

Humane Society International (HSI) is the international arm of The Humane Society of the United States (HSUS). Together, HSUS and HSI represent one of the largest animal protection organizations in the world with a constituency of over 11 million people and a significant global presence. HSI actively participates in discussions of international trade policy at international institutions, such as the World Trade Organization (WTO), addressing such issues as equitable development, humane and sustainable agriculture, environmental conservation, and wildlife and habitat protection.

HSI also implements a number of trade capacity building and technical assistance programs in developing WTO Member countries to support sustainable economic development, including humane agricultural practices and habitat and wildlife protection policies. Many of the programs that HSI runs and supports in Latin America are trade capacity building and/or environmental cooperation programs born out of the Central America-United States-Dominican Republic Free Trade Agreement (CAFTA-DR). For example, HSI's programs include hands-on training on wildlife handling, rescue and rehabilitation, and workshops on compliance with national laws implementing the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). HSI helps small cacao farmers improve production, improve quality, and work towards organic certification for shade-grown cacao, which provides a habitat for migratory birds and other wildlife. HSI's ecotourism program provides communities that are reliant on income from activities that are harmful to local endangered species and their habitats with alternative, non-extractive methods for capitalizing on their natural resources while also increasing their earnings. HSI has also worked with the beef industry in Costa Rica to strengthen animal handling, transport and slaughter practices that improve the treatment of animals, result in higher yields of better quality meat products, and will eventually expand export opportunities for Costa Rican farmers and producers to niche markets in the United States and elsewhere that will pay a premium for humanely raised and slaughtered meat products.

Through these experiences, HSI has learned that trade agreements can be a powerful tool for promoting environmental and animal protection, while also contributing to economic development and the improvement of local livelihoods.

a) What are the main environmentally-related issues (i.e. environmental requirements, environmental certification, etc.) that you encounter in your activities in trade and investment relations between the EU and Malaysia? (optional)

Wildlife Protection and Enforcement

According to Interpol, illegal wildlife crime could be worth as much as \$20 billion per year, second only to arms and narcotics trafficking. Other estimates are even higher; finding that up to \$30 billion per year of black market money is exchanged for endangered wildlife and parts in South East Asia alone. *See Smugglers and Poachers Generate RM90 Billion a Year*, The Star (October 7, 2010) available at: <http://thestar.com.my/news/story.asp?file=/2010/10/7/nation/7174224&sec=nation>. The illegal wildlife trade has far-reaching ramifications, including species extinction, spread of disease, and security threats, as there is a proven link between the black market trade in animals and animal parts and organized crime.

The United Nations Environment Programme (UNEP) includes Malaysia as one of only seventeen megadiverse countries in the world, home to animals such as pangolins, orangutans, and tigers. Given its rich biodiversity, it is not surprising that Malaysia is known as a major source country for both legal and illegal trade in wildlife. *See A Roaring Illegal Trade*, The Star (September 12, 2010) available at: <http://thestar.com.my/news/story.asp?file=/2010/9/12/nation/7017529&sec=nation>. Malaysia is also known as a transit point for illegal trade in animals like freshwater turtles, monitor lizards and snakes that are transported to countries such as Vietnam and China to feed a demand for exotic food. *Id.*

Increased trade through an EU-Malaysia Free Trade Agreement (FTA) will impact wildlife as new trade routes and markets emerge for legal and illegally traded wildlife. Further, increased demand for forest or agricultural products will likely lead to loss of habitat for thousands of animals that will then be vulnerable to poaching and illegal wildlife trade. This will put additional pressure on species populations that are already suffering due to climate change. Finally, illegal wildlife trade is linked to global organized crime in narcotics and arms trafficking and the spread of disease. These harmful effects can be mitigated if they are identified early and specific commitments are incorporated into the FTA committing the Parties to taking action.

To this end, we recommend that the FTA require the Parties to bring their national laws into compliance with CITES, commit to biodiversity conservation, and combat illegal wildlife trade in particular. In HSI's experience, trade agreements can be a useful vehicle for the development and implementation of a CITES compliance program, which would focus on all aspects of wildlife protection and enforcement, including wildlife rescue and rehabilitation, support for rescue centers, ecotourism as an alternative income source to poaching and illegal wildlife trade, and public awareness. Such a program should incorporate all sectors of society – government, academics, private industry, and non-governmental organizations.

Farm Animal Welfare

Second, an FTA is likely to increase trade (or, at a minimum, increase trade opportunities) in agricultural products, such as beef. While this could provide opportunities to improve animal welfare practices and food quality, it is critical that any future FTA does not encourage the growth of intensive farming systems, particularly since some of these systems are being phased out or banned in the EU (e.g. veal crates and battery cages for laying hens). To ensure this does not result, we recommend that any impact assessment of the FTA undertaken consider this issue; namely, how to prevent the spread of intensive farming systems while simultaneously improving animal welfare practices.

