
1. Introduction

Humane Society International (HSI)/Europe welcomes this opportunity to comment on the policy options for the Second EU Strategy on the welfare and protection of animals, which were presented at the DG SANCO stakeholders’ meeting on 31st January 2011.

We commend the Commission’s plan to develop a coherent strategy on animal welfare following the thorough evaluation of existing EU animal welfare policy. In essence, the first Animal Welfare Action Plan was little more than an inventory of planned activities. A more substantial strategic plan, which - amongst other things - proposes the introduction of new animal welfare legislation and outlines the necessary actions to improve the enforcement of existing standards, is required for the 2011-2015 period.

This strategic plan should encompass not only animals kept for the purposes of food production (including farmed fish) and animals used in scientific research and testing, but also wild animals (kept in captivity or used for commercial purposes) and companion animals.

1.1. General comments on the proposed policy options

As noted by several participants during the stakeholders’ meeting, there is too little detail given on what each policy option, particularly those involving framework legislation, would entail. It is difficult to commit ourselves to supporting specific policy options when not all the facts are available.

HSI/Europe does, however, believe that additional prescriptive legislation is necessary to further improve the protection and welfare of animals in the European Union. Although potentially useful in certain instances, we consider non-legislative measures to be generally insufficient to achieve this aim. Harmonised, mandatory standards throughout the EU are needed to ensure both a high degree of animal protection. Option A must therefore be rejected.

Nonetheless, it is important to note that the measures proposed in the various options are not mutually exclusive. The development of a framework legislation or further prescriptive legislation does not necessarily exclude the possibility of developing of a strong communication and education strategy for animal welfare in the European Union or committing Community funds to additional animal welfare research.

For this reason, a policy mix would appear to be the most attractive choice, though this should not necessarily be restricted to the development of a framework law based on animal welfare indicators with the establishment of a European Network of Reference Centres and a communication and education strategy, as proposed in Option D.

Further clarification on the envisaged nature and scope of the proposed framework law is also required. While the concept of a framework law for animal welfare is appealing, we believe that the development of any future framework law should not be at the expense of existing animal welfare
legislation, nor should it preclude the development and adoption of new (species-specific) Directives under the ordinary legislative procedure.

1.2. Elements for inclusion in the Second EU Strategy

Given that there is insufficient information to make an informed choice between policy options, HSI/Europe advocates that the Commission develop a broad policy mix for the Second EU Strategy on the welfare and protection of animals. The Strategy should focus not only on the improvement of animal welfare through the introduction of new legislative measures and policy tools, but should also ensure that existing legislation is being adequately understood, implemented and enforced in all Member States.

The following key elements should be included in the Strategy:

- Harmonised minimum welfare standards for categories of food-producing animals presently not covered by existing species-specific Directives.
- A comprehensive communication and education strategy on animal welfare.
- The establishment of a European Network of Reference Centres (or a centrally located Reference Centre) for animal welfare.¹
- The harmonisation of systems for collecting data on animal welfare from Member States and monitoring the implementation of legislation.
- A clear strategy for the improved enforcement of animal welfare legislation in Member States, including increased capacity of Food and Veterinary Office (FVO) to carry out inspections and new measures to ensure the effective and proper enforcement of Council Directive 1999/22/EC on the keeping of wild animals in zoos.
- The development of financial instruments to allow funding for animal welfare measures to be incorporated into Common Agricultural Policy (CAP) support schemes as part of CAP reform.
- The production of guidelines for responsible animal ownership and/or management.
- A clear programme for animal welfare related research to be conducted during the 2011-2015 period.
- The establishment of clear guidelines for inclusion of animal welfare and animal protection goals in EU international trade policy.

Below a number of issues for inclusion in the Second EU Strategy on the welfare and protection of animals are discussed in greater detail.

¹ With respect to a European Network of Reference Centres, it should be noted that there may be overlap with bodies (i.e. EU and National Reference laboratories) that must be created pursuant to Directive 2010/63/EU on the protection of animals used for scientific purposes.
2. Farm animals

2.1. Species-specific legislation

As the recent EUPAW evaluation observed, there are an estimated 868 million farm animals, such as dairy and beef cattle, rabbits, ducks and geese, and aquaculture species, which are presently not covered by any species-specific EU legislation. While Council Directive 98/58/EC sets down some general rules to protect animals kept for production purposes, this legislation is insufficient to provide explicit regulations for keeping these species.²

Throughout the past decade, the European Food Safety Authority (EFSA) has adopted a variety of scientific opinions that explicitly address the welfare of species for which there is currently no species-specific legislation.³ These EFSA opinions – taken together with the Recommendations previously adopted by the Council of Europe⁴ – provide a scientific basis for the preparation of legislation that could safeguard the welfare of millions of food-producing animals in the European Union.

