EU Directive 2010/63/EU: "Implementing the Three Rs Through Policy"

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Summary

Can modern policy work to advance the principle of the Three Rs? A new Directive on the protection of animals used for scientific purposes, replacing Directive 86/609/EEC, came into force in Europe in November 2010. The principle of the Three Rs – the replacement, reduction, and refinement of the use of animals in experiments – is the cornerstone of the new Directive. The Three Rs are embedded throughout the text and must be taken fully into account during all aspects of animal use and care. The requirement to use a non-animal method instead of one using animals, when such method is recognized by the EU legislation, is clear and explicit in the legal text. Moreover, the principle of Russell and Burch goes beyond just the choice of methods. In fact, it covers all animal/human interaction, from birth, to housing and care, until the end of the animal's life. Finally, more resources are foreseen for the development, validation, and application of alternative methods. With the revision, the EU can claim to have the highest standards of experimental animal welfare in the world, while promoting high quality, competitive science and research in Europe. Its implementation will show if we have accomplished our aims and if true advances can be made – through law, the strongest form of policy.

Keywords: policy, legislation, Directive, three Rs, protection of animals, Europe

1 Laws or guidance?

William Howard Taft (1857-1930) said: "*The world is not going to be saved by legislation*" (Taft, 1916). Laws or guidance? Is it a choice or a result of the society, its cultures and traditions?

Europe has a long tradition of legislation. EU legislation was and is considered part of a means to keep the peace, build Europe after the wars, and bring prosperity to its citizens. Later, it served also to provide protection to consumers and to the environment. Legislation, therefore, is seen as an integral part of modern European society, the framework under which we can work together regardless of our cultural and societal differences, contributing to the richness of European life and advancing co-operation.

Laws reflect values of our society and its conscience but, equally, they ensure that your counterparts respect and work by the same rules and ethical principles. EU laws are established to create a level playing field – to enable different countries and cultures to work seamlessly together. In this particular field, it stretches even further; in line with our belief that animal life is to be respected, it ensures a minimum level of protection for animals.

Guidance extends from the laws and complements the provisions beyond that of the legislative framework. It assists in the implementation, provides understanding, and supports the policy objectives. Or, in cases where there are no legal bases for legislation, or when laws are not considered appropriate, guidance can be adopted to steer our attitudes and thinking to a specific, desired direction.

Other cultures may rely more on guidance with minimal legislative framework. In some cases, the traditions, as well as funding opportunities and other such influences may, in practice, turn guidance into near binding standards, while in others, guidance may be respected regardless. From the animal welfare perspective, however, it is more reassuring to be able to rely on legislation that is enforceable by court, instead of mere guidance. In today's legal framework tools exist to adapt legislation flexibly – one of the main advantages of guidance over legislation in the past.

So, legislation or guidance to advance the Three Rs in Europe? The answer was dictated partly by the past and partly by our culture. In Europe we have had EU-wide binding legislation in this field for a quarter of a century, The question was not whether we should have legislation but rather how it can better reflect and support our current and future values and the ways in which we interact with animals.

Legislative process

Naturally, the birth of a new piece of legislation versus that of guidance is very different in terms of interaction, and a level of caution has to be exercised during the process. When working on developing legislation, the process is slow due to such factors as scientific opinions and various consultations at different levels. However, all these elements are needed to ensure an outcome that strikes the right balance.

I would like to bring some poetry into this dry subject: The Beauty of a drawn-out, slow legislative process. It is a slow process, but being someone who prefers to look at the sunny

side, I can also see the benefits in the slowness of the exercise:

– not only does it allow different players and stakeholders, even the sleepy ones, to be brought into the common construction site to design the building blocks together;
– it forces attention on the main subject but also on the numerous other elements surrounding it – just look at the discussions on the ethics of using human embryonic stem cells as potential alternatives to animal methods right before the adoption of the new Directive at the European Parliament or at the discussions on the needs and the current state of use and the progress on alternative approaches to animal testing;
– going further, it keeps the momentum going and is a catalyst for a wider discussion on the general justification of and the needs for animal experimentation, and it serves as a useful catalyst to other initiatives surrounding the subject;
– it is also an educational process: as an example, it brings foreign terminology into broader use – the "principle of the Three Rs" surely being among them;
– and finally, with the wider discussion, it increases understanding of what is done with animals, why, and how.

