two lines) and for the purposes of translational or applied research (e.g. cancer research, vaccine development) are to be recorded according to the purpose they are being created for. They are also to be reported in 'Creation of a new genetic line'.

Any applied research studying human cancer and human infectious disorders is to be reported under 'Translational and applied research' regardless of the target system.

Any regulatory use of animals, such as regulatory carcinogenicity studies, is excluded.

Studies on disorders of the nose should be reported under 'Human respiratory disorders' and those of the tongue should be reported under 'Human gastrointestinal disorders including liver'.

'Diagnosis of diseases' includes animals used in direct diagnosis of diseases such as rabies or botulism, but excludes those covered under regulatory use.

'Non-regulatory toxicology' covers discovery toxicology. Investigations to prepare for the regulatory submission and method development are also to be reported under 'Non-regulatory toxicology'. This category does not include studies required for regulatory submissions (preliminary studies, MTD (Maximum Tolerated Dose)).

Studies on the

- promotion of the welfare of animals or improvement of production conditions for animals reared for agricultural purposes

are to be reported under 'Animal welfare'.

Comments on basic research and on translational and applied research

Animals used for the production and maintenance of infectious agents, vectors and neoplasms, animals used for other biological material and animals used for the production of polyclonal antibodies (but excluding production of monoclonal antibodies by the ascites method (which is covered under 'Regulatory use and routine production by type')) are to be reported in the respective fields of categories 'Basic research studies' or 'Translational and applied research'. The purpose of studies must be carefully established, because listings may be possible under two categories and only the primary purpose should be reported. Other purposes, or purposes that are not given in the dropdown list, can be specified in greater detail in columns V and W (free text is possible).

Regulatory use and routine production by type

The regulatory use and routine production includes:

- the use of animals in animal experiments carried out with a view to satisfying legal requirements for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed.
- Tests carried out on products/substances for which no regulatory submission is ultimately made (e.g. tests on products/substances which were originally intended for regulatory submission but which fail to reach the end of the development process).
- Animals used in the manufacturing process of products if that manufacturing process requires regulatory approval (e.g. animals used in the manufacturing of serum-based medicinal products should be included within this category).

The efficacy testing during the development of new medicaments/medicinal products is excluded and should be reported under the category "Translational and applied research".

'Quality control' includes animals used in the testing of purity, stability, efficacy, potency and other quality control parameters of the final product and its constituents and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international regulatory requirements or to satisfy the in-house policy of the manufacturer. This includes pyrogenicity testing.

'Other efficacy and tolerance testing' includes efficacy testing of biocides and pesticides as well as the tolerance testing of additives in animal nutrition.

'Toxicity and other safety testing' (including safety evaluation of products and devices for human medicine and dentistry and veterinary medicine) covers studies carried out on any product or substance to determine its potential to cause any dangerous or undesirable effects in humans or animals as a result of its intended or abnormal use or its manufacture. It also covers studies carried out on the potential or actual presence of the product / substance as a contaminant in the environment.

'Routine production' covers the production of monoclonal antibodies (by ascites) and blood products including polyclonal antisera by established methods. This excludes immunisation of animals for hybridoma production which should be reported under 'Basic research' or 'Applied research'.

Protection of the natural environment in the interests of the health or welfare of human beings or animals

This includes studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity, and epidemiology studies in wild animals.

It excludes any regulatory use of animals for ecotoxicology purposes.

Higher education or training for the acquisition, maintenance or improvement of vocational skills

This includes training to acquire and maintain practical competence in techniques as required under Section 3(1) and (2) Experimental Animal Welfare Ordinance (cf. Article 23(2) Directive 2010/63/EU).

Testing required by legislation

The legislative requirement should be entered as per the intended primary purpose.

Data on water quality, if concerning e.g. tap water, are to be reported under 'Food legislation'.

The determining factor is not who requests the test to be carried out but which legislation is satisfied.

Where national legislation is derived from EU legislation (e.g. to implement EU law), only 'Legislation satisfying EU requirements' is to be chosen. Legislation satisfying EU requirements also includes any international requirement which at the same time satisfies EU requirements (such as testing to ICH, VICH, OECD guidelines, European Pharmacopoeia monographs).

Legislation satisfying national requirements only (within the EU) is to be chosen only when the test is carried out to satisfy the requirements of one or more Member State; not necessarily the one in which the work is being carried out. However, there is no equivalent requirement in the EU.

Legislation satisfying Non-EU requirements only is to be chosen when there is no equivalent requirement to carry out the test to satisfy EU requirements.

Quality control (incl. batch safety and potency testing)

Batch safety testing excludes pyrogenicity testing. These are to be reported under a separate category 'Pyrogenicity testing'.

Toxicity and other safety testing by test type

Immunotoxicology studies should be covered under 'Repeated dose toxicity'.

Kinetics (pharmacokinetics, toxicokinetics, residue depletion): if toxicokinetics is performed as part of the regulatory repeat dose toxicity study, it should be reported under 'Repeated dose toxicity'.

Safety testing in the food and feed area includes testing of drinking water (including target animal safety testing).

Target animal safety: this covers testing to ensure a product for a specific animal can be used safely on that species (excluding batch safety testing which is covered under 'Quality control').

6 Troubleshooting

Error	Solution
The dropdown lists in the simple (horizontal) data-entry method do not work.	There are fields that are dependent on others; in some cases, it may not be possible to select a data item if the previous data have not yet been entered. Enter the data from left to right.
An error message appears when entering data from another Excel file (error message: "The cell you are trying to change is protected and therefore read-only".)	Columns A-C need not be filled in. Click on a cell in column D and enter your data.

7 Helpful links

Working document on evaluating the effects on genetically modified animals (in German):

<http://www.bfr.bund.de>
 >ZEBET >Beratung von Behörden und Tierschutzgremien zum Schutz für wissenschaftliche Zwecke verwendeter Tiere > Mitteilungen
 (http://www.bfr.bund.de/cm/343/beurteilung-der-belastung-genetisch-veraenderter-tiere.pdf)

Final Report of the expert working group on severity classification of scientific procedures performed on animals:

<http://www.bfr.bund.de>
 >ZEBET >Beratung von Behörden und Tierschutzgremien zum Schutz für wissenschaftliche Zwecke verwendeter Tiere > Sonstiges
http://www.bfr.bund.de/cm/343/5_Beratung_Anlage%205_EU%20Belastungskatalog.pdf

"Question & Answer" document of the European Commission

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/qa.pdf

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