



# Use of animals in scientific research

Summary report of a round table discussion held on 28 March 2018

## About FEAM, The Federation of European Academies of Medicine ([www.feam.eu](http://www.feam.eu))

FEAM is the European Federation of National Academies of Medicine and Medical Sections of Academies of Sciences. It brings together under one umbrella 18 National Academies representing over 5,000 among the best scientists in Europe.

FEAM's mission is to promote cooperation between National Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

## About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community.

The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information on the FEAM European Biomedical Policy Forum or becoming a partner, please contact [silvia.bottaro@feam.eu](mailto:silvia.bottaro@feam.eu)

### Disclaimer

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Federation of European Academies of Medicine (FEAM) or the FEAM European Biomedical Policy Forum partners.

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All web references were accessed in April 2018.

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# Introduction

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This report summarises the key points of the Federation of European Academies of Medicine (FEAM) European Biomedical Policy Forum round table discussion on the use of animals in scientific research.

## Background

Directive 2010/63/EU on the protection of animals used for scientific purposes regulates the care and use of animals used for research. The aim of the Directive is to strengthen legislation and improve the welfare of those animals that still need to be used, as well as to firmly anchor the principle of the 3Rs (to Replace, Reduce and Refine the use of animals in research) in EU legislation.

In November 2017, the European Commission published a Review Report<sup>1</sup>, a Staff Working Document<sup>2</sup>, and feasibility study<sup>3</sup> on self-sustaining non-human primate colonies. The European Commission Review Report concluded that, while the Directive's framework is generally considered to be a sound foundation for the regulation of animals used for scientific purposes, it is premature to measure the impact of all of the new measures that were introduced.

The Staff Working Document also contains a number of recommendations for different stakeholders to take up, as appropriate, with the common aim of improving the attainment of the Directive objectives.

## Objectives of the meeting and expected outcomes

### Objectives:

- Discuss the recommendations of the European Commission Review Report to inform policy discussion in EU institutions and to identify recommendations for the users' community on this basis;
- Reiterate the value of the European legislation and tools for its correct implementation;
- Reiterate the reality of science - value and limitations of all research tools whether in vivo or not.

### Expected outcomes:

- Enable an open and timely dialogue between stakeholders representing different biomedical sectors and with policy-makers;
- Enable the sharing of information and generate ideas for actionable suggestions and for possible follow-up actions by the relevant stakeholders/policy-makers;

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<sup>1</sup> Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 58 of Directive 2010/63/EU on the protection of animals used for scientific purposes, COM(2017) 631 final.

<sup>2</sup> Commission Staff Working Document SWD(2017) 353 final/2 accompanying COM(2017) 631 final

<sup>3</sup> Feasibility study as required in Article 10 of Directive 2010/63/EU on the protection of animals used for scientific purposes, 31 July 2017.

- Publication of a summary report, containing a summary of the discussion and a concise outline of the key themes and messages that emerged during the meeting.

The agenda can be found at Annex I along with speakers' biographies (Annex II), a list of participants (Annex III) and a glossary (Annex IV).

# Summary

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There is overwhelming agreement that Europe has appropriate and detailed legislation regulating the use of animals in scientific research that adapts to and encourages scientific progress. However, focus is required on ensuring that the Directive 2010/63/EU is implemented in a way that focuses on welfare impacts and avoids duplicative or unnecessary processes and on sharing of good practices, in particular on issues where the scientific community can do more to deliver on 3Rs and quality of science.

The successful implementation of the Directive is a shared responsibility. The members of the research community identified opportunities to join forces and work together, as the Directive 2010/63/EU cannot be successfully implemented by organisations or individuals working in isolation. Progress can be supported and perhaps accelerated by sharing good practice and by finding or designing new ways of working. A first step would be to openly involve other stakeholders in this dialogue as it is important to include the wider community to move forward in the implementation of the Directive.

The following key messages arose from the discussion:

## Education and Training

Good animal welfare training for researchers and students equates to good science. There is a lot of knowledge and expertise in the community and lots of education and training opportunities. However, not everybody knows about or takes advantage of the knowledge or training that is on offer. The impact of patchy provisions is compounded by a lack of resources with the result that current levels of training are probably insufficient.

There are numerous ways to extend the reach and impact of existing resources and knowledge and to increase the number of participants in education and training. Developments in technology mean that it is now easier than ever to share knowledge in easy and cost-effective ways. For example, common technology platforms and other tools for pooling knowledge, sharing information and providing training are essential to bring training and education into the 21st century.

Such cost-effective options could have multiple benefits including greater consistency in the level and type of education available to researchers, technicians and students across Europe. Other mechanisms, to which organisations can and do contribute voluntarily, include road shows and networks of centres of excellence.

A combination of cost-effective, easy-to-access web-based resources and a more selective approach to training (i.e. not everybody needs to be trained in everything or in the same way) may be part of the answer to rising costs and shrinking resources.

*Every organisation is responsible for making available information that promotes knowledge of and access to training opportunities for researchers, technicians and students. It is also essential to invest in the development of modern learning techniques. This includes moving into the 21st century and using modern tools to be more cost-effective and improve levels of training.*

*The scientific community must engage with the authorities in the Member States to remind them of countries' responsibilities to ensure training is available and to inform them of the initiatives that exist on training opportunities.*

#### Animal Welfare Bodies

The work of Animal Welfare Bodies is vital and they contribute not just to animal welfare but impact positively on research itself. In some countries, Animal Welfare Bodies have been strengthened and have been more effective since the introduction of the Directive. In other Member States where they did not previously exist, the benefits have also been seen. However, across Europe the picture remains very mixed. Some Animal Welfare Bodies are more empowered than others and many bodies are uncoordinated and ineffective. It is essential that the Animal Welfare Bodies, and the personnel within them are empowered, well supported and resourced to perform their important work and that they are recognised and valued for their beneficial impact on animal welfare, the quality and conduct of research.