HSI/Europe therefore urges the Commission to include the development of legislative proposals for mandatory minimum welfare standards for the following categories of food-producing animals in its new Strategy:

- Dairy cattle
- Beef cattle
- Farmed fish

Minimum standards should not preclude the adoption of stricter requirements where necessary. Third countries seeking to export to the EU should have to meet equivalent standards.

With respect to farmed fish, it should be noted that minimum standards are not only required for the keeping, breeding and transport of live fish, but that additional regulations are also needed for the protection of fish at the time of killing. Regulation (EC) No. 1099/2009 on the protection of animals at the time of killing did not include specific provisions on farmed fish because it was felt that there was a “need for further scientific opinion and economic evaluation in this field”.⁵

EFSA has since published a series of opinions, which address the most appropriate methods of stunning and killing the main species of fish kept in aquaculture.⁶ Given the Commission’s obligation

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² Indeed, fish – along with reptiles and amphibians - are explicitly excluded from Article 4 of Council Directive 98/58/EC, which establishes a responsibility to keep animals under conditions that have regard to the species’ physiological and ethological needs in accordance with scientific knowledge and established experience.


⁶ For example, Scientific Opinion of the Panel on Animal Health and Welfare on a request from the European Commission on welfare aspect of the main systems of stunning and killing of farmed Atlantic salmon. The
to present a report on fish welfare at the time of killing by December 2014, it is hoped that fish welfare will be made a priority during the 2011-2015 period.

In addition to cattle and farmed fish, further research should be conducted and policy action taken with a view to the future development of minimum standards to protect the welfare of the following species:

- Rabbits
- Geese
- Ducks

Although these sectors of animal production are far smaller than the dairy/beef cattle and aquaculture sectors, poor welfare is often experienced by these species. This has already been acknowledged by EFSA. In 2005, it adopted an opinion on the health and welfare of (intensively) farmed rabbits, which highlighted the necessity of improving rabbit welfare through the modification of both housing and husbandry practices. Similarly, an EFSA scientific opinion concerning the harvesting of feathers from live geese was also adopted in 2010 underscoring the serious welfare problems that are associated with the removal of non-ripe feathers in particular.

HSI/Europe would equally like to see legislative improvements for farm animals for which species specific legislation exist. Below are specific suggestions for inclusion in the strategy. The issues raised are in no way exhaustive, but represent the most pressing animal welfare problems caused by EU livestock farming.

2.2. Non-compliance with EU minimum standards

FVO missions and NGO investigations alike have disclosed widespread failure to comply with the legal standards for the protection of pigs and laying hens. This includes routine tail docking and teeth clipping of pigs as well as lack of material for manipulation, overstocking of both pigs and laying hens and inadequate care for sick animals.

It is also a cause of great concern that satisfactory planning measures to safeguard the 1 January 2012 ban on non-enriched cages deadline seems to be lacking.


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9 See e.g. FVO report 2010-8387 : http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=8420


incremental part of the new strategy. HSI also urges the Commission to take all possible measures to ensure that the 2012 ban on non-enriched cages is adopted on time.

2.3. Broilers

An EFSA opinion on the influence of genetic parameters on the welfare and the resistance to stress of commercial broilers released in July 2010 found serious welfare concerns caused by skeletal disorders amongst other things. The opinion suggests that increased monitoring of gait scoring could lead to a review of the genetic selection systems for broilers.

HSI/Europe calls on the Commission to take the EFSA opinion into consideration and based on EFSA’s recommendations work towards a regulation of the EU legislation on breeding parameters of broilers.

2.4. Transport

In the EU more than 365 million heads of livestock (poultry excluded) are transported for up to several days across the member states every year. This is despite the European Parliament, as early as 2001, adopting a resolution calling for the limitation of live animal transport to a maximum duration of 8 hours for all species. Widespread public opposition to the long transports is also prominent in the European discourse. Further, already in 2004 EFSA concluded that “journeys should be as short as possible”15. This was backed by their most recent scientific opinion from January 2011 which recommended "...further research focused on ...optimal journey times for horses, pigs and calves".16

HSI/Europe therefore urges the Commission to work towards legislation that will limit the transportation of slaughter animals to 8 hours, and not merely increase the frequency of watering, feeding, and resting opportunities. This should incentivise using breeding facilities closer to feed and forage crop availability and increasing the number and regional distribution of smaller-scale non species-specific processing plants.

2.5. Sustainable agriculture

The escalation of intensive livestock farming in the EU has widespread socio-economic and environmental implications. Indeed the farm animal production sector is the single largest anthropogenic user of land worldwide, contributing to soil degradation, dwindling water supplies, and air pollution, in addition to detrimentally impacting rural and urban communities, public health, and

14 See, for example, www.8hours.eu
animal welfare\textsuperscript{17}. Low animal welfare systems are also linked with the development of antibiotic resistant pathogens\textsuperscript{18}.