Before diving into some of the details of the new piece of European legislation, a few words to help you better understand the European legal system and how new laws are developed and adopted.

– Firstly, about the choice of the legal instrument: a Regulation or a Directive? In the EU, Regulations are directly applicable and thus very detailed in terms of how objectives are to be met. Directives, on the other hand, state the objectives; the "hows" are established in the respective national legislation – proportionality and subsidiarity are principles to be respected, and flexibility is gained through the implementation. In this case, we already had a Directive in place for 25 years, and national implementation as to how to achieve its objectives varied between countries. A single Regulation requiring the same implementation methods through the 27 nations was therefore not desirable. The Directive was the natural choice dictated by the past, as well as the way the different countries already had chosen to work in this field.
– Let us now look at the Commission Proposal. The basis of any Commission proposal rests on solid scientific input. This is then worked further to assess what is needed in terms of policy and how different, sometimes competing interests can appropriately be taken into account. A thorough impact assessment is carried out on different options to be put forward and, finally, the draft proposal is submitted to a public consultation.
– Before the proposal is adopted and released by the Commission, the first level of compromises is reached through negotiations between the different Directorate Generals of the Commission. These "DGs" represent different interests such as research, public health, industry, SMEs, and so forth, in the run-up to the adoption of the Commission proposal. However, the release of the Commission proposal marks only the start of the legislative process.
– Negotiations that follow incorporate further political input through the co-decision process where 27 Member States have to agree on their common view, which they then will defend when negotiating with the European Parliament. The Commission facilitates this process by providing expert input and identifying possibilities for compromise between the two co-legislators, the Council, i.e., the 27 Member States, and the European Parliament, until the final agreement is reached.
– Stakeholders, experts, and different political groups are part of the process at every step of the way: scientific input, verification of the impact assessment, continuous lobbying of different negotiators. The stakeholder involvement is not over at the adoption of the new law: the transposition and implementation of a new Directive again call for input from experts, and national consultations are held to identify the optimal and most pragmatic way of implementing the requirements of the Directive into national legislation.

What are the key dates? Directive 2010/63/EU entered into force on November 10, 2010 (EU, 2010). The transposition, its "translation" into national legislation, has to be completed by November 10, 2012. Finally, the new Directive will take full effect from January 1, 2013.

2 The Three Rs in legislation

Moving on to the core of my talk, I shall discuss the new legislation and how it implements and advances the Three Rs.

The Directive was drafted with four very clear and fundamental principles in mind. Firstly, the recognition that the ultimate goal is to replace the use of animals. Secondly, the acknowledgement that animals, including non-human primates, are still needed today. Thirdly, the acceptance that animals have intrinsic value in themselves, which must be respected. And finally, the agreement that the principle of the Three Rs is the key to more humane and better science.

We can have long discussions on the final details of the text, but its strength comes from the very existence of the legislative framework. The Directive will provide a legal framework that will mature with the technical and scientific developments and can incorporate changes to ethical thinking and values as well as take into account cultural differences. A good piece of legislation grows with time. The framework is set, so let us look at some of the elements contained therein.

A word to explain the roles of Recitals and Articles, the provisions in the context of EU legislative framework: A recital serves to justify the need for the legally binding provision; an article is needed in the enacting terms. The recitals provide the whys, and the articles state the exact policy objectives to be met.