In some Member States, extra responsibilities have been placed on Animal Welfare Bodies. With the responsibilities that have been placed on the Animal Welfare Bodies and their numerous tasks and core functions, with often limited resources available to them, there is a definite need for the focus of the Directive's implementation to be placed on outcomes rather than adding up additional layers of processes.

The importance of the need to improve co-ordination between Animal Welfare Bodies within Member States was highlighted. The discussion about coherence within countries was mirrored by consideration of networking and co-ordination of National Committees. National Committees were identified as having important roles to play as they could have a co-ordinating role and support greater coherence by facilitating networking and co-ordination of Animal Welfare Bodies within Member States.

*Animal Welfare Bodies (and their personnel) must be empowered and well supported to fulfil their responsibilities. There is a need for better co-ordination within Member States and to avoid unnecessary processes and make best use of the available resources. This will ensure that the bodies are recognised and valued for their beneficial impact on animal welfare, the quality and conduct of research.*

#### Reproducibility

Reproducibility is an important issue and one that will have consequences on the sector in the future. Therefore, it is important to ensure proper experimental study design. It is essential to promote the use of and to disseminate information on study design tools that exist (such as the PREPARE and ARRIVE guidelines).

Additionally, it is also necessary to ensure that journals and peer reviewers are aware of best practice, so that researchers and reviewers understand how methodologies impact on the quality of research. This will improve the quality of science and 3Rs uptake.

Solutions to improve reproducibility were recommended and discussed. These included providing trainings, possibly through road shows, e-learning or video teaching, journals signing up to Registered Reports; and empowering Named Information Officers. The introduction of new research paradigms and integration of new sciences or technologies into research and regulatory practice are expected to lead to an increase in the quality of science, ensuring better reproducibility and animal welfare.

*It is essential to promote the use of and to disseminate information on study design tools that exist (such as the PREPARE and ARRIVE guidelines), as well as other solutions that may improve reproducibility. The research community must join forces to support EU and national initiatives that enable the development and validation of new research paradigms, trainings and good practice which increase the quality of science, ensuring better reproducibility and animal welfare.*

### Transparency and Openness

It was recognised that transparency has increased under the Directive. However further informed communication and openness is required by the research community.

All members of the biomedical research community share a responsibility to communicate responsibly about the use of animals. It is important that researchers communicate honestly without being defensive about their work. Communication tools, models and good practice need to be shared more widely. Collaboration is especially valuable in highly specialised research fields, where it may be beneficial for organisations to work together to develop communication tools and approaches.

The research community must avoid complacency and continue to engage with stakeholders, communicating the benefits of research and the progress made with the replacement, refinement and reduction of animals in research.

It is important to know the views of the public and to focus messages to the needs of the different groups. However, the last Eurobarometer survey of public attitudes on science and animal testing was in 2010. Therefore, it is recommended that new public polls should be conducted.

*All members of the research community share a responsibility to communicate responsibly about the use of animals. There are numerous opportunities and channels for communication, including Non-Technical Summaries, statistical reporting, opening laboratories to the public, sharing information on websites and publications.*

*Research organisations should focus on communicating the realities, robustness and quality of studies and research instead of trying to 'over sell the value' of using animals or non-animal alternatives for research.*

*The scientific community must be open to continued dialogue and to working together with stakeholders from all communities, including the animal welfare communities, national authorities and decision makers.*



### Implementation of the Directive

The Directive itself does not intend to create administrative burdens but provide tools and safety nets to be put in place. There is an identified need for intelligent implementation of the Directive (i.e. an implementation that focuses on welfare impacts and avoids duplicative or unnecessary processes), where the research community can communicate and engage with authorities in identifying and highlighting problems in the processes that have been implemented.

### Culture of Care

Culture of Care needs to be more clearly understood and integrated into the daily work of the user community. There are numerous activities, information and guidance available as starting steps. However, it may be beneficial to discuss, frame and formalise these ideas in a more structured way so that the full benefits of Culture of Care ideas can be realised.

*The research community must support and enable an implementation of Directive 2010/63/EU that focuses on welfare impacts and avoids duplicative or unnecessary processes. This can be achieved by engaging with the competent authorities, reporting problems and pointing out solutions that support welfare and transparency, while removing or reducing duplicative administrative steps that do not translate in welfare gains.*

*The Culture of Care concept needs to be implemented in a more structured way so that the full benefits of Culture of Care ideas can be realised.*

# Report of the event

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## Welcome and introduction

The meeting was opened by **Prof. Stefan Constantinescu, Vice-President of the Federation of European Academies of Medicine (FEAM)** who welcomed the participants and thanked the Chair and the Facilitator for their work and contribution to the preparation of the meeting and the partners of the FEAM European Biomedical Policy Forum.

Prof. Constantinescu introduced the FEAM Forum and described it as ‘a platform for discussion’ which allows the biomedical community to debate pressing policy issues. Prof. Constantinescu stressed the sensitivity and importance of the issues under discussion, acknowledging that they were matters of concern to some elements of society. This Forum, he said, was intended to be a platform to foster open debate.

**Prof. André Parodi, Honorary President of the French National Academy of Medicine and of the French Veterinary Academy** (the Chair) introduced the meeting, saying that it was hoped that the discussion might help moving forward on the implementation of Directive 2010/63/EU (hereinafter referred to as ‘the Directive’).

## Topic 1: Implementation of Directive 2010/63/EU

**Magda Chlebus, Executive Director of Science Policy & Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA)** (the Facilitator) introduced the first topic and set the scene for the discussion. She stated that Directive 2010/63/EU provides a sound framework in the EU for regulating the use of animals in scientific research, which in principle does not appear to block scientific progress. However, effective national implementation and enforcement are necessary to make a real impact. Implementation between countries is variable (because of limited resources or for other reasons) but it is the responsibility of the scientific community that further progress is made.

There is a lot taking place with many activities leading to good quality science. However, the group was asked to consider whether the scientific community is doing enough and delivering on the 3Rs. In particular, there were three topics proposed for the discussion: these areas were where improvements were felt to be necessary. The participants considered their previous experiences, related problems and where possible proposed solutions.