The recent Foresight report on Global Food and Farming Futures concludes that further intensification is not necessary to meet global food needs and that sustainability needs to move to centre stage\textsuperscript{19}. A move towards more small scale, extensive farming with locally sourced animal feed would create better animal welfare, have less environmental implications and create stronger local economies.

HSI/Europe therefore urges the Commission to include measures in the strategy that will stimulate financial incentives for creating more small-scale, extensive farms in the EU as well as phasing out financial incentives for intensive animal agriculture\textsuperscript{20}.

3. Animals used in research and testing

Progress toward realisation of the EU’s commitment to replace animals used for experiments has been mixed. On the one hand, policies such as a Europe-wide ban on the sale of animal tested cosmetics have been welcomed by citizens; however, the number of animals who will be spared by this ban (if implemented and enforced) will be dwarfed by other policy measures such as REACH, which is expected to lead to the death of tens of millions of animals in new toxicity testing.

EU research efforts aimed at the replacement, reduction and refinement (3Rs) of animal use in experiments have, for the most part, focused on the area of regulatory testing. This is understandable given the policy measures noted above and the fact that many of the most severe and distressing animal procedures occur in this area. However, it must also be recognised that regulatory testing accounts for only about 10\% of the more than 12 million animals use for experimental purposes each year across the EU. Thus, an EU strategy to move towards replacement of animals in basic and applied life sciences research must be given greater priority and resources going forward.

Specific issues that HSI/Europe would like to see addressed by future policy include the following:

3.1. Legislative Tools & Enforcement

3.1.1. Resolving the discordance between the requirements of Directive 86/609 and sectoral data requirements, accepted testing methods and guidelines, etc.

Article 7 of Directive 86/609 stipulates that:

2. “An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.”

3. “When an experiment has to be performed, the choice of species shall be carefully considered and, where necessary, explained to the authority. In a choice between experiments, those which use the


\textsuperscript{19} \texttt{http://www.bis.gov.uk/foresight/our-work/projects/current-projects/global-food-and-farming-futures}

\textsuperscript{20} This would support a move in the CAP for lower payments in Pillar 1 and increased payments in Pillar two.
minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected. …”

4. “All experiments shall be designed to avoid distress and unnecessary pain and suffering to the experimental animals. …”

Contrary to these requirements, there are numerous examples in EU legislation and regulations of in vivo tests being required/permitted despite the availability of valid and/or accepted non-animal methods/testing strategies; of highly invasive and distressing tests being required absent pain relief of any kind; requirements for clearly duplicative animal testing using multiple species and/or exposure routes; and similar violations of Directive 86/609. In some instances, the problem is one of failure to ensure the timely adaptation of data requirements to reflect technical progress (e.g., REACH Article 13.2 requires such action by the Commission “as soon as possible … so as to replace, reduce or refine animal testing”; however, REACH data requirements have yet to be revisited despite several substantial 3Rs advances in the years since the regulation entered into force).

There have also been cases where proposed revisions to data requirements that could reduce animal testing without jeopardising human safety (e.g., dropping the mouse carcinogenicity study and dermal lethal dose test for plant protection products and biocides) have been or are being blocked by Member States, despite compelling evidence that these studies do not provide “value added” in safety assessment.

A related issue is the process and efficiency by which scientifically valid 3Rs test methods/strategies achieve regulatory acceptance by EU and Member State authorities. At the behest of animal welfare organisations and the European Parliament, Commission services have taken steps to streamline the EU acceptance process for certain testing methods, i.e., this process applies mainly to chemical test guidelines, whereas different processes exist in other regulated product sectors (e.g., human pharmaceuticals, vaccines, and shellfish biotoxins). Thus, there is room for further improvement, particularly in the face of obstructive interventions by certain EU authorities, which have at times created delays in acceptance of priority 3Rs methods.

A transparent exploration of options for resolving these longstanding, systemic challenges is recommended such that the letter and spirit of Directive 86/609 and its successor are more consistently reflected in EU sectoral legislation as well as in the actions and decisions of Union and Member State authorities.

### 3.1.2. Ensuring adequate resources are available for transposition, implementation, monitoring and enforcement of existing and new legislation

Directive 2010/63 on the protection of animals used for scientific purposes must be transposed into national law by 10th November 2012, and much work is needed to ensure optimum conditions for transposition, implementation, monitoring and enforcement of the new legislation. HSI/Europe expects the Commission to provide support to Member States, including help establishing processes relating to ethical review, authorisation, and retrospective assessment of projects, and by providing expertise in areas such as application of severity classifications, where harmonisation and uniform interpretation is required but may be difficult to achieve.

Each Member State must ensure compliance with the Directive, but few structures or opportunities exist for knowledge and experience to be shared across the EU. Where these do exist, through the Committee (Article 56), reporting requirements (Article 57), thematic review (Article 58), contact
points (Article 59 and Article 47) and controls of national inspections (Article 35), these should be fully exploited by the Commission so as to improve harmonisation and increase protection of animals. As the majority of these coordination functions are entirely new, it will be necessary for the Commission to significantly increase staffing in this area.

