European legislation
Impact on the scientific use of animals

Report WP 3, Task 3.1

WP3 – The Directive, the Ethical Landscape and the Practice of Ethical Review

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Final Report on Task 3.1: Map ethical bodies and ethical review systems for animal research in EU by expanding and updating the FELASA WG Report

1. BACKGROUND

The ANIMPACT project analyses the interaction between legislation and practice in biomedical research using animals, in the light of the recently completed implementation of Directive 2010/63/EU. This Directive, adopted by the European Union on 2010, updated and replaced the Directive 86/609/EEC. As of March 2015, all Member States have completed the transposition process (European Commission transposition scoreboard[1]).

This report presents the result of a mapping of the different approaches to evaluation and authorisation of projects with animals in different Member States. Specifically, the mapping has focused on general organization and the expertise and representation in evaluation bodies.

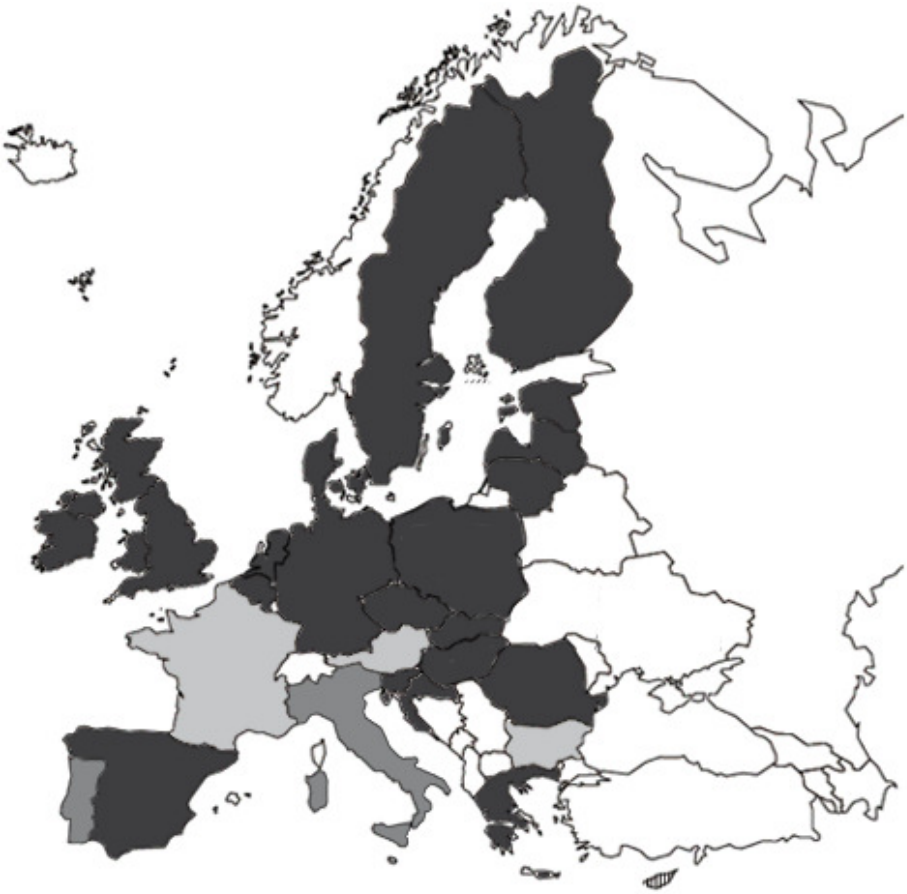
2. METHODOLOGY

The data presented here were collected through a combined approach, in which first a web search was combined with individual informants in each Member States (MS) to generate a first set of country-specific information. This was then sent to the respective competent authority (MS authorities for Directive 2010/63/EU/ National contact points as per article 59 of the Directive), asking them to confirm, complement or correct the existing information.

At the time of writing (August 2015), competent authorities (CA) from 20 Member States have responded, allowing the process to be completed for these countries. This document will be updated as additional confirmations are received. The map illustrates the status of information for the different MS.

[1] Available at: http://ec.europa.eu/environment/chemicals/lab_animals/transposition_en.htm accessed on 06.07.2015, last update on 22.04.2015

Fig.1. State of the art of the mapping process (more information available on Table 2/Appendix 1)



Fully informed information (by CA)
Confirmed by local ANIMPACT team member
Awaiting confirmation
Excluded due to marginal relevance of animal research

3. RESULTS

3.1. Changes to the project evaluation and authorisation process introduced by Directive 2010/63/EU

In most Member States, the transposition of the Directive has not introduced major changes to the review and authorisation procedure for projects with animals.

3.2. Main actors in the regulation and authorisation process

3.2.1. Ministries and Competent Authorities

As described in the **Appendix 2**, the regulation of animal experiments falls under the Ministry of Agriculture in most MS.