The principle of the Three Rs is spelled out in this Directive. Replacement, Reduction, and Refinement can be found explicitly in Recitals 10-13 and in the enacting terms, in Articles

1, 4 and 13. The principle of the Three Rs can be found in three layers:

i. it is explicitly spelled out and is a specific legal requirement in its own right,
ii. there are a number of provisions aimed at directly implementing the Three Rs or to furthering the development and use of alternatives, and
iii. there are provisions that do not at first seem to be connected with the Three Rs, but a closer look will prove otherwise.

The Directive also ensures that Refinement is not limited solely to scientific procedures, i.e., the choice of methods to be used, but also are relevant in relation to care, accommodation, and breeding of animals. In fact, Refinement covers all animal and human interaction in this respect, during the entire life of the animal. There is also an added emphasis on new resources foreseen for the development, validation, and regulatory acceptance, as well as dissemination of information on alternative approaches. We can therefore safely say that the Three Rs are at the very heart of this piece of legislation.

2.1 The principle of the Three Rs in its own right

Moving on and looking at the details of the enacting terms and how they work to advance the Three Rs through policy. Firstly, the principle of the Three Rs in its own right: The very first Article of the Directive outlines the subject matter and scope and reads:

"*This Directive establishes measures for the protection of animals used for scientific or educational purposes. To that end, it lays down rules on the following:*
(a) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures; …"

Article 4 spells out the principle itself and makes it a requirement to Replace, Reduce, and Refine as inspired by Russell and Burch, making sure, however, that the refinement goes beyond a mere consideration when choosing methods.

"*Article 4 Principle of Replacement, Reduction, and Refinement*
1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.
2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.
3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.
4. This Article shall, in the choice of methods, be implemented in accordance with Article 13."

As can be seen, there is a formal and unambiguous recognition of the principle of the Three Rs, and further obligations are derived from this principle.

2.2 Direct implementation of the Three Rs

Let us now look at the implementation. There are a number of provisions aimed at implementing the Three Rs directly, such as:

– Project authorization with a *systematic project (ethical) evaluation*
– Retrospective *assessment* of projects with high concern
– Severity classification of procedures and re-use
– *Animal welfare body in each establishment*
– National animal welfare committee
– Binding housing and care requirements

I have chosen three of them, highlighted in italics, to go into more detail: project evaluation, animal welfare body, and retrospective assessment.

Project evaluation

Starting with the project evaluation and how it responds to the requirements of Articles 1 and 4 more closely. Project evaluation is at the very heart of implementation and practical application of the Three Rs in my view. The competence of the personnel involved in animal use, handling, and care – be it at the planning stage or during direct interaction – together with a proper, thoroughly conducted project evaluation – creates one of the biggest impacts of this Directive on the welfare of the animals.

Therefore, a quality evaluation requires the attention of all involved: those who design the project proposals, those who decide how project evaluation is implemented, those who take part in the evaluation – either directly or indirectly – and, finally, those who oversee the implementation of the project in accordance with the authorization.

The Directive requires considering expertise, particularly in:

– *the areas of scientific use and Three Rs in the respective areas*
– *experimental design, including statistics*
– *veterinary practice in laboratory animal science*
– *animal husbandry and care of the species in question*

It further requires that the project evaluation process be *transparent* and be *performed in an impartial manner* so that it *may integrate the opinion of independent parties*.

What steps are included in the project evaluation? It should assess its contents in relation to the aims and objectives of the project, followed by an assessment of application of the Three Rs.

Before running through the full list in Annex VI of the Directive, it is important to remember that Annexes of both Regulations and Directives are binding within the EU legislative framework. In practice, this means that all the elements we will cover here are elements that the applicant as well as the competent authority carrying out the project evaluation are required to reflect upon.

This is to be read, naturally, in conjunction with the requirement for project evaluation that states that the evaluation "shall be performed with a degree of detail appropriate for the type of project." The necessary flexibility is provided to ensure that common sense can prevail.