Inspections and EU controls of national inspections are of particular importance, and it is essential that the Commission meets the challenge afforded by the new Directive to monitor the proportion of national inspections carried out without prior warning and investigate the “infrastructure and operation” of inspections. This should include close examination of the application of processes mentioned above, as well as other compliance issues.

HSI/Europe does not believe that extending the FVO inspectorate is necessarily the correct means by which to apply national controls relating to the use of animals for scientific purposes, but would favour any system that ensures (a) frequent and transparent monitoring and (b) that specialist expertise is available, including persons expert in application of alternatives to animal procedures.

A centralised system which allocates appropriate experts to carry out the necessary tasks is needed, and, because the frequency of EU interventions is not defined in the Directive, the Commission should publish commitments relating to carrying out the functions listed in Article 35. It should be envisaged that the Commission applies formal “controls of Member State inspections” by auditing each national inspectorate at least twice each year, and should make experts permanently available to answer questions on compliance. A significant proportion of projects in each Member State should also be audited as part of this process to ensure satisfactory and uniform application of ethical review, authorisation and retrospective review criteria so that national inspectors can be sure that compliance in these areas is being assessed uniformly in all Member States.

The Commission should ensure transparency regarding controls of Member State inspections; while this is not a requirement of Directive 2010/63, increased transparency around enforcement of animal welfare legislation is an appropriate function for the centralised animal welfare body or framework law.

In addition to the above, HSI/Europe would also like to see general transparency requirements relating to animal welfare aspects of implementation of REACH and the REACH review, updates of regulations relating to replacement of animal tests used to detect marine bioxins, and testing requirements associated with other regulated products applied through animal welfare framework legislation and/or the centralised animal welfare body.

3.2. Science & Research

Research to benefit animals use for scientific purposes should not be limited to such areas as welfare indicators, application of welfare standards, or development of non-animal test methods/strategies in toxicology. In the broader area of life sciences research, there are many opportunities to reduce and ultimately replace animal use through investment and appropriate use of advanced “21st century” tools and technologies. Research aimed at establishing alternatives to animal procedures, together with funding incentives for researchers to explore non-animal (and potentially more human-relevant) approaches to understanding fundamental biology and diseases, should be seen as a distinct aspect of research conducted to benefit animal welfare, and policy on that is worthy of separate attention. Additionally, HSI/Europe agrees with the finding that ethics procedures and policies governing EU Framework Programme (FP) funding for animal-based research could be strengthened and augmented, together with funding levels for 3Rs-relevant research (with a continued emphasis on replacement).
3.2.1. **Animal-based research funded through the Framework Programmes**

HSI/Europe would like to see an increase in the transparency with which ethical reviews are carried out during evaluation of FP funding applications and for more project applications to be subject to ethical review and retrospective assessment. In particular, we would like to see any project that is expected to cause more than moderate suffering undergo both ethical review and retrospective assessment, regardless of species, with particular emphasis on primate experiments and those involving genetically modified animals.

It is also necessary for the EU to more actively enforce and provide incentives for adherence to Decision No 1982/2006/EC to reduce use of animals in research & testing under FP7 (i.e., “Research activities should also take into account the Protocol on the Protection and Welfare of Animals and reduce the use of animals in research and testing, with a view ultimately to replacing animal use”). To this end, the EU should commit to the development of a strategy for phasing out experiments (i) classified as severe and (ii) involving GM animals, including establishment of annual reductions in levels of FP funding made available for such experiments, to be reduced to zero within a prescribed time-frame (e.g., 10 years). The EU should not fund any research using wild-caught of F1 primates.

3.2.2. **Role and responsibilities of the European Reference Laboratory (EU-RL)**

Directive 2010/63 requires creation of structures at Member State and EU level to advance the replacement of animal procedures, and HSI/Europe hopes that while these structures will provide the basis for research and coordination activity, a new animal welfare framework will require additional functions and allocation of resources.

At EU-level, the European Reference Laboratory (EU-RL) is defined in Annex VII of Directive 2010/63 as being the Commission’s Joint Research Centre. Recital 47 of the Directive requires formal establishment of the reference laboratory and Annex VII sets out its functions as including “coordinating and promoting the development and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing.” HSI/Europe strongly welcomes the functions listed and would like to see active engagement by the Commission in each of the tasks listed.

In particular we would like to see functions relating to the development and use of alternatives to procedures carried out for the purpose of basic and applied research fully implemented, and believe that an initial scoping exercise should be undertaken to identify animal procedures used in biomedical research that should be prioritised for replacement research activity due, e.g., to their overall poor performance (indicated by projects failing to produce useful information), causing severe suffering to animals used, etc.