3.3. Key aspects of the project evaluation and authorisation process: Similarities and differences between MS

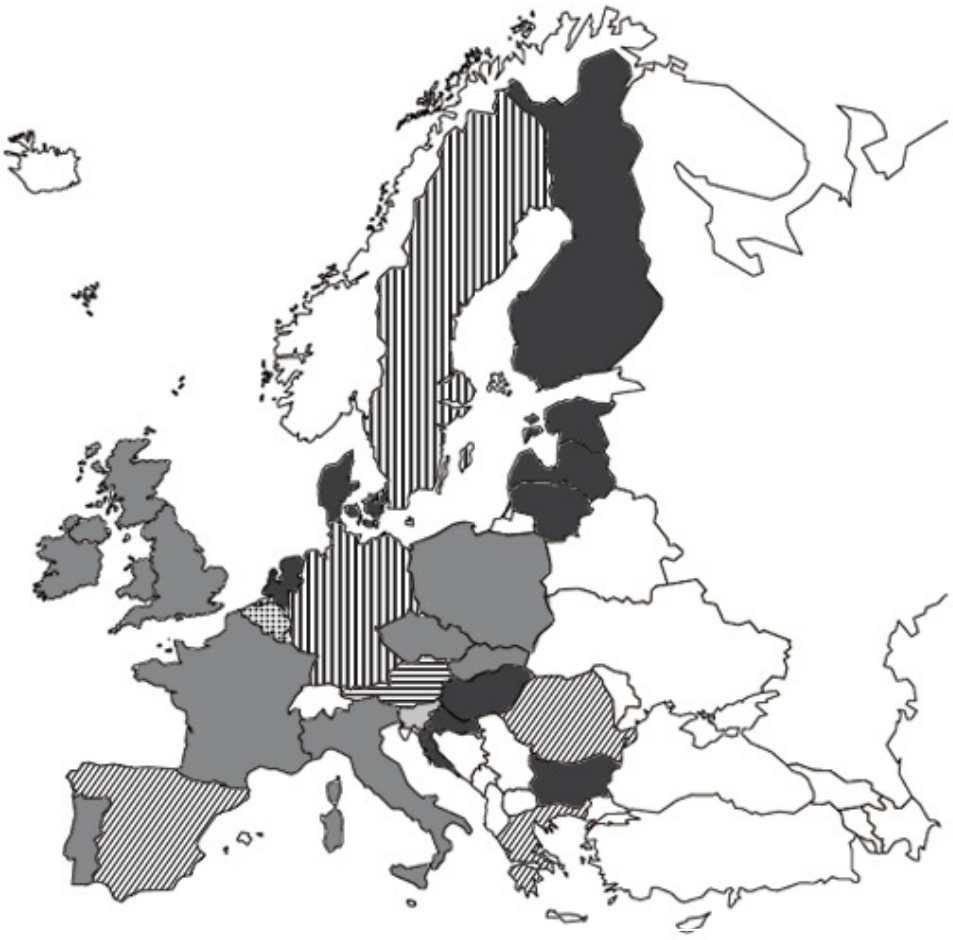
3.3.1. Organization of the project evaluation and the authorisation process

There is considerable variation in organization as regards at which level the evaluation and the authorisation takes place. In many MS there is a combination of several approaches. The two most common approaches are:

- The projects' evaluation and authorisation at a national level (the evaluation is conducted at a national level, by a national committee, and the authorisation is also provided at a national level, usually by the competent authority)

- The projects' evaluation at institutional/local or regional level combined with an evaluation at a national level with the authorisation being provided also at a national level (the evaluation is primarily conducted by a committee at an institutional, local or regional level and after this step the applications are sent to national entities for a second evaluation, by committees and/or officers). More information is available in the **Appendix 3**.

Fig.2. Characterization of the MS concerning the organization of the project evaluation and the authorisation process (more information is available in the appendix 3)



- Evaluation + Authorisation at a national level
- Evaluation at institutional, local or regional level + Evaluation at a national level + Authorisation at a national level
- Evaluation at national level + Authorisation at regional level
- Evaluation + Authorisation at a local or regional level
- Evaluation at institutional level + Authorisation at regional level
- Evaluation + Authorisation at an institutional level
- Austria: applications from academic institutions are evaluated at a national level, while applications from industry are evaluated at a federal level

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3.3.2. Evaluation process: committee composition

From the 20 MS for which information has been confirmed by the competent authorities, information on the minimum mandatory or recommended committees' composition is available for 17 MS. The information reported here refers to the recommended or required composition and not the actual composition of different committees.

The different types of expertise and representation identified are presented in the textbox below. Their presence in different MS is presented in Table 1.