### Education and Training

The participants considered the following questions:

1. Are you aware of all education and training possibilities?
2. Have modules been improved since the Directive’s implementation?
3. Within your organisations do you offer trainings that would benefit others?

**The participants stressed the importance of training on good animal welfare and use in research, noting that good training for researchers and students equates to good science and that a Culture of Care is linked with good training and education.**

Many training opportunities exist, many having positive outcomes. However, not everybody knows about or takes advantage of the training that is on offer. Participants thought that such opportunities should be promoted more widely, especially in Member States where few researchers have participated to date. Moreover, at the present time, the provision and uptake of training and education across Europe is patchy and what is on offer varies significantly from country to country.

Training is mandatory and it is the responsibility of Member States to ensure that personnel are trained. In some countries, the responsibility falls to national competent authorities but participants observed that some competent authorities are not presently effective or active in informing and leading researchers and students into training.

Numerous **examples of diversity with training** were highlighted and discussed:

- Training on the welfare of specific species is not available in all Member States that use those species, resulting in the need for students and researchers to travel to other countries for the necessary training and education.
- Training on 3Rs specifically is very scattered across Europe. The European Commission's Joint Research Centre is therefore presently mapping what training is offered by whom, and will determine whether there are any gaps through a survey on training in the 3Rs<sup>4</sup>.
- Participants also noted that a present hindrance is where there is no cross-border acceptance of training from other Member States. Acceptance of training certificates from other Member States would see the movement of students and researchers between Member States and allow the better circulation of knowledge, and expertise of those with previous training.
- Different Member States, even those more advanced in the implementation of the Directive, have different levels of training.
- Numerous participants spoke of the lack of resources, especially highlighting the concerns of available funding or money which leads to current levels of insufficient training.

Despite these challenges, good **examples of initiatives to compile knowledge and improve training** were cited:

- ETPLAS<sup>5</sup> was recently established and it is an open window to access a database of training opportunities. If such web-based resources were more widely made available, it would be possible to envisage more students in Europe undertaking a basic level of training on animal welfare. This would enable more uniformity in training across Europe. It will also help promoting free movement of competent personnel in the EU.

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<sup>4</sup> More information about the survey and contact details to participate are available at:

<https://ec.europa.eu/jrc/en/science-update/education-and-training-3rs>

<sup>5</sup> <https://www.etplas.eu>

- One initiative identified, specific to veterinarians, consists in the mapping of the training available to students of veterinary science by the Federation of Veterinarians of Europe and the European Association of Establishments for Veterinary Education<sup>6</sup>. The aim was to explore the extent to which laboratory animal medicine has been incorporated into undergraduate veterinary curricula. Their findings suggest that training varies from institution to institution but at least one university in every country provides training. It is also possible that other non-veterinary science courses include relevant training (e.g. ethics) and that there are separate courses that can be taken as elective subjects. For post-graduate continuous professional development, the veterinary profession has developed VETCEE (Veterinary Continuous Education in Europe)<sup>7</sup> to evaluate programmes addressed to veterinary practitioners. VETCEE scheme also accredits programmes for veterinarians active in laboratory animal medicine.
- A variety of mechanisms were noted, to which organisations can and do already contribute voluntarily, such as road shows (on severity classification) and networks of centres of excellence. However, there remains a need to seek additional funds especially to make certain mechanisms sustainable.

**Participants identified a range of ways to extend the reach and impact of these existing resources, knowledge and expertise and to increase the number of participants in education and training.**

Training and education has traditionally centred on people attending meetings in person but these models are limited in their reach and can be expensive. This is problematic because, as participants noted, financial resources are limited. However, there are other models for training and different ways to enable and promote the diffusion of knowledge within communities.

For example, modernisation of technology means that it is now easier than ever to share knowledge in cost-effective ways. Participants discussed the merits of common technology platforms for pooling knowledge, sharing information and providing training, noting that the use of modern tools is essential to bring training and education into the 21st century.

Such cost-effective options could have multiple benefits. There would be greater consistency in the level and type of education available to researchers, technicians and students across Europe. It would also be a solution to the concerns over rising costs and shrinking resources.

Therefore, it was noted that members of the research community need to work together to harmonise training across Europe and to develop common applications that can be used for training and knowledge exchange. This might be based on the pooling and sharing of existing knowledge, for example in databases or through road shows and workshops. Where there is a limit in funding opportunities available for education and training, voluntary sharing of expertise and knowledge is essential.

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<sup>6</sup> The results will be published in the Journal of Veterinary Medical Education (JVME) by September 2018.

<sup>7</sup> <http://fve.org/education/vetcee.php#STANDARD>

## Animal Welfare Bodies

The participants considered the following question:

1. Are we providing the necessary resources, framework, expertise, infrastructures to have effective Animal Welfare Bodies?

**The participants considered whether the Animal Welfare Bodies are empowered enough** (as well as whether the personnel in the Animal Welfare Bodies are empowered enough to carry out their tasks), **and what can be improved.**

It was agreed that the Animal Welfare Bodies were one of the biggest achievements and benefits of the Directive. The work of Animal Welfare Bodies is vital as they contribute not just to animal welfare but impact positively on research itself. There is some evidence that, in some Member States where ethical committees existed prior to the Directive, Animal Welfare Bodies have been further strengthened and have been more effective since the introduction of the Directive. In other Member States, where there were no ethical committees or bodies prior to the Directive, significant improvements have been seen to animal welfare and the way of working of the research community.

However, **it was acknowledged that across Europe the picture remains very mixed.** Some Animal Welfare Bodies are more empowered than others and others are uncoordinated, lack guidance and are seeking to establish effective ways of working. In some countries Animal Welfare Bodies have had little or no support from government and have relied on research organisations to give the necessary direction and guidance.