We would like to see the EU-RL’s functions relating to “the exchange of information on the development of alternative approaches” extended through the EU’s animal welfare framework policies (and/or legislation) to include programmes designed to educate animal users and inspectors on application of the 3Rs and to bring together researchers interested in developing new replacement techniques. A range of functions should be in evidence and information disseminated. A good model for the EU-RL is, we believe, the UK’s National Centre for the 3Rs (NC3Rs.org.uk). Functions listed on that website under “Centre-led Programmes” serve as examples of the range of work we would expect the EU-RL and the animal welfare framework to be promoting.
3.2.3. Development of an EU strategy and research roadmap for achieving the next generation of safety testing

The EU has long led the world in the development, validation, acceptance and use of 3Rs methods in regulatory testing. However, the days of one-to-one replacement of an animal test by a non-animal method (e.g., for local toxicities such as skin irritation) are fast coming to an end. Beginning in FP6 and continuing into FP7, the EU has invested millions in a number of large-scale projects aimed at developing replacement tools for systemic and various organ-specific toxicities. However, despite progress in some projects (e.g., ReProTect and Sens-it-iv), it is clear that replacement solutions for complex toxicological endpoints cannot be delivered within the five-year timeframe of an FP grant. (Nor is the “integrated project” model necessarily the optimal tool for the task.)

In 2007, the US National Research Council issued the report Toxicity Testing in the 21st Century: A Vision and a Strategy,21 calling for a fundamental shift in toxicology away from observations of apical effects at high doses in whole animals toward a mechanistic understanding of xenobiotic effects on cellular response pathways in vitro at environmentally relevant exposure levels. This vision anticipates the enhancement and integration of such tools and technologies as computational systems biology and bioinformatics, functional genomics, robotic high throughput screening, and advanced pharmacokinetic modelling to provide robust and reliable data for risk assessment purposes. Potential advantages of such an approach include the capacity to examine a far greater number of substances, mixtures and biological outcomes at more relevant exposure levels; a substantial reduction in testing costs, time and animal use; and the grounding of regulatory decisions on human rather than rodent biology.

This call for a shift in regulatory testing paradigm is being echoed by an increasing number of voices in the EU scientific community, including the FP7 coordination project AXLR8.22 In its 2010 report, the AXLR8 project critically assesses the EU’s approach to 3Rs research and recommends a shift from disparate, endpoint-oriented “bottom-up” initiatives toward a unifying “top-down” strategy to ensure better long-term coordination at the project, national, European and international levels.

It is projected that the research effort required to translate the vision of “21st century toxicology” into reality could entail an investment on the order of €1.5 billion over at least a decade. As with the Human Genome Project of the 1990s, such an ambitious undertaking will require buy-in and close cooperation among major global economies. The EU is encouraged to make use of the research roadmaps developed by the AXLR8 project to position itself alongside the United States at the forefront of this major R&D and translational effort through FP8 and beyond. This should include more tightly coordinated programmes and intramural and extramural research, potentially through funding models other than integrated projects (e.g., longer-term, larger budgets, fewer partners). The fruits of a major investment in 21st century tools and technologies, e.g., in terms diversifying and strengthening the EU science base, fostering a more technical work force, and stimulating new economic growth, could be substantial indeed.

3.2.4. Development of an EU strategy and research roadmap for achieving the next generation of life sciences research

The revision of Directive 86/609 provided an opportunity for EU Institutions and Member States to demonstrate a material commitment to moving beyond the use of animals, not only for safety testing,
but also as “models” in basic and biomedical research. This latter use accounts for nearly 90% of the more than 12 million animals consumed for scientific purposes each year across the EU. Unfortunately, despite mandating the creation of dedicated EU and Member State-level structures to support and advance the 3Rs, the “National Reference Laboratory” model prescribed in the revised Directive remains oriented very much towards the validation of tools for toxicology, rather than toward the development of strategy and incentives to accelerate the replacement of animals in fundamental and biomedical research.

An investment in the science needed to replace the use of animals as “research models” is not simply political objective driven by animal welfare considerations; it is also an opportunity to improve our understanding of human biology through the use of modern tools and technologies that are directly relevant to our species. As with regulatory testing, there is a need for European thought leaders in each discipline (e.g., immunology, cancer, etc.) to come together to identify opportunities to increase the prominence of in vitro, genomic, computational and other non-animal methods in EU research strategies. Dedicated FP funding should be made available to support implementation of these discipline-specific roadmaps, as above, through tightly coordinated programmes and intramural and extramural research.

3.2.5. **Funding for 3Rs research & development within existing and future Framework Programmes**

The EU’s Fifth, Sixth and Seventh Framework Programmes for Research and Development have allocated an average of € 3 million per year to projects designed to replace the use of animals in regulatory testing. For the expected benefit to be gained (not only relating to animal welfare but in creation of faster, cheaper and more effective safety testing to benefit companies, consumers and the environment), this figure is simply too small a proportion of overall research spending. This is especially true in relation to funding needs to effectuate a meaningful reduction in animal use in the larger life sciences domain, as discussed above. HSI/Europe does not support the redirection of funds from replacement-oriented projects to support research into refinement; if such redirects are to occur, the funds should be drawn from other areas of animal use.