Testbox: expertise and representation

1. **Scientific & Science-related expertise**: includes members with scientific expertise/background and with expertise in experimental design or experimental procedures, research techniques and statistical analysis (e.g. statistician or a person with expertise in statistics).
2. **Veterinary & Animal health and welfare**: includes the persons responsible for overseeing the health, welfare, housing and care of the animal and/or the designated veterinarian.
3. **Legal expertise:** Including lawyers, judges and members with a degree in Law.
4. **Ethics:** includes members with expertise/experts in ethics [in the Danish committee, a member appointed by the Board of Animal Ethics]
5. **Alternatives to animal experiments:** members with expertise in alternatives to animal experiments/research or alternative methods.
6. **Other technical expertise:** only in Denmark - one member appointed by the Danish Research Council for Technology and Production and 1 member from the Danish Industry.
7. **Representation of special interest groups**
   - 7.1. **Animal welfare/protection:** representatives of animal protection' or welfare' non-profit organizations [NGOs]/associations or appointed by these associations to represent their interests
   - 7.2. **Patients:** only in Denmark – one member appointed by a patients' association
8. **Society representation:** includes references to "lay persons", public interest representatives or independent persons.

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Table 1. Overview of expertise that is required or recommended in the evaluation committees in different MS

Scientific & science-related technical expertise	Veterinary & Animal health and welfare	Legal	Ethics	Alternatives to AE	Other technical expertise	Special interest groups		Society
						Animal welfare/ protection	Patients	"Lay persons"
Belgium	Belgium	Denmark	Belgium	Belgium	Denmark	Croatia	Denmark	Ireland**
Croatia	Croatia	Estonia	Denmark	Estonia		Denmark	*Ireland****	*Portugal****
Czech Republic	Czech Republic	Finland	Finland	Latvia		Estonia	Poland	Sweden
Denmark[2]	Estonia	Poland	Estonia	Netherlands		Finland		*UK****
Estonia	Finland	Sweden	*Ireland****			Germany		
Finland	**France***		Netherlands			Poland		
France*	Germany		Poland			Slovenia		
Germany	Greece		*Portugal****			Sweden		
Greece	Ireland**		Slovenia					
Ireland**	Italy*							
Italy*	Latvia							
Latvia	Poland							
Netherlands	Portugal*							
Poland	Slovenia							
Portugal*	Spain							
Slovakia	Sweden							
Slovenia	UK							
Spain								
Sweden								
UK								

***Information not confirmed by the national competent authorities.** However, information regarding Portugal and Italy was confirmed by local ANIMPACT team members.

**Recommended composition.

****Additional members recommended:*

Ireland: Additional members recommended by the HRPA - Health Products Regulatory Authority in the "Guide to Ethics Committee Assessment of Project Applications under Directive 2010/63/EU and S.I. No. 543 of 2012".

Portugal: Additional members mentioned in the Order n.º 2880/2015.

UK: Additional member under ASPA Schedule 3, Part 2, paragraph 6(2)(c).

[2] In Denmark, it is not the expertise that is indicated, but the entities which are to nominate members (the members are proposed by several national organizations and appointed by the head of the CA, the Minister for Food, Agriculture and Fisheries). However, the committee's composition is public – the members' identities, affiliation, and the organizations that proposed them are available at http://www.foedevarestyrelsen.dk/fvst_ansvar_opgaver/Sider/Dyreforsoegstilsynet.aspx?Indgang=Dyr&Ind.

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APPENDIX 1

State of the art of the mapping process: confirmation with Competent Authorities (Table 2, August 2015, EU-27)

Fully confirmed information (by CA)	Information confirmed by local ANIMPACT team member[3]	Awaiting confirmation	Excluded due to marginal relevance of animal research
Belgium	**Italy**	**Austria**	Cyprus
Croatia	**Portugal**	**Bulgaria**	Luxembourg
Czech Republic		**France**	Malta
Denmark			
Estonia			
Finland			
Germany			
Greece			
Hungary			
Ireland			
Latvia			
Lithuania			
Netherlands			
Poland			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden			
UK			

[3] For Italy: Augusto Vitale; for Portugal: Anna Olsson.

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APPENDIX 2
Identification of the main regulatory actors in each MS (Table 3)