HSI further recommends that the FTA itself incorporate animal welfare by including it as a key cooperation/trade capacity building program, and by explicitly addressing it in the Sanitary and Phytosanitary Chapter (SPS Chapter) as was done in the EU-Chile FTA and, most recently, in the EU-Korea FTA.

In terms of cooperation/trade capacity building, HSI supports the prioritization of environmental cooperation programs aimed at promoting higher animal welfare standards and practices, such as those HSI is engaged in through CAFTA-DR. For example, HSI developed and implemented a Farm Animal Welfare program under CAFTA-DR that includes establishing animal welfare as a relevant issue to the animal agriculture industry and introducing basic humane handling practices that address growing concerns for improved animal welfare and food quality. Additionally, HSI assisted with the development of lesion studies to measure evident economic losses due to poor practices during handling, a direct result of deficient animal welfare policies. This first-hand evidence is a great tool for directly establishing the benefits of higher animal welfare in the beef industry. Several members of the industry work alongside HSI to improve animal welfare practices, in recognition and preparation of possible market access in the future.

With regard to the language of the Agreement itself, HSI recognizes that animal welfare is of great importance to the EU and its citizens, and we were pleased to see that the SPS chapter of the EU-Chile Agreement includes provisions governing animal welfare with respect to stunning and slaughter. We believe that the EU-Malaysia Association Agreement can go even further to promote animal welfare and protection. Specifically, we support inclusion of higher animal welfare practices during transport, which includes loading, off-loading, and lairage, as well as handling in the SPS chapter to complement

the provisions on stunning and slaughter in the EU-Chile Agreement. Clearly, the EU recognizes the importance of higher animal welfare during transport and handling, as reflected in its legislation and regional research and outreach efforts with members of the production chain both within its Member Countries and abroad.

Animal Testing

In the recent EU-Korea FTA, an Annex on market access for chemicals Annex indicates that the agreement should promote “alternative methods for assessment of hazards of substances and reducing animal testing.” HSI is encouraged by this explicit language, and would like future FTAs to go further towards addressing animal testing issues. Below are some recommendations.

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

The lack of international harmonization of regulatory data requirements and assessment approaches in some product sectors (e.g., agrochemicals, biocides, chemicals, food additives and flavorings, cosmetics), coupled with inconsistent approaches to the application of the “3Rs” tenet of Replacement, Reduction and Refinement of vertebrate animal testing, 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 minimizing redundant testing and preventing undue costs, delays and animal use, increased effort to identify and promote **global harmonization 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 Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use/International Cooperation on Harmonization 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 fundamental paradigm shifts, such as the proposal from the US National Research Council to transition to a “toxicity pathway”-based approach), efforts to achieve international agreement regarding 3Rs best practices will become increasingly important. See <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11970>. 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.

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

Outsourcing animal testing and research to contract research organizations (CROs) in developing countries is a strategy being used with increasing regularity by multinational companies for reducing overhead costs (i.e., cheap labor 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 the European Union (i.e., Directive 2010/63/EU). See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF>. Permitting activities to be carried out in third countries according to standards that are substantially lower than those in place in the country of origin is inconsistent with both the letter and the spirit of first-country legislation designed to ensure the welfare and protection of animals used for testing and other scientific purposes.

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.

3. Trade in wild-caught animals for scientific purposes

The use of wild-caught animals in testing, research or other scientific purposes is generally discouraged (on welfare and conservation grounds) unless compelling evidence is provided that the purpose of the procedure cannot be achieved by the use of an animal which has been bred for use in procedures. To the extent that wild-caught animals continue to be acquired from third countries, it must be shown that the capture of such animals is carried out only by competent persons using methods which do not cause the animals avoidable pain, suffering, distress or lasting harm. It should be required that any animal found, at or after capture, to be injured or in poor health shall be examined by a veterinarian or another competent person and action shall be taken to minimize or end the suffering of the animal. Conservation considerations are especially significant in relation to non-human primates and other species listed under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or equivalent national frameworks; however, animal welfare considerations apply equally to all wild-caught species.

Funding and Resources

Finally, we recommend that research be done to determine adequate levels of funding necessary to implement technical assistance and trade capacity building programs in Malaysia that enhance environmental and animal protection, and promote economic development for local communities.

b) What is your assessment of the current level of implementation of environmental legislation in Malaysia? (optional)

With respect to wildlife in particular, HSI is encouraged that Malaysia recognized the pressing need to combat illegal wildlife trade by passing a new law called the International Trade in Endangered Species Act of 2010 (Act 686), which increases penalties and jail terms for wildlife crime. See *Ministry Upbeat Over New Law to Curb Wildlife Trafficking*, Natural Resources and Environment Ministry, Malaysia (October 18, 2010), available at: <http://freemalaysiatoday.com/fmt->

[english/opinion/letters/11678-ministry-upbeat-over-new-law-to-curb-wildlife-trafficking](#). The main focus must now be on ensuring effective enforcement and implementation of the law, which the FTA can assist with in terms of trade capacity building and environmental cooperation.