With the responsibilities that have been placed on the Animal Welfare Bodies and their numerous tasks and core functions, with often limited resources available to them, there is a definite need for the focus of the Directive's implementation to be placed on outcomes rather than adding up additional layers of processes. This would avoid unnecessary processes and optimise impact from the Animal Welfare Bodies, while making better use of the available resources and keeping focus on their reason of establishment which is to ensure that 3Rs are actively implemented in everyday work.

It was also noted that in some Member States, extra responsibilities have been placed on Animal Welfare Bodies. This poses a risk because, with limited resources, Animal Welfare Bodies are unlikely to fulfil additional duties without compromising their core functions or responsibilities.

**To empower the Animal Welfare Bodies, there is a need to empower the people within.** There is a unique structure within the Animal Welfare Bodies, which brings together people of different backgrounds and level of engagement with the animals within the establishments. However, they must feel empowered to ensure the best functioning of the Body.

**The importance of the need to improve co-ordination between Animal Welfare Bodies within Member States was highlighted.** In Member States where animal welfare is governed by different regions, this has been seen to lead to differences in legislation governing animal use and functioning of Animal Welfare Bodies within one country.

A positive example of coordination among Animal Welfare Bodies was from the United Kingdom, where an animal welfare charity, the RSPCA, plays an important independent co-ordinating role across Animal Welfare Bodies and also sometimes participates as a lay member within them.



The discussion about coherence within countries was mirrored by consideration of networking and co-ordination of National Committees. National Committees were identified as having important roles to play as they could have a co-ordinating role and support greater coherence by facilitating networking and co-ordination of Animal Welfare Bodies within Member States. Within the Directive, specific roles are identified for the National Committees and it is important for the research community to engage with them and create a demand to ensure they advise Animal Welfare Bodies as required in the Directive and exchange information on the operation of Animal Welfare Bodies.

Coordination of National Committees at an EU level was discussed. There are noted language barriers and difficulties in reaching those who lead animal welfare work at ‘ground level’ which means that co-ordination of Animal Welfare Bodies is likely to be more effective at national rather than EU level. The Dutch National Committee started an initiative to foster closer collaboration between different National Committees and planned a kick-off meeting for 12 April 2018, with the aim of discussing how to facilitate the work of Animal Welfare Bodies. The Commission will host a meeting of National Committees later in the year.

### Reproducibility

The participants considered the following questions:

1. Do you invest in improved study design?
2. Does your organisation endorse or systematically use the ARRIVE guidelines?
3. Do you know of trainings available?

**The participants agreed that reproducibility will be a big issue for the sector for the coming years. Reproducibility is linked to good quality science and starts with proper study design.**

The participants discussed actions taken first upstream, focusing on whether they are improving the design of studies, using the right guidelines, right resources and informing researchers correctly. Then downstream, with implementing the ARRIVE guidelines, which promote high-quality, comprehensive reporting to allow an accurate critical review of research using animals. Every effort should be made to improve the design of research, using the best available research guidelines and to ensure that research and research techniques are recorded and reported correctly. It is also necessary to ensure that peer reviewers are aware of best practice, so that researchers and reviewers understand how methodologies impact on the quality of research. This will improve quality of science and 3Rs uptake.

Upstream guidance recognised as useful by participants were the PREPARE<sup>8</sup> guidelines, a set of guidelines for planning animal experiments. With a downstream focus, the ARRIVE<sup>9</sup> guidelines, which are intended to improve the reporting of research using animals - maximising information published and minimising unnecessary studies - received much endorsement.

Incentives for publication versus incentives linked to ‘getting the research right’ were linked to study design. An apparent misalignment of incentives makes it difficult for good research practice to fully

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<sup>8</sup> <https://norecopa.no/PREPARE>

<sup>9</sup> <https://www.nc3rs.org.uk/arrive-guidelines>

permeate the research system. While researchers are required to focus on the 3Rs, evaluation at institutional level tends to be driven by number of publications and high impact factors.

**Acknowledging the concerns over reproducibility, numerous solutions to be considered were discussed:**

- Trainings could be offered, for example through road shows which focus on research reproducibility and promote tools that have been developed including the ARRIVE guidelines, the Experimental Design Assistant (EDA)<sup>10</sup> and SYFR<sup>11</sup> tools of the NC3Rs.
- Animal study design is difficult, but it could be aided by e-learning or video teaching. The European Commission has been tasked with funding a pilot project on alternatives with open access interactive e-learning modules (including a topic on design of procedures and projects) and it was suggested that more support of this kind could be made available if there was a clear demand for such tools. The call will be published soon.
- Get journals to use Registered Reports<sup>12</sup>. The tool which is linked to peer review, would be in principle an agreement for publication as researchers would start off with good robust science, even if studies were to lead to negative results.
- Use the findings of the Innovative Medicines initiative (IMI) project EQIPD<sup>13</sup>, which is looking at quality of science across research fields and will develop an online educational platform, delivering certified courses. These aim to pave the way for cultural change in approaches to data quality in medical research and drug development.
- Named Information Officers (who ensure that staff dealing with animals have access to information specific to the species housed in the establishment) could be empowered and better resourced, to play a role in supporting researchers in experimental design.
- Applying the principles of One Health research could be advantageous. If studies were jointly designed (e.g. medical and veterinarian focus) so that the results could be published in both veterinary and medical science publications, fewer animals might be used in research.

#### Conclusions from Topic 1

The Chair drew the following conclusions from the discussion of Topic 1:

- The members of the research community must identify further opportunities to join forces and work together, as the Directive cannot be successfully implemented by organisations or individuals working in isolation. Progress can be supported and perhaps accelerated through sharing good practice and by finding or designing new ways of working.
- Proper implementation of the Directive is the responsibility of individuals and institutions.

