Guide to
Technical Specifications for Completion of Non-technical Project Summaries

1 SCOPE

This guidance is intended to assist applicants submitting a Health Products Regulatory Authority (HPRA) 'Application for a Project Authorisation under Scientific Animal Protection Legislation', to understand the technical specifications required for entering data in the European Commission Excel template, which must be used for submission of non-technical project summaries (NTS) as part of the project application process.

2 INTRODUCTION

The protection of animals used for scientific procedures is governed by Directive 2010/63/EU which was transposed into Irish law by S.I. No. 543 of 2012. Article 43 of Directive 2010/63/EU and Regulation 33 of S.I. No. 543 of 2012 describe both the content of the NTS and the requirements for publication.

Article 43 of Directive 2010/63/EU and Regulation 33 of S.I. No. 543 of 2012 have been amended as a result of Article 6 of Regulation (EU) 2019/1010 on the alignment of reporting obligations. The changes introduced by Regulation (EU) 2019/1010 are intended to facilitate the publication of the NTS in a centralised, searchable European Union (EU) database. Commission Implementing Decision 2020/569/EU sets out a common format for submitting information to the Commission, and the NTS must now be submitted using a new ~~European Commission (EC) Excel template (available here~~European Commission (EC) Excel template)~~.~~.

The purpose of this document is to provide guidance specifically in relation to the technical specifications of entering data into this Excel template. The EC has published ~~draft~~ guidance on the content of the NTS which is available here. It is important that applicants refer to both this guidance on technical specifications, and the EC guidance on the content of the NTS when drafting an NTS as part of the project application process.

3 TECHNICAL SPECIFICATIONS FOR THE EXCEL TEMPLATE

3.1 Country

This is a compulsory field. Please select 'IE' (country code for Ireland) from the dropdown list.

3.2   Language

This is a compulsory field. Please select 'EN' (language code for English) from the dropdown list.

3.3   EU submission

This is a compulsory field. Please select 'Yes' from the dropdown list.

3.4   Title of the project

This is a compulsory field with a maximum length of 500 characters.

3.5   NTS identifier

Please leave this field blank.

3.6   NTS national identifier

Please leave this field blank.

3.7   Duration of the project

This is a compulsory field. The project duration should be expressed in months (this must be entered as a whole number between 1 and 60).

3.8   Keywords

This is a compulsory field. Keywords can consist of more than one word (i.e. can be a multi-word term). At least one keyword must be entered, with a total of five keywords permissible. Keywords should not be a repeat of any of the words in the project title and should not include the species to be used. The maximum length for each keyword is 50 characters including word spacing.

3.9   Purpose(s) of the project

Select the *Purpose of the project* tab to access the dropdown menu listing project purposes. These are the purposes in accordance with statistical reporting categories and some sub-categories in Annex III to Decision (EU) 2020/569. At least one purpose must be chosen, with the

option to choose more than one if appropriate. The purpose should match the purpose selected in Section D1 of the project application form.

3.10 Objectives and predicted benefits of the project

3.10.1 Objectives of the project

This is a compulsory field with a maximum length of 2,500 characters.

3.10.2 Potential benefits likely to derive from this project

This is a compulsory field with a maximum length of 2,500 characters.

3.11 Predicted harms

3.11.1 In what procedures will the animals typically be used

This is a compulsory field with a maximum length of 2,500 characters.

3.11.2 Expected impacts/adverse effects on the animals

This is a compulsory field with a maximum length of 2,500 characters.

3.12 Expected harms

SelectClick the *Expected harms* link (on line 26) to bring you to the *Expected harms* tab to access. (This is not a free-text field, do not overwrite this field on line 26.) On this sheet, use the dropdown menu which captures expected severitiesto select the animal species, and input the estimated number of animals in each severity category (further sub-divided per. Use a new line for each species),. Insert 0 for any overall severity that animals are not expected to experience. This tab is a compulsory field – at least one row must be filled in for the submission to validate.

3.13 Fate of animals kept alive

Please note, this tab is only applicable if animals are kept alive following the end of their time on a particular study. If all animals used under a project authorisation are killed during/at the end of their time on study, then this tab should not be completed as it is not relevant.

For projects in which some/all of the animals used are kept alive at the end of their time on study, ~~select the~~ click the *Fate of animals kept alive* link (on line 27) to access the *Fate of animals kept alive* tab ~~to access~~. (This is not a free-text field, do not overwrite this field on line 27.) On this sheet, use the dropdown menu. ~~This dropdown menu captures~~ to select the animal species, then input the numbers of animals to be re-used (in another procedure/project authorisation), returned to habitat/husbandry, or rehomed. Any animals to which these categories are relevant should be captured per species. Insert 0 for any fate that is <u>not</u> applicable. Use a new line for each species.

3.14   Reasons for the planned fate of the animals after the procedure

This is a compulsory field requiring the description of the reasons for the planned fate of <u>all</u> animals to be used in the project, using a maximum of 2,500 characters.

3.15   Application of the 3Rs

3.15.1   Replacement

This is a compulsory field with a maximum length of 2,500 characters.

3.15.2   Reduction

This is a compulsory field with a maximum length of 2,500 characters.

3.15.3   Refinement

This is a compulsory field with a maximum length of 2,500 characters.

3.15.4   Explain the choice of species and the related life stages

This is a compulsory field with a maximum length of 2,500 characters.

3.16   Projects selected for retrospective assessment

Please leave all ~~of the~~ fields in this section of the Excel blank.

3.17   Additional fields

Please leave all ~~of the~~ fields in this section of the Excel blank.

4   QUALITY CONTROL

The EC has created a File Quality Control resource for project applicants, to ensure that all compulsory fields are correctly completed and no errors on the file structure can be detected.

The File Quality Control module is accessible at the following link:

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

File quality for all NTS submissions <u>must</u> be checked using this portal prior to inclusion in applications for HPRA project authorisation. Any NTS found to have quality issues that would prevent validation following submission to the EC database (e.g. compulsory fields not completed, or character count exceeded) **will be returned to the applicant** for correction. The evaluation of applications for project authorisation will be halted while applicants are addressing quality issues, which may result in delays to the project evaluation process.