National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes

Working document on Non-Technical Project summaries

Brussels, 23-24 January 2013

The National Contact Points of the Member States responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes and the Commission agreed to discuss the practical implementation of the requirement under Article 43 of the Directive with a view to finding a common approach throughout the EU.

The consensus on the approach discussed and endorsed at the meeting of 23-24 January 2013 is presented below to promote uniform implementation and application of the Directive.

Disclaimer:

The following is intended as guidance to assist the Member States and others affected by this Directive to arrive at a common understanding of the provisions contained in the Directive. All comments should be considered within the context of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority.

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Article 43 of Directive 2010/63/EU

Non-technical project summaries

1. Subject to safeguarding intellectual property and confidential information, the nontechnical project summary shall provide the following:

> *(a) information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used;*
>
> *(b) a demonstration of compliance with the requirement of replacement, reduction and refinement.*

The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.

2. Member States may require the non-technical project summary to specify whether a project is to undergo a retrospective assessment and by what deadline. In such a case, Member States shall ensure that the non-technical project summary is updated with the results of any retrospective assessment.

3. Member States shall publish the non-technical project summaries of authorised projects and any updates thereto.

Content of Non-technical Project Summaries

Article 43 of the Directive gives some guidance on what has to be included in the Nontechnical Project Summaries (NTS), but some additional guidance is considered helpful to promote consistency between Member States.

A recommended word limit of 500 (one A4 page) should be sufficient to include all necessary information for all but the most complex projects.

A standard framework or list of headings should be provided to ensure that all relevant information is submitted. For the purposes of consistency, a common template has been proposed in Annex I.

Publication of Non-Technical Summaries

NTS should be published when the project is authorised. Delays to publication may be necessary where concerns over confidentiality have not been satisfactorily addressed.

The summaries should be published on the Member State/National Contact Point webpage, and should be accessible for at least five years after a project is finished.

In cases when a NTS is updated as a result of Retrospective Assessment, the summaries should be accessible for at least five years after the completion of the Retrospective Assessment.

For smaller Member States, there may be a risk that publication nationally could jeopardise the conduct of the project by identifying (indirectly) the institution where the study is being conducted (even if not explicit, certain studies could only be carried out in one or two

institutions). It is important that such risks are given due consideration.

A group of Member States could opt to publish consolidated NTS at a single site – the source of the NTS would then be much less likely to be identified.

Published abstracts, and the place where they are published, should be in a format that is searchable by intuitive keywords such as individual species, purpose of procedure, refinement.

Updating of Non-Technical Summaries following a retrospective assessment

It is optional whether or not Member State decides to update NTS following a retrospective assessment (RA) (Article 43(2)).

New/replacement project applications to continue a programme of work will often include information on results achieved under previous project which can simplify and facilitate updating of the NTS where RA has been required.

Any update to the NTS following RA should be agreed with the applicant to ensure accuracy with regards to the result of the RA and anonymity.

How to ensure that Non-Technical Summaries are accurate and representative of the project

This should form part of the project evaluation process by the competent authority who shall ensure that NTS is accurate and representative of the project. The project should not be authorized until a satisfactory NTS is completed.

Input from a "lay person" in the project application process should encourage the development of easily understood NTS.

The Animal Welfare Body may be helpful in assisting the applicant on content and accuracy.

The National Committees for the protection of animals used for scientific purposes may be helpful in reviewing the consistency of NTS submissions retrospectively.

Ensuring the safeguarding of intellectual property and confidential information

Article 43 requires that intellectual property (IP) and confidential information shall be safeguarded.

The NTS shall be anonymous and shall not contain the names and addresses of the user and its personnel. The NTS shall not violate proprietary rights or expose confidential information (Article 43(1))

Applicants for projects should be aware of these constraints, know that NTS will be made

publicly available and that it is their responsibility to ensure that the NTS included in the application does not contain such information.

Meaningful and relevant information should be made available in the summaries and information should only be omitted where necessary on the above grounds.

Public confidence in the publication of NTS may be adversely affected should the information be inaccurate or incomplete.

Additional information for authors

- Audience is general public not fellow scientists.
- Use language which will be easily understood by the public. For example, use "under the skin" rather than "subcutaneous".
- Use words that can be clearly understood such as "medicine" rather than "drugs", and if necessary, give an explanation.
- Provide a balanced view consistent with the project application as far as potential benefits and welfare costs to the animals are concerned.