<sup>10</sup> <https://www.nc3rs.org.uk/experimental-design-assistant-eda>

<sup>11</sup> <https://www.nc3rs.org.uk/camarades-nc3rs-systematic-review-facility-syrf>

<sup>12</sup> <https://cos.io/rr/>

<sup>13</sup> <http://quality-preclinical-data.eu/>

- *Education and Training:*
  - Every organisation is responsible for making available information that promotes knowledge of and access to training opportunities for researchers, technicians and students. It is also essential to invest in the development of modern learning techniques. This includes moving into the 21st century and using modern tools to be more cost-effective and improve levels of training.
  - The scientific community must engage with the authorities in the Member States to remind them of countries' responsibilities to ensure training is available and to inform them of the initiatives that exist on training opportunities.
- *Animal Welfare Bodies:* Animal Welfare Bodies (and their personnel) must be empowered and well supported to fulfil their responsibilities. There is a need for better co-ordination within Member States and to avoid unnecessary processes and make best use of the available resources. This will ensure that the bodies are recognised and valued for their beneficial impact on animal welfare, the quality and conduct of research.
- *Reproducibility:* It is essential to promote the use of and to disseminate information on study design tools that exist (such as the PREPARE and ARRIVE guidelines), as well as other solutions that may improve reproducibility. The research community must join forces to support EU and national initiatives that enable the development and validation of new research paradigms, trainings and good practice which increase the quality of science, ensuring better reproducibility and animal welfare.

## Topic 2: Improving Transparency and Openness

The Facilitator introduced this topic by questioning the participants on how open their organisations are on what is being said about animal research on their websites and whether collectively as a community they were doing enough to be transparent and open about their work. Ultimately, transparency could be improved and there is frequent criticism of the research community on their lack of transparency. This raises the question, is the research community collectively doing enough?

The participants considered the following questions:

1. How do we communicate about the use of animals in research?
2. How to better communicate at the national and European levels toward the public in order to explain the reality of science? (Including focus on value and limitations of animal experiments).
3. How to facilitate transparency?

The European Commission Review Report states that transparency has increased under the Directive. However, further attention and progress is required on the quality and transparency of information given on the use of animals.

The failure to explain or contextualise statistics of animals' use in experiments is a missed opportunity to promote messages that could inform the public discussion about the use of animals in research. Similarly, other **actions are being taken or could be taken to support transparency, openness and debate:**

- Member States' competent authorities need to be encouraged and supported to help communicate and explain statistics more clearly.
- The quality of Non-Technical Summaries (NTS) for lay people could also be improved by using simpler and clearer language that can be understood by the general public.
- National Transparency Agreements, signed by research institutions which agree to various commitments on openness, are also a good way to promote better communication and these have worked well in the UK and Spain and are under consideration in Belgium and Portugal.
- The European Animal Research Association (EARA) is currently carrying out a mapping exercise to assess the websites of institutions that conduct animal research on the basis of openness and transparency, with the aim of collecting good practices on communicating on animal research.

**The session discussion centred on how researchers communicate with their audiences and how to improve, incentivise and support transparent communication.**

It is important that researchers communicate honestly and responsibly without being defensive about their work. Transparency and openness can be attained in many ways, for example by publishing data and information about the use and numbers of animals in research on institutions' websites or by inviting people to visit laboratories. However face-to-face, one-to-one communication has been recognised to be most effective.

Scientists must be encouraged to be both responsive and proactive in their communication. Researchers should be clear about the nature of their work and its benefits. They should explain clearly that research is about pursuing knowledge and making discoveries that have the potential to transform people's lives, that this often involves the use of animals and that in some such cases, at the frontiers of medical research it is not possible to replace animals.

The research community must avoid complacency and continue to engage with stakeholders, communicating the benefits of their research and the progress made with the replacement, refinement and reduction of animals in research.

**The following suggestions were made on how and where to communicate:**

- It may be beneficial to invest more time and money not only on communication but also on education at a young age - for example, explaining the value and achievements of research (including research using animals) - to school age children.
- It would be good to have a Biomedical Awareness Day across Europe, where institutions can organise open days and citizens can engage directly with researchers.
- There is a need for education about how to communicate about animals in research. It was acknowledged that researchers are not trained to be communicators, which means that some education and training should be designed to equip scientists to communicate effectively.

Communication tools, models and good practice need to be shared more widely in the biomedical sector. **Examples put forward to facilitate the communication on animal use by researchers included:**

- To improve the way researchers communicate in lay language in their Non-Technical Summaries, they could collaborate with external experts especially in highly specialised research fields, where communication tools and approaches could be developed to help researchers improve their communication skills.
- Specific communication could be developed in areas where animal use appears distressful or dramatic but in fact the actual severity experienced by the animal is low or it is the most humane method. The European Animal Research Association (EARA) and Understanding Animal Research (UAR) could be organisations well placed to take on the role of coordination and dissemination on these issues.
- Produce on-line public access education with videos explaining and showing specific procedures and also on-line open-lab access videos.

Whatever the approach, it is important to know what the public's opinion and understanding is on animal research. Without reliable information it is impossible to establish a robust or clear baseline. The last Eurobarometer survey of public attitudes on science and animal testing was in 2010. A recommendation from the discussion was to approach DG Research and request they carry out a new survey through the 'Science with and for Society' programme<sup>14</sup>.

It was noted that the public generally accepts the use of animals in research if the research clearly serves the public good. But concerns are raised once there is unnecessary suffering to the animal. It is therefore important to communicate how animal welfare has been taken into account to ensure ethical research takes place and that all possible steps have been taken to avoid or reduce the suffering of animals used in research.

Public trust needs to be built up. Some groups (such as veterinarians, who are trusted by the public to take care of animals, and patients who can speak first-hand about the benefits of research) enjoy high levels of trust with the public and their views are more accepted in explaining the benefits that animal research has led to.

## Conclusions for Topic 2

The Chair drew the following conclusions from the discussion of Topic 2:

- The European Commission Review Report is clear that the Directive has led to an increase in transparency. Nonetheless, there remains room for improvement.
- All members of the research community share a responsibility to communicate responsibly about the use of animals. There are numerous opportunities and channels for communication, including Non-Technical Summaries, statistical reporting, opening laboratories to the public, sharing information on websites and publications.