HSI/Europe expects an animal welfare framework policy to dovetail with research priorities so that policy objectives such as the replacement of animal use in testing and research are identified and supported in the animal welfare policy and funding allocated from the appropriate research budget. The quality of research funded through the Framework Programmes, which necessarily cover five-year periods, would be enhanced by identification of long-term policy objectives and the sense of continuity that such objectives provide. Strategic investment in projects that cannot be completed within five years will be necessary (as outlined above), and in such cases it should be possible for the Commission’s Joint Research Centre to provide for coordination of long-term projects following a more “top-down” approach.

3.3. **International Initiatives**

3.3.1. **Promoting greater harmonisation of 3Rs best practices (data requirements & acceptance of alternative/non-animal testing strategies) across regulated product sectors**

The lack of international harmonisation of regulatory data requirements and assessment approaches in some product sectors (e.g., agrochemicals, biocides, chemicals, food additives and flavourings, cosmetics), coupled with inconsistent approaches to the application of the 3Rs, means that
unnecessary testing is inevitably taking place. This could involve a vertebrate test being required in a third country where a non-animal method is accepted elsewhere (i.e., redundant testing due to lack of mutual recognition), a hazard-driven testing requirement that could be waived according to a risk-based paradigm, testing requirements peculiar to emerging markets, and numerous other scenarios. At the very least, these scenarios represent wasteful duplication. They can also lead to protracted delays in market access, which can be enormously costly to industry.

In the interests of minimising redundant testing and preventing undue costs, delays and animal use, increased effort to identify and promote global harmonisation of 3Rs best practices is recommended. This should be a transparent process (with opportunities for stakeholder involvement) in all regulated product sectors. Multilateral models such as the ICH/VICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use/International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) have been successful in improving regulatory cooperation and in reducing divergences/redundancies in the human and veterinary pharmaceutical sectors. In light of current efforts to revise chemicals and pesticides legislation/regulations in Europe, the United States and elsewhere, comparable initiatives in these sectors are should be pursued without delay.

As the range of approaches to addressing regulatory data requirements continues to increase and become more complex (i.e., the evolution from one or more OECD test guidelines for a particular toxicological endpoint to “integrated testing strategies”, which can combine multiple sources of testing and non-testing information, to a more fundamental paradigm shift as described above), efforts to achieve international agreement regarding 3Rs best practices will become increasingly important. These discussions of regulatory acceptability need to take place among national risk assessors and managers, and cannot be left in the hands of a validation review body alone. Thus, to the extent that continued investment is to be made in the International Cooperation on Alternative Test Methods (ICATM), steps should be taken to improve the transparency of its operations, and to ensure that the influence of certain national validation bodies does not become a barrier to the uptake of 21st century methodologies.

3.3.2. **Ensuring that animal-based testing/research in third countries meets first-world standards**

Outsourcing animal testing and research to company laboratories and contract research organisations (CROs) in developing countries is a strategy being used with increasing regularity by multinational companies for reducing overhead costs (i.e., cheap labour and supply of animals, minimal or no government or other oversight), addressing capacity issues in European and North American CROs (which is insufficient to meet the demands of legislative mandates such as REACH), gaining access to new markets (which may require in-country testing, e.g., China), and guarding their activities from a disapproving public in developed countries. However, this practice raises serious concerns from both animal welfare and scientific perspectives.

In relation to the former, standards and controls in developing (and some developed) countries in relation to ethical/scientific merit review of proposed experiments and for the acquisition, housing and care, use, monitoring and pain relief, and humane euthanasia of animals, do not even remotely approximate those of Directive 2010/63/EU. Permitting activities to be carried out in third countries according to standards that are substantially lower than those in place in the EU is not acceptable.

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23 [http://iccvam.niehs.nih.gov/docs/about_docs/ICATM-MOC.pdf](http://iccvam.niehs.nih.gov/docs/about_docs/ICATM-MOC.pdf)
Adherence to animal welfare standards also serves an important scientific purpose. For example, use of animals whose genetic background is unknown (i.e., random source) or who have not been microbiologically screened and certified pathogen-free, can introduce uncontrolled variables and inconsistencies that can undermine the reliability, reproducibility and the relevance of test/research results. The same is true regarding failure to adhere to “Good Laboratory Practice” (GLP) criteria, which is still an issue in many developing countries.

It is therefore essential that a system of animal use oversight be implemented in each country to which outsourcing of animal-based testing/research occurs, and that the national system and standards in the third country be shown to be consistent with those of the country of origin. In this vein, HSI/Europe does not consider minimal guidelines promulgated by the OIE to represent a true or meaningful global standard to which countries should aspire, and would instead favour the pursuit of (enforceable) bilateral trade agreements between the EU and third countries, which we believe will inspire uptake and adherence to higher standards.