Annex I – Template/Headings for a Non-Technical Summary

Project Title			
Duration of Project			
Key Words (maximum of 5)			
Purpose of Project (as in Article 5)	Basic research	Yes	No
	Translational and applied research	Yes	No
	Regulatory use and routine production	Yes	No
	Protection of the natural environment in the interests of the health or welfare of human beings or animals	Yes	No
	Preservation of species	Yes	No
	Higher education or training	Yes	No
	Forensic enquiries	Yes	No
	Maintenance of colonies of genetically altered animals, not used in other procedures	Yes	No
Describe the Objectives of the Project (e.g the scientific unknowns or scientific or, clinical needs being addressed)			
What are the potential benefits likely to derive from this Project (how science could be advanced or humans or animals could benefit from the project)?			
What species and approximate numbers of animals are expected to be used?			
In the context of what is being done to the animals, what are the expected adverse effects on the animals, the likely/expected level of severity and the fate of the animals?			
Application of the 3Rs			
1. Replacement State why animals need to be used and why non-animal alternatives cannot be used			
2. Reduction Explain how the use of minimum numbers can be assured			
3. Refinement Explain the choice of species and why the animal model(s) used are the most refined, having regard for the scientific objectives Explain the general measures to be taken to minimise welfare costs (harms) to the animals.			

Annex II - An illustrative example of a completed Non-Technical Summary

Project Title	Understanding bone marrow failure in leukaemia		
Duration of Project	Five years		
Key Words (maximum of 5)	Tumour ; leukaemia; chemotherapy; radiation		
Purpose of Project (as in Article 5)	Basic research		No
	Translational and applied research	Yes	
	Regulatory use and routine production		No
	Protection of the natural environment in the interests of the health or welfare of human beings or animals		No
	Preservation of species		No
	Higher education or training		No
	Forensic enquiries		No
	Maintenance of colonies of genetically altered animals, not used in other procedures		No
Describe the Objectives of the Project (e.g the scientific unknowns or scientific or, clinical needs being addressed)	Leukaemia is a cancer of the bone marrow. Treatment of adults with leukaemia is unsatisfactory with only a minority being cured. Drugs against acute myeloid leukaemia were discovered in the 1960s, but no more effective drugs have been discovered since then. For a common type of adult leukaemia, acute myeloid leukaemia, most patients die from the disease despite chemotherapy. New approaches to developing drugs are required. A problem with leukaemia is that it appears to go away completely, but relapses after treatment has ended. This may be because a few 'tough' leukaemia cells (leukaemic stem cells) survive and grow again. We will study how leukaemia cells dominate the bone marrow and make it stop producing normal blood cells such as red blood cells (that carry oxygen round the body) or white blood cells (that fight infection). Mice with deficient immune systems will be used, following transplantation with human leukaemic cells, to assess the effects of new drugs. Although assessment in cells in test-tubes will provide some information, we need to follow the effects over a longer time period in an animal to ensure all the leukaemic cells have been killed and relapses do not occur.		
What are the potential benefits likely to derive from this Project (how science could be advanced or humans or animals could benefit from the project)?	The overall aim of the work is to improve understanding of leukaemia and to develop improved treatments for patients, especially to prevent relapses.		
What species and approximate numbers of animals are expected to be used?	Up to 5000 mice over a period of 5 years.		
In the context of what is being done to the animals, what are the expected adverse effects on the animals, the likely/expected level of severity and the fate of the animals?	The animal's own bone marrow will be depleted by injecting a drug or by radiation. This will cause tiredness and reduced appetite for about a week. Leukaemia will then be induced by intravenous injection of leukaemic bone marrow. Mice with leukaemia may become lethargic and lose weight. The expected level of severity is moderate. Animals will be humanely killed at the end of the study.		
Application of the 3Rs			
1. Replacement State why animals need to be used and why non-animal alternatives cannot be used	Human leukaemia cells grow poorly and only for short periods (a few days) once taken out of a living body and maintained in cell culture systems. This prevents us from studying anything but short term effects in the test tube. Given that leukaemias take weeks to months to develop, we need other ways to study leukaemia cells. Immunodeficient mice exist that do not reject human bone marrow cells. We can transplant human bone marrow cells into these mice. Similarly, we can transplant leukaemia cells into the mice. This allows us to study how the leukaemias grow over several weeks.		
2. Reduction Explain how the use of minimum numbers can be assured	The estimated number of animals is based on our current experience of designing these types of studies. We consult with a biostatistician before conducting each study to ensure that we are using the minimum number of animals to achieve the desired result.		

3. Refinement Explain the choice of species and why the animal model(s) used are the most refined, having regard for the scientific objectives. Explain the general measures to be taken to minimise welfare costs (harms) to the animals.	The immune-deficient mice will be kept in a protected environment to reduce the risk of infection. They will be group housed with appropriate litter, nesting material and nest boxes. Chemotherapy and radiation treatments will cause some adverse effects. Doses are calculated to minimise these, consistent with the scientific objectives. If animals get infections or become seriously ill they will be humanely killed.