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<sup>14</sup> <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/science-and-society>



- Research organisations should focus on communicating the realities, robustness and quality of studies and research instead of trying to ‘over sell the value’ of using animals or non-animal alternatives for research.
- The scientific community must be open to continued dialogue and to working together with stakeholders from all communities, including the animal welfare communities, national authorities and decision makers.

## Topic 3: Ideas for further areas to be tackled

The participants considered the following questions:

1. Which areas need further implementation and harmonisation?
2. What concrete actions are to be taken by: i) Scientific community; ii) Member States; iii) European Commission and iv) Other stakeholders?
3. Which pragmatic opportunities and resources are needed to enhance collaboration between participating stakeholders?

Although implementation is not yet uniform across Member States, Directive 2010/63/EU is considered to be one of the better implemented directives. This mirrored the findings of the European Commission Review Report. There have been notable improvements, and this is partly attributable to the Directive itself. However, implementation can be improved and ideas were discussed amongst participants.

### Support for 3Rs Centres

The participants voiced support for 3Rs Centres which have been established in some Member States to help research. 3Rs Centres are not a requirement of the Directive: they have been established voluntarily and proved to be beneficial. The UK’s National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) is considered to be an exemplar in Europe and there should be other similar good examples in other countries.

It was acknowledged that with limited resources, it would be best to share knowledge as much as possible to achieve better results collectively. This suggests a model based on a distributed network of excellence between existing 3Rs Centres. The European Commission recognises the value of 3Rs Centres and has begun to work with them to identify how and where they can work together strategically with support from the Commission. Previously, the European Union Reference Laboratory for alternatives to animal testing (EURL-ECVAM) has organised workshops with the 3Rs Centres to bring them together to identify the areas in which they have been specialising and look at pulling resources together to increase efficiency.

### Publication of negative results

There need to be more incentives to publish negative results and, at the same time, to shift away from focus on good impact factors as one of the primary measures of success in institutional evaluations. This might entail consideration of a separate but related set of issues concerned with Open Access publishing and the cost of Open Access publications.

### Improving competences of national authorities and inspectors

The level of expertise of those involved in the approval processes for animals used for scientific purposes are very different in different Member States. It was also noted that the levels of experience and competency within competent authorities and National Committees varies across Member States. It was highlighted that there is a need for more training for those overseeing research involving the use of animals so that they are kept up to date and are empowered with the skills needed to fulfil their role. In addition, specialised training in laboratory animals should be made available for those carrying out inspections of establishments and animal use. It is not the task of the Commission to determine the competencies of the Member States competent authorities. However, in the context of a pilot project, the Commission will publish an open call for the establishment of training modules to harmonise the level of training amongst competent authorities involved in the project evaluation process. There are already numerous road shows throughout the EU on severity classification and many competent authorities are actively participating in these learning experiences.

### Developing and implementing a Culture of Care

Culture of Care lives at the heart of a number of issues linked to the establishments, management, personnel etc. Culture of Care needs to be more clearly understood and it is a difficult concept to define. It is a topic of discussion in many networks and some guidance is available. For example, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has developed a wider research community checklist to help researchers engage or enhance discussions on Culture of Care<sup>15</sup>. It was suggested that it may be beneficial to discuss, frame and formalise this concept in a more structured way so that the full benefits of Culture of Care ideas can be realised.

### Implementation of the Directive

For the evaluation and authorisation process, Member States are free to implement the process as they see best in their infrastructure. This has led to notable variations in project authorisation requirements and project evaluations. The Directive itself does not require or demand administrative burdens to these processes. Therefore, there is a need for intelligent implementation of the Directive (i.e. an implementation that focuses on welfare impacts and avoids duplicative or unnecessary processes). The research community has the responsibility to promote and support such an approach to implementation by identifying and communicating problems to the relevant authorities. This would avoid waste of resources and will allow to achieve the objectives set by the Directive, i.e. to have the 3Rs implemented and that the animals are taken care of in the best way.

A pan European approach could be supported by a repository of examples of good practice. There is guidance available that has been developed at European level and is available in the majority of the EU languages<sup>16</sup>. Furthermore, some of the foundations for such repositories already exist. For example, the League of European Research Universities (LERU) will map and audit what 3Rs Centres do and what capabilities already exist in Europe and the European Commission and the Federation for Laboratory Animal Science Associations (FELASA) already offer high quality information and guidance. The question is perhaps, whether the community makes good use of existing resources

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<sup>15</sup> <https://efpia.eu/about-medicines/development-of-medicines/animal-use-and-welfare/>

<sup>16</sup> [http://ec.europa.eu/environment/chemicals/lab\\_animals/interpretation\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm)

and expertise and it was suggested that the European Open Science Cloud<sup>17</sup> might enable more people to access and use these resources (as long as they can be quality assured).

### Conclusions for Topic 3

The Chair drew the following conclusions from the discussion of Topic 3:

- The research community must support and enable an implementation of Directive 2010/63/EU that focuses on welfare impacts and avoids duplicative or unnecessary processes. This can be achieved by engaging with the competent authorities, reporting problems and pointing out solutions that support welfare and transparency, while removing or reducing duplicative administrative steps that do not translate in welfare gains.
- The Culture of Care concept needs to be implemented in a more structured way so that the full benefits of Culture of Care ideas can be realised.

## Concluding remarks

The Chair concluded the round table discussion by saying that from the discussions it appears that the scientific community is committed to supporting the implementation of the Directive and recognises the importance to uptake good practice.

He underlined the collective responsibility of the research community for the realisation of the benefits offered by the Directive. The successful implementation of the Directive is a shared responsibility, as is the obligation to use the Directive to drive scientific progress. This means that members of the research community are required to consider what they can do, whether it be sharing good practices or providing leadership or resources.

The group was encouraged to remain open and participate in future discussions as a community of interest, involving also other stakeholders. The FEAM Forum is seen as a potential platform for future discussions.