Ministry & Competent Authority (CA): MS where it falls on the Ministry of Agriculture		
Croatia	Ministry of Agriculture	**CA:** Veterinary and Food Safety Directorate
Denmark	Ministry of Food, Agriculture and Fisheries (Veterinary and Food Administration)	
Estonia	Ministry of Agriculture (Food Safety Department)	**CA:** Ministry of Agriculture (Food Safety Department) and Veterinary and Food Board
Finland	Ministry of Agriculture and Forestry (Department of Food and Health)	
Germany	Federal Ministry of Food and Agriculture	**CA:** Public authorities responsible under "Land" law (one in each 16 states)
Greece	Minister of Rural Development and Food	**CA:** Regional Veterinarian Authority (there are 54 regional authorities)
Hungary	Ministry of Agriculture and Rural Development	**CA**: National Food Chain Safety Office (1 central, and 19 regional offices)
Latvia	Ministry of Agriculture	**CA**: Food and Veterinary Service - Veterinary Surveillance Department
Portugal	Ministry of Agriculture and Sea	**CA:** Portuguese National Authority for Animal Health (DGAV)
Romania	Minister of Agriculture and Rural Development coordination	**CA:** National Sanitary-Veterinary and Food Safety Authority (NSVFSA)
Slovakia	Ministry of Agriculture and Rural Development	**CA:** State Veterinary and Food Administration of Slovak Republic (SVFA SR)
Slovenia	Ministry of Agriculture, Forestry and Food	**CA:** Administration for Food Safety, Veterinary Sector and Plant Protection (AFSVSPP)
Spain	Ministry of Agriculture, Food and Environment and Ministry of Economy and Competitiveness	**CA:** Regional administrative competent authorities
Sweden	Ministry for Rural Affairs	**CA:** Swedish Board of Agriculture
Ministry & Competent Authority (CA): MS where it falls on the Ministry of Health		
Ireland	Ministry/ Department of Health	**CA:** HPRA – Health Products Regulatory Authority
Italy	Ministry of Health	
Ministry & Competent Authority (CA): MS where it falls on the Ministry of Science, Education and Research		
Austria*	Ministry of Science and Research	**CA** Academic institutions: Ministry of Science and Research **CA** Industry: Head of each one of the 9 Federal Governments
France*	Ministry of Higher Education and Research	
Poland	Ministry of Science and Higher Education	
Ministry & Competent Authority (CA): MS where it falls on other ministries/departments		
Belgium	**Brussels**: State Secretary of the Brussels - Capital Region, responsible Animal Welfare	**CA:** Brussels Environment - Inspectorate Division and contaminated lands - Animal welfare
	Flanders: Ministry for Mobility, Public Works, the Vlaamse Rand, Tourism and Animal Welfare	**CA:** Government of Flanders - Department Environment & Nature - Division Animal Welfare
	Wallonia: Ministry of the Environment, Spatial Planning, Mobility and Transport, Airports and Animal Welfare	**CA:** Public Service Wallonia – Research & Development Department – Animal Welfare
Czech Republic	Ministry of Agriculture, Ministry of Environment, Ministry of Health, the Czech Academy of Science, Ministry of Education Youth and Sports, Ministry of Industry and Trade, Ministry of Culture, Ministry of Defence	**CA:** Ministry of Agriculture
Lithuania	Government of the Republic of Lithuania	**CA:** The State Food and Veterinary Service (SFVS) and its territorial divisions
Netherlands	Ministry of Economic Affairs	**CA:** Central Committee Animal Experiments (CCD)
UK	Home Office of the UK Government	**CA:** Animals in Science Regulation Unit (ASRU), Home Office

***Information not confirmed by the national competent authorities.**

APPENDIX 3

Detailed information about the organization of the project evaluation and authorisation process

Table 4. Overview of the project evaluation and authorisation process

Geographical organization of the evaluation and authorisation process		MS
1	Evaluation + Authorisation at a national level	Austria# Bulgaria* Croatia Denmark Estonia Finland Latvia Lithuania
2	Evaluation at institutional, local or regional level + Evaluation at a national level + Authorisation at a national level	Czech Republic France* Ireland Italy Netherlands Portugal Slovakia UK
3	Evaluation at national level + Authorisation at regional level	Hungary Slovenia
4	Evaluation + Authorisation at a local or regional level	Austria# Germany Poland Sweden
5	Evaluation at institutional level + Authorisation at regional level	Greece Romania Spain
6	Evaluation + Authorisation at an institutional level	Belgium

*** Information not confirmed by the national competent authorities.**

 # According to information not yet confirmed by the CA, in Austria the applications from academic institutions are evaluated at a national level, while applications from industry are evaluated at a federal level

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1. Project evaluation at a national level + Authorisation at a national level

In this category the evaluation is conducted at a national level, by a national committee. The authorisation is also provided at a national level, usually by the competent authority. MS with this organization:

1.1. Austria: Projects from academic institutions. Information not yet confirmed by the CA. This section will be updated as soon as we have the confirmation.

1.2. Bulgaria: Information not yet confirmed by the CA. This section will be updated as soon as we have the confirmation.

1.3. Croatia: The project evaluation is conducted at a national level, by a national ethics committee (it is also encouraged a prior evaluation, by institutional committees). The authorisation is provided by the national competent authority - the Veterinary and Food Safety Directorate, following the advice of the national ethics committee.

1.4. Denmark: The project evaluation is conducted at a national level, by the Board/Council for Animal Experiments, a national committee who composes and manages the Animal Experiments Inspectorate (AEI). The authorisation is provided by this national entity, AEI, under the Ministry of Food, Agriculture and Fisheries. So, in Denmark, the evaluation and authorisation is delegated to another entity than the CA (Ministry of Food, Agriculture and Fisheries).

1.5. Estonia: The project evaluation is conducted at a national level, by the "project authorisation committee". This committee is responsible for the project authorisation (the head of the committee is responsible for the final decision).

1.6. Finland: The evaluation and authorisation is conducted at a national level, by the Project Authorisation Board. This board is a national committee divided into 4 sections, which have their meetings in different cities. The applications are primarily handled (evaluated and authorised) in one of the sections – only in case of disagreement they are referred to the board meeting with all sections.

1.7. Latvia: The project evaluation is conducted at a national level, by a national commission under the national competent authority, the Food and Veterinary Service. The project authorisation is provided by the Director of this entity, the competent authority, with advice from the national commission.