Annex VI states that when assessing the implementation of the Three Rs, the project evaluation shall look at
"*1. Relevance and justification of the following:*
(a) use of animals including their origin, estimated numbers, species and life stages;
(b) procedures.
2. Application of methods to replace, reduce and refine the use of animals in procedures.
3. The planned use of anaesthesia, analgesia and other pain relieving methods.
4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.
5. Use of humane end-points.
6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.
7. Reuse of animals and the accumulative effect thereof on the animals.
8. The proposed severity classification of procedures.
9. Avoidance of unjustified duplication of procedures where appropriate.
10. Housing, husbandry and care conditions for the animals.
11. Methods of killing.
12. Competence of persons involved in the project."
As you can see, each and every one of these elements contributes directly to the implementation of the Three Rs. Far more important than the specific details in the Annex, however, are the practical consequences and impacts of the existence of the Annex itself. As is true elsewhere in the Directive, it forces people into a thinking process, to consider different elements. In some cases, it forces the thinking to take new paths, paths that have not been necessarily explored in the past – at least not in a systematic way.

Furthermore, it is not only those who use animals that are affected. The legislators and the control bodies – whether at the local, regional, or national level – who will design and implement the tools that will allow the objectives of the Directive to be achieved – are likewise affected. A thought process is necessary for the development of practical implementation – a thought process that in itself is an educational journey, the starting point for a change in attitudes. The true path in bringing life into the principle of Russell and Burch is through policy.

As I have said, and will repeat, we can discuss the rightness of specific details, the wordings, but by far the bigger policy impact for advancing the Three Rs comes from the fact that this and other provisions now exist in legislation. The legal framework is set – the details will change with time.

Once the project evaluation has assessed the way in which the Three Rs are applied in the project proposal, the two remaining steps are the prospective severity classification of the procedures in the project proposal, for which Annex VII provides further assistance, and finally, the harm-benefit analysis of the project to assess whether the harm to the animals can be justified by the expected outcomes, taking into account ethical considerations. Project evaluation also will determine the need for, and the timing of, a retrospective assessment. I remain convinced that a detailed and constructive dialogue in the form of a project evaluation is one of the key tools for more humane treatment of animals and improved science.

Animal Welfare Body

Moving on to the requirement for all breeding, supplying, and user establishments to set up an Animal Welfare Body, as required by Articles 26 and 27:

Firstly, an important note to combat one of the biggest misunderstandings of this Directive. The co-legislators did not see project evaluation as one of the tasks of the Animal Welfare Body. Therefore, any comparison with the tasks of Institutional Animal Care and Use Committees (IACUCs) should be drawn with great caution. The tasks of an Animal Welfare Body are of a very different nature from those of evaluating projects, a task entrusted to the competent authorities under this Directive.

The competent authority, the body to carry out project evaluation, is governed by a set of requirements for project evaluation as well as those for a competent authority. These will not be discussed here. We will look at the Animal Welfare Body and its role as it was designed by the co-legislators. As you will see from the tasks and the composition, it is designed to bring the Three Rs truly alive in the day-to-day life of an establishment.

An Animal Welfare Body must:
– include a person(s) responsible for the welfare and care of animals
– include, in case of a user establishment, a scientific member and
– receive input from the designated veterinarian

The tasks assigned to an Animal Welfare Body include:
– *advising* the staff on *welfare of animals*
– *advising* the staff on the *application of the Three Rs* and especially the developments on their application
– establishing/reviewing internal operational processes
– *following* the development and outcome of *projects*
– advising on re-homing schemes

As was the case with the list of Annex VI on the application of the Three Rs within a project proposal, here again we are looking at a number of tasks that are to be considered and carried out. All of those have a direct impact on the implementation of the Three Rs. The tasks that were chosen are of course of primary importance; more importantly, however, the concept of an Animal Welfare Body of this type guides the thinking into ways we can, in our day-to-day lives, better implement the Three Rs. It gives focus and brings the Three Rs to the forefront of how we should operate. It provides a golden opportunity to grasp a new path of thinking and to bring this attitude of a climate of care into the daily life of any establishment using or housing animals.