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<sup>17</sup> <http://ec.europa.eu/research/openscience/index.cfm?pg=open-science-cloud>

# Annex I - Agenda

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28 March 2018 (12:00-16:30)

University Foundation, rue d'Egmont 11, 1000 Brussels / Room Emile Francqui

12:00-12:50	<b>Registration and lunch</b>
12:50-13:00	<b>Welcome</b> <ul style="list-style-type: none"> <li>Stefan Constantinescu, Vice-President, Federation of European Academies of Medicine (FEAM)</li> </ul>
13:00-13:10	<b>Introduction</b> <ul style="list-style-type: none"> <li>André Parodi, Honorary President of the French National Academy of Medicine and of the French Veterinary Academy - <i>Chair</i></li> </ul>
13:10-13:20	<b>Ground rules</b> <ul style="list-style-type: none"> <li>Magda Chlebus, Executive Director of Science Policy &amp; Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA) - <i>Facilitator</i></li> </ul>
13:20-14:10	<b>Round table discussion focused on 3 topics</b> <i>Moderated by Chair and Facilitator</i> <b>Topic 1: Implementation of Directive 2010/63/EU</b> <i>Proposed questions:</i> <ol style="list-style-type: none"> <li>Education and training – Are you aware of all education and training possibilities? Have modules been improved since the Directive's implementation? Within your organisations do you offer trainings that would benefit others?</li> <li>Animal Welfare Bodies – Are we providing the necessary resources, framework, expertise, infrastructures to have effective animal welfare bodies?</li> <li>Reproducibility – Do you invest in improved study design? Does your organisation endorse or systematically use the ARRIVE guidelines? Do you know of trainings available?</li> </ol>
14:10-15:00	<b>Topic 2: Improving Transparency and Openness</b> <i>Proposed questions:</i> <ol style="list-style-type: none"> <li>How do we communicate about the use of animals in research?</li> <li>How to better communicate at the national and European levels toward the public in order to explain the reality of science? (Including focus on value and limitations of animal experiments).</li> <li>How to facilitate transparency?</li> </ol>
15:00-15:20	<b>Coffee break</b>
15:20-16:15	<b>Topic 3: Ideas for further areas to be tackled</b> <i>Suggested questions:</i> <ol style="list-style-type: none"> <li>Which areas need further implementation and harmonisation?</li> <li>What concrete actions are to be taken by: i) Scientific community; ii) Member States; iii) European Commission and iv) Other stakeholders?</li> <li>Which pragmatic opportunities and resources are needed to enhance collaboration between participating stakeholders?</li> </ol> <p>Some issues raised during the review process which merit further discussion: Publication of negative results to avoid duplication, Culture of Care, Reporting standards – quality of research, ....</p>
16:15-16:30	<b>Concluding remarks</b> <ul style="list-style-type: none"> <li>André Parodi, Honorary President of the French National Academy of Medicine and of the French Veterinary Academy (<i>Chair</i>)</li> </ul>

## Annex II - Speakers' biographies

### Stefan Constantinescu

*Vice-President, Federation of European Academies of Medicine (FEAM)*



Stefan N. Constantinescu is Professor of Cell and Molecular Biology at Université catholique de Louvain. He coordinates the Cell Signaling and Molecular Hematology Pole of de Duve Institute at UCL and is a Member of Ludwig Institute for Cancer Research, at the Brussels Branch. Trained as an MD at the Carol Davila University of Medicine and Pharmacy in Bucharest, he uncovered in 1989 a major pediatric AIDS outbreak in Romania that has changed blood transfusion practices and impacted the pediatric AIDS field. His PhD thesis concerned mechanisms of signaling by type I interferons. He undertook postdoctoral work with Prof. Harvey F. Lodish at Whitehead Institute at Massachusetts Institute of Technology (1995-2000) on oncogenesis via erythropoietin receptor and is an independent group leader since 2000.

His research focuses on molecular bases of blood formation and cancer, and on fundamental aspects of cytokine receptor and transmembrane protein structure and function. His laboratory at de Duve Institute (UCL) and Ludwig Cancer Research has contributed to the identification and study of the driver mutations in human myeloproliferative neoplasms Polycythemia Vera, Essential Thrombocythemia and Myelofibrosis (JAK2 V617F, W515 mutants of Tpo receptor, mechanism of oncogenesis by calreticulin mutants). He was elected to both the Royal Academy of Medicine in Belgium, and the Romanian Academy of Medical Sciences, and is Vice-President of FEAM since 2016.

### Chair

### André Parodi

*Honorary President of the French National Academy of Medicine and of the French Veterinary Academy*



Professor André, Laurent, Marie PARODI was born on 6/08/1933 in Algeria. Nationality: French

He is Doctor in Veterinary Medicine (Ecole Nationale Vétérinaire d'Alfort (ENVA), Paris University), PhD and Paris Pasteur Institute Graduated.

He has been Professor, Head of the Department of Veterinary Pathology, and then Director of ENVA. Co Director of the Paris V University Diploma (DU) on "Pathology of Laboratory Animals".

He is *Doctor Honoris Causa*, University of Cordoba (Spain), Bucarest (Romania) and Liège (Belgium).

He was a Member of the European Commission Scientific Committee for Animal Health and Animal Welfare (DG XXIV), President of the French Commission for Veterinary Products registration and President of the *Comité de Réflexion éthique pour l'Expérimentation animale* (French Committee for Ethics in Animal Experimentation) (Ministry of Investigation and Ministry of Agriculture).

He is a Member of the *Académie Vétérinaire de France* (President 2000), of the *Académie nationale de Médecine* (France) (President 2012) and Honorary member of the *Académie nationale de Pharmacie* (France).

He was member of the WHO expert group for Animal Tumours Classification, member of the European Committee for Investigation in Animal Pathology, President of the Scientific Committee of the French "Centre National d'Etudes Vétérinaires et



*Alimentaires*” (CNEVA), American College of Veterinary Pathology (ACVP) honorary Member and President of the Board of the European College of Veterinary Pathology (ECVP).