3.3.3. Trade in wild-caught animals for scientific purposes

HSI/Europe believes that wild-caught animals should not be used for scientific purposes unless the procedures in question are intended to benefit the individual animal being used. While Directive 2010/63 will limit the use of wild-caught animals in testing, research and for other scientific purposes on welfare and conservation grounds, wild-caught animals will continue to be acquired from third countries and the offspring of wild-caught primates, although their use is expected to be phased out, will be used in EU laboratories for some years to come. In terms of an overarching animal welfare policy, the need to phase out the use of F₁ primates and all wild-caught animals should be strongly reiterated; the foreseen feasibility study regarding the F₁ primate phase out should not be allowed to delay legislative action or override public opinion.

3.4. Stakeholders & Citizens

HSI/Europe supports in principle the establishment of stakeholder platforms and sub-groups to address the transposition/implementation of Directive 2010/63/EU and other issues, as appropriate.

4. Wild Animals

It is hoped that the Commission will pay due regard to the protection of the welfare of wild animals in the Second EU Strategy on the welfare and protection of animals.

4.1. Zoos

As the recent evaluation of EU animal welfare policy highlighted, the present legislation for zoo animals is aimed primarily at biodiversity conservation, rather than the protection of the welfare of zoo animals. Not only are more detailed requirements needed to safeguard the welfare of wild animals kept in captivity, but also the enforcement of the existing legislation must be urgently improved.

The EU Zoo Inquiry 201124 launched by Born Free underscores the failures of zoos in many Member States to meet legal requirements and of national authorities to ensure that the legislation is properly


4.2. Wildlife trade

The trade in wild animal species is also an area to which the Commission should devote attention in its Strategy. Council Regulation (EC) No 338/97 on the protection of species of wild flora and fauna by regulating the trade therein – and its implementing Regulation (EC) No. 865/2006 - offer the possibility of safeguarding the welfare of species protected under CITES. The basic Regulation establishes the requirements for the movement of live specimens, which are intended to minimise risk of injury, damage to health and preclude cruel treatment during transit.

There are, however, no standards with regard to how living specimens are prepared by, for example, collectors and dealers, for shipment. This issue has indeed never been discussed by the CITES Parties. HSI/Europe therefore urges the EU to take the lead by drawing up standards for the preparation of live specimens for shipment. In so doing, live animals destined for shipment will be given additional protection.

We also call on the Commission to pay greater heed to the treatment of all live specimens during any period of transit, holding or shipment to and through EU Member States. This is essential given the risk of injury, stress and mortality during the transport of live animals. As a corollary to this, HSI/Europe contends that Commission Regulation (EC) No. 865/2006 should be revised to ensure the improved and harmonised Member State reporting on the trade in protected wild animal species (including those listed under Annex D), including mortality rates. Such data should assist with identifying unacceptably high mortality rates in wild animals subjected to trade. This would afford the possibility of the EU applying the precautionary principle in order to prohibit the trade in species that suffer high mortality.

Under the terms of Regulation (EC) No 338/97, Member State Scientific Authorities are also obliged to ensure that the accommodation and care to be provided at the point of destination are also adequate. There is room for further clarification of requirements for housing and care at the point of destination for protected species imported to the EU.

With respect to species listed on CITES Appendix I, the Scientific Authorities of Member States must be satisfied that the proposed recipient of a living specimen is suitably equipped to house and care for it. The aforementioned Born Free Foundation study clearly illustrates that zoo animals, such as elephants, with an Appendix I status are found in facilities that fail to care for them adequately. This is an issue that should urgently be addressed by the EU.

Finally, HSI/Europe urges the EU to fund rescue centres for exotic, non-domesticated species in both the European Union and abroad in the countries from which these animals are (illegally) imported. Under the terms of CITES Article VIII, paragraph 4, Member State Management Authorities must either return (confiscated) live specimens to the State of export, or send them to an appropriate rescue centre. There are too few appropriate rescue centres in Member States, many of which rely on charitable funding from private individuals and corporate sponsors to continue to be able to look after the welfare of not only confiscated non-domesticated animals, but also those that have been relinquished, abandoned or released into the wild by their owners.
4.3. *Invasive alien species*

The trade in non-domesticated species to supply the market for exotic pets – and the keeping of such animals for other purposes, such as fur production - also has implications for other policy areas. In addition to the suffering caused by a failure to meet the environmental, behavioural and nutritional needs of non-domesticated animal species, non-domesticated animals that are deliberately released or escape into the natural environment can be classified as invasive alien species and may pose a threat to biodiversity, particularly if they continue to breed in the wild.

The control of such invasive alien species has serious implications for animal welfare, particularly when inhumane methods are employed in an attempt to eradicate them. The use of submersion traps for muskrats in the Netherlands provides a prime example of how the welfare of wild animals categorised as invasive alien species can be seriously compromised.