Retrospective assessment

Tying back to the project evaluation, at the end of which it is to be decided if and when a project should go through a retrospective assessment as described in Article 39.

Retrospective assessment is targeted for "high risk projects," and it is always tailor-made to the project in question. The assessment should cover *inter alia* "*any elements that may contribute to the further implementation of the requirement of replacement, reduction and refinement*."

Looking specifically at the last requirement: if advancements are to be made with the Three Rs on all fronts, these need to be captured, recorded, and disseminated to a wider audience. Retrospective assessment is designed to provide another tool in the toolbox to facilitate this process.

2.3 The hidden Rs

Let us now move to some of the other elements of the new Directive – elements that do not at first seem relevant to the Three Rs principle but at the end of the day will contribute to its implementation in its widest sense.

A number of these elements, such as those on competence, inspections, designated veterinarian, individual history file, non-technical summaries, or installation and equipment, especially affect the refinement of use, the furthering of animal welfare and/or minimizing the suffering in areas where animals are waiting to be used or have been used in procedures. In my view, the competence of personnel is of foremost importance – however, I will not go into the competence, as we had a separate session dedicated to this subject during this Congress.

I will instead focus on two examples of the hidden promotion of the Three Rs through this policy: first, the role of the designated veterinarian in Article 25. Each breeder, user, and supplier must have a designated veterinarian. In some cases, e.g., in connection with more uncommon species from groups such as cephalopods, a suitably qualified expert may be more appropriate. This suitably qualified expert or a veterinarian does not need to be employed in-house, but one must be designated for each establishment.

Naturally, the experts are required to fulfil their traditional role in providing appropriate veterinary care. However, their role goes beyond that. The designated veterinarians have a central role in ensuring compliance with the Three Rs through a number of elements, such as through the work of the Animal Welfare Body, project (ethical) evaluation, decisions on re-use as well as on exemption decisions, e.g., on space allowances.

Moving on to non-technical project summaries as described in Article 43. These are designed to provide brief and easily understandable summaries of authorized projects. They accompany project requests for authorization and are to be made publicly available by the Competent Authority when a project is authorized. What are the elements they should contain? Information on the objectives of the project, including its predicted harms and benefits, but more importantly, information on the ways in which the Three Rs are implemented in that particular project.

As a good demonstration of the way in which the Directive is built and how its different elements support one another, I would like to go back to the retrospective assessment, which I referred to as a tool to capture new ideas in the practical application of the Three Rs developed during the life cycle of a project. Non-technical project summaries are another tool in the toolbox to foster the information exchange on the Three Rs. The non-technical project summaries are to be updated with the results of retrospective assessments, which specifically call for elements that may contribute to the further implementation of the Three Rs. The non-technical project summaries serve, therefore, to inform the wider community of any further advances in the Three Rs. Naturally, the contents of non-technical summaries are to be drafted in a way that does not violate confidentiality or rights for proprietary information.

2.4 More resources for the development and validation of alternative approaches

Finally, let's look at how alternative approaches are promoted and further pushed forward with this policy. There are a number of obligations for both Member States and the Commission covered in Articles 47 and 48.

The Directive obliges the Member States and the Commission to contribute to the development and validation of alternative approaches. It is interesting to note in this context that the wording of Directive 86/609/EEC asked for the Member States and the Commission to "encourage" the development and validation of alternative methods (EEC, 1986). The wording of the new Directive makes a clear and firm step forward, from mere "encouragement" into "contribution." Europe is stepping up its efforts to advance alternatives.

Member States also are required to assist the Commission in identifying and nominating suitable specialized and qualified laboratories to carry out validation studies. They also are expected to promote and disseminate information on alternative approaches at national level.