His main Scientific investigation activities were developed in the field of Viruses associated Malignant Lymphomas in Domestic Animals (*Enzootic Bovine Leukosis and Feline Leukemia /Sarcoma complex*), as animal models for human medicine.

His more relevant personal achievements were (i) the isolation of a strain of *Bovine LeukemiaVirus (BLV)* in France and implementation of a national campaign of detection and eradication of the viral infection in bovine at the national level ( European Commission expert group for Enzootic Bovine Leukosis Investigation member, Delegate of France), (ii) the characterization of a new strain of Feline Sarcoma virus and (iii) isolation of various viral strains of the agent of the Viral Feline Immunodeficiency Syndrome (*Fe AIDS*).

## Facilitator

### Magda Chlebus

*Executive Director of Science Policy & Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA)*



Magda Chlebus is Executive Director of Science Policy & Regulatory Affairs at the European Federation of Pharmaceutical Industries and Associations (EFPIA), representing the R&D-based pharmaceutical industry in Europe.

Magda and her team are in charge of following policy and legislative developments that influence the research and regulatory environments for the healthcare industry in Europe. This includes public private collaborations (inter alia the Innovative Medicines Initiative), enabling and sensitive technologies and the interface between new science and technology and regulation.

She joined EFPIA in 1995. Her experience covers public and government affairs mainly at EU level, on a range of legislative and non-legislative files in the area of research, animal welfare, development and access to medicines and enabling technologies.

Magda, a Polish national, holds a Master Degree in Applied Linguistics from the University of Warsaw.

## Annex III - Participants' list

Last Name	First name	Position	Organisation
Aan den Toorn	Marije	Policy advisor Natural Sciences	The Royal Netherlands Academy of Arts and Sciences
Alvis	Sam	Policy Officer	Wellcome Trust
Balansard	Ivan	President	Groupe Interprofessionnel de Réflexion et de Communication sur la Recherche (GIRCOR)
Bottaro	Silvia	FEAM Forum Policy Officer	Federation of European Academies of Medicine (FEAM)
Bușoi	Cristian-Silviu	MEP	European Parliament
Chlebus	Magda	Executive Director of Science Policy & Regulatory Affairs	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Cinca	Sabin	Professor, Dr.	Bucharest Oncology Institute
Constantinescu	Stefan	Vice President	Federation of European Academies of Medicine (FEAM)
Destrebecq	Frédéric	Executive Director	European Brain Council (EBC)
Foidart	Jean-Michel	Perpetual secretary	Belgian Royal Academy of Medicine
Iatridou	Despoina	Veterinary Policy Officer	Federation of Veterinarians of Europe (FVE)
Janssen	Peter	Chair of FENS-CARE committee on animals in research	Federation of European Neuroscience Societies (FENS)
Kipling	Jeff	Scientific Adviser	Federation of European Academies of Medicine (FEAM)
Kristiansen	Lars	Executive Director	Federation of European Neuroscience Societies (FENS)
Leech	Kirk	Executive Director	European Animal Research Association (EARA)
Legros	Laurence	Executive Director	Federation of European Academies of Medicine (FEAM)
Livermore	Tom	Policy Officer	UK Academy of Medical Sciences
Louhimies	Susanna	Policy Co-ordinator	Policy Co-ordinator, Unit B.2 Sustainable chemicals, Directorate-General for the Environment
McBride	Tony	Director	Futura Consulting
Morosan	Serban	Director of Unit UMS28 phénotypage du petit animal	University of Sorbonne, Faculty of Medicine
Moura Santos	Ana Isabel	President elect	Federation for Laboratory Animal Science Associations (FELASA)
Parodi	André	Honorary President	French National Academy of Medicine French Veterinary Academy
Raedt	Robrecht	Director animal facilities	Ghent University Hospital
Reid	Kirsty	Senior Manager Science Policy and Animal Welfare	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Schmit	Marthe	Board member	European Society for Laboratory Animal Veterinarians (ESLAV)

Last Name	First name	Position	Organisation
Slater	Natasha	Office Manager	Federation of European Neuroscience Societies (FENS)
St Clair Pearce	Emma	Research and Collaboration Policy Officer	Association of the British Pharmaceutical Industry (ABPI)
Tolliday	Bob	Communications and Media Manager	European Animal Research Association (EARA)
Vermeulen	Anne	Animal Welfare Officer and designated veterinary	University of Namur
Voipio	Hanna-Marja	President	Federation for Laboratory Animal Science Associations (FELASA)
Williams	Bella	Head of Engagement	Understanding Animal Research

## Annex IV - Glossary

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**Animal Welfare Body:** A body that breeders, suppliers and users should have in place with the primary task of focusing on giving advice on animal welfare issues. The body should also follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals. Legal requirements are defined in recital 31 and articles 26 and 27 of Directive 2010/63/EU.

**ARRIVE Guidelines:** The ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines were developed as part of an NC3Rs (National Centre for the Replacement Refinement and Reduction of Animals in Research) initiative to improve the design, analysis and reporting of research using animals - maximising information published and minimising unnecessary studies.

**Competent Authority:** As defined in article 3 of Directive 2010/63/EU, an authority or authorities or bodies designated by a Member State of the European Union to carry out the obligations arising from Directive 2010/63/EU. Legal requirements are defined in article 59 of Directive 2010/63/EU.

**Culture of Care:** The term Culture of Care refers to an organizational culture that supports and values caring and respectful behaviour towards animals and co-workers

**National Committee:** A Committee for the protection of animals used for scientific purposes established by each Member State of the European Union. The Committee advises the Competent Authorities and Animal Welfare Bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. Legal requirements are defined in recital 48 and articles 49 of Directive 2010/63/EU.

**PREPARE Guidelines:** The PREPARE (Planning Research and Experimental Procedures on Animals) guidelines covers the three broad areas which determine the quality of the preparation for animal studies: formulation, dialogue between scientists and the animal facility, and quality control of the various components in the study.



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