1.8. Lithuania: The project evaluation is conducted at a national level, by a national committee under supervision of the State Food and Veterinary Service (SFVS) – this entity and its territorial divisions is the Lithuanian competent authority. The project authorisation is provided by the SFVS with advice from the national ethics committee.

2. Project evaluation at institutional/local or regional level combined with evaluation at a national level + authorisation at a national level

In this category the evaluation is primarily conducted by a committee at an institutional, local or regional level. After this step the applications are sent to national entities for a second evaluation (by committees and/or officers). The authorisation is usually provided by the national competent authority. 8 MS have this organization:

2.1. Czech Republic: The evaluation is conducted, in first place, at an institutional level, by the animal welfare bodies (AWB). After the institutional approval, the applications are evaluated by one of the 8 committees of Ministries and Czech Academy of Science. After evaluation by one of these committees, the authorisation is provided by one of the Ministries or by the Czech Academy of Science.

2.2. France: Information not yet confirmed by the CA. This section will be updated as soon as we have the confirmation.

2.3. Ireland: The formal project evaluation and authorisation is conducted at national level by the national competent authority, the HPRA - Health Products Regulatory Authority. However, this entity encourages a prior evaluation by institutional committees. Currently, there are approximately 20 committees in Ireland. The evaluation is usually conducted by these committees, and also by technical personnel at the HPRA, where the Management Committee is responsible for the project authorisation.

2.4. Italy: (Information confirmed by an ANIMPACT team member but not yet by the CA) Evaluation is conducted at institutional level (by the institutional animal welfare bodies – AWBs) and also at a national level (by individual experts at *Istituto Superiore di Sanità*). The project authorisation is provided by national competent authority, the Ministry of Health, with advice from these individual experts at the *Istituto Superiore di Sanità.*

2.5. Netherlands: The project evaluation is firstly conducted at an institutional/local level by one of the 17 established Animal Experiments Committees (DECs). Subsequently, the application is evaluated at a national level, by the Central Committee Animal Experiments (CCD) – the Dutch competent authority – to provide authorisation.

2.6. Portugal: (Information confirmed by an ANIMPACT team member but not yet by the CA) Evaluation is conducted at an institutional level, by the animal welfare bodies (AWBs) and at a national level by the officers at DGAV (the Portuguese competent authority, the National Authority for Food and Animal Health). The project authorisation is provided by DGAV with advice from institutional committees/AWBs.

2.7. Slovakia: The project evaluation is conducted first by local or institutional committees. These committees advise the national competent authority, the State Veterinary and Food Administrations of the Slovak Republic (SVFA SR). The project authorisation is provided by the SVFA SR based on the advice of the institutional/local committees and the SVFA's Advisory Board.

2.8. United Kingdom: The project evaluation is conducted at institutional level, by the Local Animal Welfare and Ethical Review Bodies (AWERB's) and at national level by one of the 22 inspectors of the national competent authority, the Animals in Science Regulation Unit (ASRU), from the Home Office. The authorisation is provided by ASRU, with advice from the AWERBs.

3. Project evaluation at national level + Authorisation at a regional level

In this category, the project evaluation is conducted at a national level, by one committee, but the authorisation is provided by the regional offices of the competent authorities. Only 2 MS have this organization:

3.1. Hungary: In this MS, all applications should be submitted to one of the regional National Food Chain Safety Offices (one in each 20 Hungarian administrative regions). Project evaluation is then carried out by the national ethics committee ("Állatkísérleti Tudományos Etikai Tanács - ÁTET"). The outcome of the evaluation conducted by the committee is forwarded to the regional National Food Chain Safety Office, entity responsible for providing the project authorisation.

3.2. Slovenia: The project evaluation is conducted at a national level by an ethics committee established since 2005. The projects' authorisation is provided at a regional level, by the regional offices of the Slovenian competent authority, the Administration for Food Safety, Veterinary Sector and Plant Protection (AFSVSPP), with advice from the national ethics committee.

4. Project evaluation + Authorisation at a local or regional level

In this category the projects' evaluation and the authorisation is conducted/provided at a local or regional level, by the regional competent authorities. 3 MS have this organization:

4.1. Austria: Projects from industry. Information not yet confirmed by the CA. This section will be updated as soon as we have the confirmation.

4.2. Germany: The applications must be submitted to one of the 16 regional competent authorities for evaluation after a first review by the institutional Animal Welfare Officer. Each authority has its own committee – the "Tierversuchskommission", which evaluates the applications and advises/assists the authorities in this evaluation and authorisation process. The project authorisation is provided by the regional competent authorities.

4.3. Poland: The Minister of Science and Higher Education appoints the National Ethics Committee which nominates the members of the local ethics committees. The project evaluation is conducted by one of these 11 local ethics committees, who also provide the projects' authorisation.

4.4. Sweden: The project evaluation and authorisation is conducted and provided by one of the 7 Regional Animal Ethics Committees (AEC), located in Stockholm North; Stockholm South; Uppsala; Linköping; Malmö / Lund; Gothenburg, and Umeå.