Last but not least, PARERE, a new process through which the relevance of a newly proposed alternative method is assessed by regulators – those who ultimately will need to agree on its usefulness – prior to its acceptance into the validation process. PARERE, literally meaning an "opinion" in Italian, comes from the words **P**reliminary **A**ssessment of **Re**gulatory **Re**levance. This network will ensure that those methods that have the highest potential in terms of their use in regulatory contexts and benefits to the Three Rs will be prioritized. PARERE also will improve validation by ensuring that the right target substances can be included in the validation process from the start. Finally, the early involvement of regulators, as we have heard several times during this Congress, is a key to a speedy regulatory acceptance at the end of the process. This is Europe's direct response to the demand.

The obligations are not only for the Member States. The Commission will establish the Union Reference Laboratory, ECVAM (the European Centre for the Validation of Alternative Methods), with tasks described in Annex VII. It is important to note that, until now, there has been no formal legal basis for ECVAM. ECVAM was the response of the Commission to the 1986 Directive to encourage the development and validation of alternative methods, established through a 1991 Communication (EC, 1991). This has now changed, and a firm legal basis

has been set for the work of ECVAM. As for the network of laboratories at the level of Member States, the Commission will set the priorities and allocate the tasks between the laboratories after consulting with the Member States. Just as Member States are required to act at a national level, the Commission is required to make efforts to obtain international acceptance of alternative approaches at international fora.

3 The opportunities and challenges

Moving on to the last part of my talk – where are we today and what are the next steps? We have real opportunities ahead of us – are we grabbing them? The new Directive equips us with a series of tools to increase animal welfare through a systematic implementation of the Three Rs. In return this will allow us to improve science and reduce waste, a matter of importance, especially during times when resources are scarce. We have a golden opportunity to cut down red type and implement best practice to free resources for the essential. Furthermore, with concentrated efforts to develop new alternative approaches, we have an additional opportunity to cut down costs and time, as well as to create new business opportunities, a field in which we already can note a number of SMEs realizing the future prospects.

However, there are no opportunities without challenges. To ensure a proper implementation throughout Europe, we need a uniform understanding and interpretation of the Directive. The question of available resources, both for the authorities and for breeders/suppliers/users, during an economic slowdown is not to be disregarded. An even bigger challenge than resources: are we capable of changing the mind-set, both top down and bottom up, to roll out of the concept of "climate of care" so that each and every one of us embraces it? What about existing infrastructures, the human unwillingness for change? Are these obstacles too big to stop us from carrying out an intelligent transposition that incorporates proactive engagement of all involved instead of just copying and pasting the legal requirement? And then there is the matter of time – only a little over a year left for the Member States to finalize the formal transposition.

Responding to challenges

The Member States already are engaged in drafting, holding consultations, adopting and implementing national legislation. This includes setting up their infrastructures and designating the appropriate competent authorities for tasks such as project evaluation, project authorization, retrospective assessment, and inspections. In addition, each Member State needs to establish a National Animal Welfare Committee.

Streamlined processes, clear responsibilities, avoidance of duplication of tasks, the identification of the optimum setup – at national, regional or local level – all requires thorough reflection, as well as co-operation across borders, to benefit from best practice. The Member States need to discuss internally how to best contribute to the development, validation, and regulatory acceptance of alternative methods, identify suitable laboratories, and set up channels for the dissemination of information on and the promotion of alternative approaches. Last but not least, the most challenging of the tasks: how to make users, breeders, and suppliers take ownership of the Three Rs.

The national transposition is a golden opportunity to critically review the current setup and procedures and, where appropriate, streamline and improve on the existing systems: as I said, an intelligent transposition instead of a mere copy/paste exercise into a national legislation.

The Commission has an equal role to play. To facilitate the transposition we have drafted, together with the Member States, into an implementation action plan. The Commission will establish a number of stakeholder expert working groups to arrive at a common understanding of specific terms used in the text, terms such as "debilitating clinical condition," "prolonged suffering." Similarly, experts will be called upon to develop guidance on issues such as retrospective severity assessment, education and training, non-technical project summaries, project evaluation, and inspections. The results of expert discussions, their conclusions and guidance, will be made publicly available to ensure widest possible dissemination. A lot of this work is of interest to everyone in the field, regardless of his or her location. Therefore, we should not work in isolation but instead seek widest possible co-operation – between the Member States and, equally, beyond the borders of Europe. A successful implementation can only be achieved through a close co-operation between different actors. The timely and intelligent transposition is a challenge as big as the adoption itself.

