HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Technical guidance for
Completion of Statistical Returns form under Scientific Animal Protection Legislation

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1 INTRODUCTION

This guidance is intended to outline the technical specifications required for entering data in the updated European Commission (EC) Excel template (for reporting years 2021 onwards), which must be used for submission of annual statistical returns on the scientific use animals to the Health Products Regulatory Authority (HPRA). This technical guidance must be used alongside the following two guides:

- Guide to statistical reporting under scientific animal protection legislation
- Help file – Completing the European Commission spreadsheet for statistical returns

2 TECHNICAL SPECIFICATIONS FOR THE EXCEL TEMPLATE

2.1 Notes

- Data can be entered in two ways: by completing rows on the Excel sheet entitled 'List' or by clicking the grey button on the 'List' sheet entitled 'Click to enter data' and using the data entry form that pops up. It may be preferable to use the data entry form as all fields can be viewed at once, there is less room for error, and there is the option to duplicate rows.

- The data entry form may not be fully visible on a computer screen that is scaled to greater than 100%. Computer display settings should be scaled to 100% (or less) in order to view the data entry form in full.

- To begin data entry, click into **row 4** on the sheet (the first available row for data entry). If row 4 is inadvertently skipped, and data is entered in other rows, the file will be invalid.

- If using the Excel sheet for data entry, where there is a drop down list, this must be used. Entering free text over drop down lists will cause the file to be invalid.

- Compulsory fields are marked with an asterix (*). Failure to complete compulsory fields will render the file invalid.

- In the data entry form, there are a number of fields entitled 'Ignore'; no data should be entered in these fields.

2.2 Entering data in each field

The following table illustrates how to enter data in each field.

FIELD	INSTRUCTIONS
EU Submission	Select [Y] Yes if animals have undergone procedures, or [N] No if animals have not undergone procedures and instead were killed for tissues and organs, or as surplus animals.
Estab Auth No	Enter the establishment authorisation number in the format AEXXXXX.
Project Auth No	If animals have undergone procedures within the framework of a HPRA project authorisation, enter the project authorisation number in the format AEXXXXX/PXXX (do not use any spaces). This field is mandatory if animals were part of a project authorisation, however it should be left blank if animals did not undergo procedures under a project authorisation, but rather were killed for tissues and organs, or as surplus animals.
PM initials	Enter the initials of the project manager (PM) if the entry relates to animals that have undergone procedures within the framework of a project authorisation. However, where animals did not undergo procedures (e.g. killed for tissues and organs only, or because they were surplus breeding animals), the initials of the person completing the form should be entered.
Animal species	Choose from the drop down list.
Specify other	Enter a species in this field only if the species used is not included in the drop down list in *Animal species*.
Number of animals	Enter the number of animals.
Re-use	Select [Y] Yes or [N] No.
Place of birth	Choose from the drop down list. This field should be left blank if [Y] Yes for *Re-use* was selected.
Genetic status	Choose from the drop down list.
Creation of a new GA line	Select [Y] Yes or [N] No.

FIELD	INSTRUCTIONS
Purpose	Choose from the drop down list. Use the 'Browse' button to browse the subcategories (Levels 2, 3 and 4). When reporting animals that did not undergo procedures, but were killed for tissues and organs, select the most appropriate purpose that applies to the use of their tissues. If animals were killed as surplus animals select [PN107] Non-EU Purpose.
Specify other	This field should only be populated if the Level 2 purpose selected contained the word 'other'; in this case, text should be entered to provide information on what the exact purpose of the animal use was.
Type of legislation	This should only be completed for projects of a regulatory nature. Choose from the drop down list.
Specify other	This field should only be populated if the *Type of legislation* selected contained the word 'other'; in this case, this field should be used to provide additional information on the specific legislation the testing was performed to satisfy.
Origin of legislation	This should only be populated to report the use of animals in projects of a regulatory nature. Choose from the drop down list.
Actual severity	Choose from the drop down list. Ensure to enter the **actual severity** experienced, rather than the prospective severity included in the authorisation document.
Custom severity	This field should only be populated in circumstances where actual severity experienced exceeded the 'severe' severity banding; in this case this field should be used to provide an explanation as to why 'severe' severity was exceeded. Please note, this would be considered an extremely rare occurrence and should be discussed with the HPRA before completing the relevant statistical return.
Explanation of warnings	After performing the mandatory file quality check using the EC website (see Part 4 - Quality Control), this field can be used to provide clarification on any 'warnings' received in relation to the submission.

FIELD	INSTRUCTIONS
Comments	This field should only be populated to provide an explanation in relation to why this file cannot be validated (see Part 3.2 - Validating the file).
Method of tissue sampling	If animals have been genotyped (including through the use of surplus tissue from identification), choose the relevant method from the drop down list. Otherwise leave this field blank.
Specify other method	If the *Method of tissue sampling* used is not included in the previous drop down list, enter details of the method used in this field. Otherwise leave this field blank.
Severity of genotyping	Choose from the drop down list. This drop down list will only appear if an invasive method of genotyping was selected.
Killing only?	Type 'Yes' in this field to report animals that did **not** undergo procedures but were killed for tissues and organs or as surplus animals (ensuring that [N] No has already been selected in the *EU Submission* field). Leave blank if animals have undergone procedures.

3 SAVING AND VALIDATING

3.1 Saving the entry

Always click 'Save' before closing the data entry box. To duplicate an entry (i.e. create a second line with the same data which can be amended as necessary), click 'Save and Duplicate'.

3.2 Validating the file

Once the file has been populated with data and saved, close the data entry form and click on the second sheet in the Excel document entitled 'Validation'. Click the 'Validate' button and fix any errors that are flagged in red on the first sheet entitled 'List'. Return to the 'Validation' sheet, click 'Clean Validation', and then 'Validate' again. Continue this process until all errors have been cleared from the sheet and confirmation is received that 'Animal use details tab is correct'. If it is not possible to correct all of the errors, and the file cannot be validated, enter an explanation (for HPRA staff to assess) in the *Comments* field of all the rows with errors (see table for details).

4 QUALITY CONTROL

The EC has created a quality control resource which should be used to ensure that all compulsory fields are correctly completed and no errors on the file structure can be detected. It also flags unusual entries as 'warnings' (e.g. very large animal numbers, unusual combinations of species combined with certain types of testing) to allow the user to check that the data has not been entered erroneously.

The quality control resource is accessible at the following link:

https://webgate.ec.europa.eu/envdataportal/web/resources/public/alures/statistics/validate

File quality for all annual statistical returns submissions for 2021 onwards must be checked using this portal prior to submission to the HPRA. The year selected should be the year that the data relates to. Any 'warnings' that remain after any errors have been rectified (and the file quality checked again) should be explained in the file prior to submission to the HPRA (see *Explanation of warnings* in the table for details). Any statistical returns found to have quality issues that would prevent validation following final submission to the EC database (where explanations are not provided by the user) will be returned to the user for correction and flagged to the breeder/supplier/user establishment's compliance officer.