5. Project evaluation at institutional (or local) level + Authorisation at "regional" level

In this category, the project authorisation is also provided at a regional level, but the evaluation is conducted at an institutional or local level (the evaluation conducted at this level is the basis for the regional competent authorities provide the projects' authorisation). There are 3 MS with this organization:

5.1. Greece: The evaluation is conducted by "project evaluation committees", which are mainly institutional but can be shared between institutes since there are no conflicts of interest. These committees are approved by the Head of the Local Prefectural Service. The projects' authorisation is provided by the Regional Veterinary Authorities, the Greek competent authorities, with advice from the "project evaluation committees".

5.2. Romania: The projects' evaluation is conducted by existent ethics committees at specialized academic centers or user establishments in which the projects will take place. The projects' authorisation is provided by the competent authority (the National Sanitary-Veterinary and Food Safety Authority, NSVFSA) directorates in counties with advice from the institutional committees.

5.3. Spain: The projects' evaluation is conducted by the "habilitated bodies" [usually institutional or local ethics committees. The animal welfare bodies (AWBs) can conduct the evaluation if they meet additional requirements]. The authorisation is provided by one of the regional competent authorities with advice from these "habilitated bodies".

6. Project evaluation + Authorisation at institutional level

There is only one MS with evaluation and authorisation exclusively at an institutional level:

6.1. Belgium: The project evaluation and authorisation is conducted and provided at an institutional level, by committees that can be shared between institutions. The functioning of these committees (n=36) is controlled by the regional authorities.

APPENDIX 4

Detailed information about the committee composition [by expertise]

1. Scientific and science-related technical expertise [experimental design, research techniques and statistical analysis]

This category includes members with scientific expertise/background and with expertise in experimental design or experimental procedures, research techniques and statistical analysis (e.g. statistician or a person with expertise in statistics). The following MS have this expertise in its minimum recommended or mandatory composition:

1.1. Belgium: The institutional committees must have at least 7 members, including experts in experimental design, research techniques and statistical analysis.

1.2. Croatia: The national committee is composed by 6 members and should include experts in the fields of veterinary medicine, human medicine, biology, pharmacy, biochemistry and agronomy, as well as representatives from the state administration body responsible for science and education.

1.3. Czech Republic: The institutional committees/AWBs must be composed by at least 3 persons and have at least one scientific expert. The committees from the Ministries and the Czech Academy of Sciences usually comprise 5 to 8 persons and must have members adequately educated for carrying out and designing procedures and projects.

1.4. Denmark: The Danish national committee must have 11 members (1 chairman + 10 members) proposed by several national organizations and appointed by the head of the CA, the Minister for Food, Agriculture and Fisheries. The committee includes one member appointed by the National Research Council for Medical Sciences and one by the Board of Health.

1.5. Estonia: In this MS the committee members are proposed by several national institutions (Ministries, Universities, a Health Agency and animal protection organizations) and appointed by the Minister of Agriculture. The committee must have up to 17 members including members with expertise in statistics and use of genetically modified animals in animal studies, planning animal experiments, reproduction and rearing; statistics and animal test methods.

1.6. Finland: The Project Authorisation Board must be composed by 4 members with recognized competence and experience in scientific research and 4 members with recognized competence and experience in laboratory animal care/experimental techniques in animals.

1.7. France: Information not yet confirmed by the CA. This section will be updated as soon as we have the confirmation.

1.8. Germany: In the German regional committees, the majority of members (two-thirds), must possess a specialist knowledge in veterinary medicine, medicine or other natural scientific disciplines, reason why integrates this and the following category.

1.9. Greece: In this MS, the chairman of the “project evaluation committees” must have scientific background and the committees must include at least 1 expert in statistics and experimental design.

1.10. Ireland: The Irish CA, the HPRA, recommends the presence of 1 or more representatives of the research community and a statistician or a person with expertise in statistical analysis (where relevant).

1.11. Italy: In this MS, the AWBs are responsible for a first project evaluation and must be composed by at least 3 members, including 1 scientific member. However, additional guidelines regarding the composition and functioning of the AWBs are to be issued and approved.

1.12. Latvia: The national commission under the CA must be composed by 10 members (representing several Ministries, different research institutes and the Latvia University of Agriculture), including member(s) with expertise in experimental design and statistics where appropriate.

1.13. Netherlands: The Dutch Animal Experiments Committees (DECs) consists of at least seven members with expertise in four main areas, including animal testing.

1.14. Poland: In this MS, the local ethics committees are composed by 12 members and half of the members (6) should be representatives of biological, pharmaceutical, medical, agricultural or veterinary sciences with a degree or a PhD and knowledge and experience of using animals for research or educational purposes.

1.15. Portugal: In this MS, the evaluation will be conducted, in a first stage, by the AWBs, which should have at least 1 scientific member. Additionally, it could integrate an expert in statistics or experimental design.