4 Conclusions

A good policy is often implemented through a mix of tools: legislative framework, complementary guidance, and voluntary initiatives. The legislative process is lengthy but carries benefits in ensuring a wider reflection and input from all players.

The new Directive strikes the right balance. The principle of the Three Rs is embedded in the text and has been brought to life. The timely and intelligent transposition is a challenge requiring reflection and effort from all. There is a true opportunity to advance the Three Rs through policy – are we taking it?

We have discussed today the choice of policy as means to advance the Three Rs. I believe that progress through legislation fits the European culture and tradition. More importantly, it is the way to achieve better and more humane science as envisaged by Russell and Burch over a half a century ago. A question for other regions: is this a model that could work elsewhere as well?

At the end of the day, whether it is or is not is only of limited relevance to the need to work together. Any framework, legal or otherwise, should be sufficiently flexible to adjust and adopt best practices as they become evident over time. Some areas, for example, education and training, develop at a rapid pace and thus require constant work. It would be foolish to think that we sit in isolation in this day and age. Only by combining our efforts across regions and sharing the work can we effectively advance the Three Rs.

We can have endless discussions on the details, and there may be provisions that prove difficult, even erroneous. On the other hand, we are hopeful that plenty of people who are ambitious and forward looking will bring about further progress in this – even over decades to come. The revision has given us an opportunity to bring the words of Russell and Burch to the next level: not only looking at experiments in isolation but encompassing The Three Rs in all interaction with animals when they are kept and used for scientific purposes.

The devil may be in the detail but, equally, the details carry the power to change attitudes. A perfect piece of legislation does not exist. But we should always aim at perfection. At the beginning of the process, the bar should be put at the highest, not the lowest denominator, as legislation is always a result of a balancing act. It starts from the reflection of societal norms and our cultural conscience – an ambition and idealism that meets with the realities during the long journey of the legislatives process.

Good policy requires insight, the ability to think forward, plus perseverance and good timing. Whether it succeeds is a result of multiple factors. The transposition and implementation, throughout a region with not just one or two but 27 different national cultures and 23 languages is a challenge. In other words, only time will tell.

Rounding up… legislation or guidance? Implementing the Three Rs through policy – reality or dream?

There is one exclusive benefit of having principles laid out in a horizontal piece of legislation that guidance does not have: the snowball effect. Once set in legislation, any related future legislation or policy can no longer ignore it. A principle set in legislation has to be taken into account and incorporated in future policies whenever animal use is touched upon. With the new Directive, this snowball effect is set in motion for the Three Rs and, hopefully, into a long and powerful avalanche. A positive avalanche starting from the higher altitudes and picking up speed as it rolls down stronger and wider.

As one of the authors of "one of the worst pieces of draft legislation ever published," as described by my former colleague Professor Balls at the Rome World Congress two years ago (Balls, 2010), I still strongly believe that the new Directive has succeeded in anchoring the Three Rs firmly in the legislative framework – to the benefit of all experimental animals and science. Europe has confirmed – in black and white – its commitment to the Three Rs, not only as an abstract concept but equally as a pragmatic day-to-day tool of work. The seed is planted for changing attitudes and the way we operate. If Directive 2010/63/EU turns out to be "one of the worst pieces of legislation," I am happy to admit defeat and buy Professor Balls a drink; otherwise, I shall be waiting for him at the Congress bar in Prague in 2014.

Returning back to the words by William Harold Taft and slightly modifying them: "*The world is maybe not going to be saved by legislation, but it can sure save some animals and inspire people to do more*" – for the animals, and ultimately for better science!

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