Muskrats were originally introduced by the fur trade for the purposes of fur production. These animals have bred prolifically in the wild and are deemed to pose a threat to the stability of inland dykes. Submersion traps are the preferred lethal method for muskrat control in the Netherlands. Muskrats caught in submersion traps drown due to hypoxia. Hypoxia has, however, been deemed an inhumane method of euthanasia within both veterinary and laboratory animal science, and is an equally inhumane killing method for wild animals. In addition, such traps are indiscriminate and thus also lead to the capture and death of significant numbers of native wild species, which are protected under EU legislation.

An EU Strategy on Invasive Alien Species is currently under preparation. While this will ostensibly be a strategy to protect biodiversity, animal welfare should also be given due consideration. Education on the implications and responsibilities of keeping non-domesticated species as pets should also be included in a broader comprehensive EU communication and education strategy. Restrictions on the trade in such species by means of a ‘positive’ list are thus also desirable.

5. *Trade*

Animal welfare and protection is enshrined in more recent EU trade agreements such as those with Chile and Korea. For example, in the EU-Chile agreement, there is a provision in the Sanitary and Phytosanitary (SPS) Chapter regarding the stunning and slaughter of animals. In the EU-Korea FTA, there are provisions concerning animal testing in one of the market access annexes.

Because overall trade between the EU and third countries is likely to continue increasing, owing in large part to the proliferation of bilateral and regional trade agreements, trade in live animals and animal products is also likely to increase. For example, increased market access for agricultural products such as eggs or beef may mean increased EU production and export and/or increased EU imports from third countries. Additionally, increased legal trade between the EU and partner countries is also likely to result in increased illegal trade in endangered species and products thereof. *It is therefore imperative that the Commission include trade policy issues in the scope of its strategy on the welfare and protection of animals.*

The inverse is also true; namely, *the Commission should seek to establish clear guidelines for inclusion of animal welfare and animal protection goals in EU international trade policy.* This should extend not only to existing provisions on stunning and slaughter and animal testing, but also to the protection of wildlife and wildlife habitat. The Commission’s guidelines should also strive for even
stronger provisions in pending and future trade agreements by building on existing provisions and seeking to anticipate new issues.

For example, trade agreements could address the need to combat the illegal wildlife trade (as between the EU and its trading partners) in a manner that complements the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and assists developing countries with their implementation and enforcement of CITES. Trade agreements could also look to requiring that third countries seeking to export animals and animal products to the EU have equivalent animal welfare standards. This would help level the playing field for EU producers while simultaneously ensuring at least a minimum level of protection for animals/animal products originating in third countries.

It bears noting that linking animal welfare and trade need not be viewed as a trade barrier for developing countries. If the EU were to focus on providing the necessary trade capacity building assistance to such countries through on-the-ground programmes, developing countries would not only have the means to improve animal welfare standards, but would also have more of an opportunity to take advantage of the benefits of the trade agreement by being able to service consumers demanding products such as cage free eggs. Moreover, in the context of wildlife, trade capacity building assistance could be offered to help developing countries strengthen, implement, and enforce national laws implementing CITES.

Internationally, HSI has been involved in programmes such as these in Central America under the U.S. – Central America- Dominican Republic Free Trade Agreement and has witnessed firsthand their success. Trade capacity building programmes are helping livestock farmers in Costa Rica to work towards humane certification, which would enable them to access more market opportunities abroad. Trade capacity building programmes are also helping local communities switch from poaching and illegal wildlife trade to sustainable ecotourism, with benefits for the animals as well as local livelihoods.

In sum, HSI/Europe believes there is a unique opportunity for the Commission to more closely consider how to link animal welfare and protection through trade. A first step would be including trade policy in the strategy on animal welfare and protection for 2011-2015. We would be happy to provide more detail on our suggestions, and refer you to prior HSI submissions on this topic.  

6. Companion animals

Until the adoption of the Council Conclusions on the welfare of dogs and cats in November 2010, it had always been argued that the welfare of companion animals did not fall within the legislative competencies conferred on the European Union in the Treaties and thus were the responsibility of the individual Member States. HSI/Europe welcomes the Council Conclusions, which called for the preparation of policy options for the harmonisation of rules concerning the breeding of and trade in the dogs and cats.

We urge the Commission to pursue the Council’s proposal to investigate the establishment of compatible systems of identification and registration for such companion animals and to develop actions to promote and support the education of animal owners and responsible companion animal

26 Council Conclusions on the welfare of dogs and cats, 3050th Agriculture and Fisheries Council meeting, Brussels, 29th November 2010.
ownership. The inclusion of policy action for companion animals in the Second EU Strategy on the welfare and protection of animals would help to prevent the illicit (puppy) trade, ensure effective control of various zoonotic diseases and improve the traceability of lost or abandoned animals.

Contact information

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