1.16. Slovakia: The local/institutional committees should be composed by at least 5 members, including workers (scientists). We have no specific information regarding the composition of the Advisory Board.

1.17. Slovenia: In this MS, the national committee must include members with expertise in veterinary science, medicine, biology, pharmacology and zootechnology.

1.18. Spain: The "habilitated bodies" must comprise the minimum composition of the AWBs and some additional members. They must have at least 2 scientific members and from these, 1 researcher should not be connected with the project that will be assessed.

1.19. Sweden: In the Swedish regional committees, detached scientists, laboratory animal technicians and other facility personnel make up half of the committee's composition (excluding the chairman and the vice-chairman).

1.20. UK: In this MS, the AWERBs (local animal welfare and ethical review bodies) must have at least 3 members, including 1 scientific member.

2. Veterinary & Animal health and welfare expertise

This category includes the persons responsible for overseeing the health, welfare, housing and care of the animal and/or the designated veterinarian. This expertise in represented in the committees of the following MS:

2.1. Belgium: In this MS, the institutional committees must include a member with expertise in animal health and welfare and also the veterinarian (or the expert responsible for the health and welfare of the animals) of the institution should be a member.

2.2. Croatia: Like mentioned before, the national ethics committee should be composed by 6 members and include, besides other experts, experts in veterinary medicine, reason why Croatia integrates this and the previous category.

2.3. Czech Republic: The institutional committees/AWBs must have in their composition all the persons responsible for overseeing the welfare and care of animals.

2.4. Estonia: The Estonian national committee must include members with expertise and experience in veterinary medicine and animal welfare in animal experiments.

2.5. Finland: The Finnish Project Authorisation Board must be composed by 4 members with expertise in veterinarian medicine and 4 members with recognized competence and experience in laboratory animal care/experimental techniques in animals.

2.6. France: Information not yet confirmed by the CA. This section will be updated as soon as we have the confirmation.

2.7. Germany: In the German regional committees, the majority of members (two-thirds), must possess a specialist knowledge in veterinary medicine, medicine or other natural scientific disciplines, reason why integrates this and the above mentioned category.

2.8. Greece: The Greek project evaluation committees must include the responsible veterinarian and a Veterinarian from the Local Prefectural Services (this member is the Veterinarian responsible for the inspections and also have the right to vote).

2.9. Ireland: The inclusion of the designated veterinarian and the animal care and welfare officer is recommended. Also, it is recommended the inclusion of a specialist in a particular animals species being investigated, or suitably qualified expert and additional animal technicians.

2.10. Italy: The Italian committees, based on the minimum composition of the AWBs, should include the person or persons responsible for the welfare and care of the animals and the designated veterinarian.

2.11. Latvia: In this MS, the national commission must include member(s) with expertise in veterinary practice and in animal husbandry and care.

2.12. Poland: Like mentioned before, in this MS, the local ethics committees are composed by 12 members and half of the members (n=6) should be representatives of biological, pharmaceutical, medical, agricultural or veterinary sciences with a degree or a PhD and knowledge and experience of using animals for research or educational purposes, reason why this MS is mentioned in this and in the previous category.

2.13. Portugal: The Portuguese committees are, like the Italian, based on the minimum composition of the AWBs. The AWBs must include at least the person or persons responsible for the welfare and care of the animals and the designated veterinarian. Also, additionally, it could integrate a representative of the animal care/laboratory animal technicians.

2.14. Slovenia: The national committee, whose members are appointed by the Minister of Agriculture in agreement with the Ministry of Education, Science and Sport and the Minister for Environment and Spatial Planning, must include member(s) with expertise in veterinary medicine/science, reason why this MS is mentioned in this category and in the previous category.

2.15. Spain: The "habilitated bodies" should have at least 1 animal care and welfare officer, the designated veterinarian and 1 person with expertise in animal welfare without direct relation to the user of the project.

2.16. Sweden: Like mentioned before, we have the information that the Swedish regional committees should be composed by detached scientists, laboratory animal technicians and other facility personnel (these make up half of the committee's composition, excluding the chairman and the vice-chairman), reason why this MS is mentioned in this and in the previous category.

2.17. UK: The AWERBs must include at least 1 of the establishment's Named Animal Care and Welfare Officers (NACWO) and 1 of the Named Veterinary Surgeons (NVS).

3. Legal expertise

This category comprises MS where is mandatory the inclusion of lawyers, judges and members with a degree in Law in the committees' composition. This situation happens mainly in MS where a national committee performs evaluation and Authorisation[4] and the members with this expertise usually are the chairman and vice-chairman.

[4] Poland and Sweden are the exception, as the project evaluation is conducted at a local and regional level.

3.1. Denmark: The chairman of the Danish national committee is a judge appointed by the CA, the Ministry of Food, Agriculture and Fisheries.

3.2. Estonia: The Estonian committee must include one lawyer proposed and appointed by the Ministry of Agriculture.

3.3. Finland: The chairman and the vice chairman of the Project Authorisation Board must have a Master's degree in Law.

3.4. Poland: The local ethics committees are composed by 12 members and one fourth of these members (n=3) should be representatives of the humanities or social sciences, in particular in ethics, philosophy or law, among them 1 representative of an organization with the protection of the patients' rights as a statutory goal.

3.5. Sweden: The chairman and vice chairman of each one of the Swedish regional animal ethics committees must be lawyers.

4. Ethical expertise

This category includes the MS whose committees must include members with expertise in ethics.

4.1. Belgium: The institutional committees must include an expert in ethics.

4.2. Denmark: The national committee must include 1 member appointed by the Board of Animal Ethics (however, the present member of this category is not an ethicist).

4.3. Finland: The Project Authorisation Board includes 4 members with expertise in practical animal welfare or ethical issues.

4.4. Estonia: The Estonian national committee must include member(s) with expertise in ethics.

4.5. Ireland: The HRPA recommends the presence of additional participants to enhance the value of the ethics committee's assessment, namely, an ethicist or member of an ethical review group for clinical trials in humans.

4.6. Netherlands: The Dutch Animal Experiments Committees (DECs) consists of at least 7 members with expertise in four main areas, including ethical review.

4.7. Poland: Like mentioned before, in this MS, the local ethics committees are composed by 12 members and one fourth of these members (n=3) should be representatives of the humanities or social sciences, in particular in ethics, philosophy or law, among them 1 representative of an organization with the protection of the patients' rights as a statutory goal, reason why this MS is mentioned in this and in the previous category.

4.8. Portugal: According to the Order n.º 2880/2015, additionally, the AWB could integrate a representative from an health or clinical research ethics committee from the same institution/establishment.

4.9. Slovenia: The national committee must include member(s) with expertise in ethics in research.

5. Alternatives to animal experiments:

5.1. Belgium: The Belgian institutional committees must include members with expertise in alternatives to animal experiments.

5.2. Estonia: In this MS, the national committee includes member(s) with expertise in alternative methods.

5.3. Latvia: The national commission must include member(s) with expertise in alternatives to animal experiments [introduction of alternative methods in order to replace, reduce and refine the existing methods].

5.4. Netherlands: The Animal Experiments Committees (DECs) consists of at least 7 members with expertise in four main areas, including alternatives to animal experiments.

6. Other technical expertise

6.1. Denmark: The Danish committee includes 1 member appointed by the Danish Research Council for Technology and Production and 1 member appointed by the Danish Industry.

7. Representation of special interest groups

7.1. Animal welfare/protection organizations

This category includes MS whose committees include representatives of animal protection' or welfare' non-profit organizations [NGOs]/associations or appointed by these associations to represent their interests

7.1.1. Croatia: In this MS, the national committee should be composed by 6 members, including representatives from animal protection associations.

7.1.2. Denmark: The Danish committee has 4 members appointed by animal protection associations**.**

7.1.3. Estonia: The Estonian committee is composed by 2 members proposed by animal protection organizations (Animal Protection Society of Estonia and the Estonian Animal Welfare League).

7.1.4. Finland: The Project Authorisation Board includes 4 members with expertise in practical animal welfare or ethical issues

7.1.5. Germany: One-third of the members of the German regional committees must come from nominee lists of animal welfare organizations.

7.1.6. Netherlands: The Animal Experiments Committees (DECs) consists of at least 7 members with expertise in four main areas, including animal protection.

7.1.7. Poland: The Polish local ethics committees are composed by 12 members and one fourth of these members (3) should be representatives of NGOs with animal protection as a statutory goal.

7.1.8. Slovenia: In this MS, 1 member of the national committee can be a member of a NGO working in the field of animal welfare and protection.

7.1.9. Sweden: The Swedish regional animal ethics committees must have 6 lay persons (including at least 1, maximum 2 members from animal welfare NGOs).

7.2. Patient organizations

7.2.1. Denmark: The Danish committee has 1 member appointed by the major health associations (disease fighting non-profit organizations).

7.2.2. Ireland: Like mentioned before, besides a minimum committee's' composition, the HPRA recommends additional participants to enhance the value of the ethics committee's assessment – e.g. a patients' representative.

7.2.3. Poland: Like mentioned before, in this MS, the local ethics committees are composed by 12 members and one fourth of these members (n=3) should be representatives of the humanities or social sciences, in particular in ethics,

philosophy or law, among them 1 representative of an organization with the protection of the patients' rights as a statutory goal, reason why this MS is mentioned in this and in two of the previous categories.

8. Society representation

This category includes references to "lay persons", public interest representatives or independent persons.

8.1. Ireland: The HPRA recommends the participation of a public interest representative independent of the research being conducted at the user establishment.

8.2. Sweden: The Swedish regional animal ethics committees must have 6 lay persons [including at least 1, maximum 2 members from animal welfare NGOs], reason why this MS is included in this and in the previous category.

8.3. Portugal: According to the Order n. º 2880/2015, an AWB, aditionally, could integrate a representative from civil society to provide the public perspective.

8.4. UK: The AWERBs must include at least 1 independent person.