HUMANE SOCIETY INTERNATIONAL
EUROPEAN UNION

THE HUMANE SOCIETY OF THE UNITED STATES

To: Ambassador Miriam Sapiro, Deputy US Trade Representative
Daniel Mullaney, Assistant US Trade Representative for Europe and the Middle East
Boris Bershteyn, Acting Administrator, Office of Information and Regulatory Affairs
Daniel Calleja Crespo, Director General, DG Enterprise and Industry
Jean-Luc Demarty, Director General, DG Trade

Re: Response to Sept. 2012 Joint Solicitation by US-EU High-Level Regulatory Cooperation Forum

Date: 31 October 2012

These comments are submitted on behalf of Humane Society International and The Humane Society of the United States and our more than 11 million members across North America, Europe and the globe in response to the USTR comment request of 28 September 2012 (77 Fed. Reg. 59702). We appreciate the initiative of the US-EU High-Level Regulatory Cooperation Forum to promote greater transatlantic regulatory compatibility across economic sectors, and would like to highlight one sector in particular where we believe there is room for concrete, near-term progress—the pesticide sector.

Regulatory data requirements for pesticide registration differ somewhat between European, U.S. and other global markets, such that companies are generally unable to prepare a single registration dossier that will satisfy authorities in different regions. ***In practical terms, this can lead to duplicative testing costs and delays in market access.*** Accordingly, we are submitting these comments to highlight key areas that can be improved and we are providing recommendations as to how this can be done.

A 2010 study commissioned by the European Crop Protection Association and CropLife America, which compares the costs of new crop protection product discovery and development between 2000 and 2008, reflects an cost escalation of 39.1% (US$184 million to $256 million) over this period. The most dramatic cost increases (77.7% and 116%) are attributable to regulatory testing for product registration, i.e., toxicological safety assessment and field trials, respectively (*www.croplife.org/view_document.aspx?docId=2478*).

It should also be noted that from an animal welfare perspective, upwards of 10,000 dogs, rabbits and other animals can be used in dozens of separate toxicological and ecotoxicological studies to satisfy regulatory data requirements for a single active ingredient. For many endpoints, there is substantial redundancy among *in vivo* data requirements, e.g., acute toxicity testing by up to 3 different exposure routes (oral, dermal, inhalation) for both active ingredients and finished products, subchronic toxicity testing using both dogs and rats, developmental toxicity testing using both rabbits and rats, etc.

Recent and ongoing revisions to EU regulations for biocides and plant protection products are leading to the uptake of numerous state-of-the-art toxicological testing methods and strategies, which maintain a high level of regulatory rigor to protect human health and the environment while making substantial strides toward elimination of unwarranted redundancies, cost savings for industry, and the replacement, reduction and refinement (3Rs) of vertebrate animal testing (*http://eusaat.org/images/*

2012/presentations/seidle_troy_2012_09_07_pesticide_regulation_eusaat_2012.pdf).

1. NON-FOOD ANTIMICROBIAL PESTICIDES / BIOCIDES

	European Union	United States
Agency / Directorate General	DG Environment European Chemicals Agency	Environmental Protection Agency
Relevant regulatory / statutory provisions	Annexes II-III of Regulation (EU) No. 528/2012	40 CFR § 158W
Regulatory differences & their negative effects on stakeholders	In June 2012, the EU replaced its former Biocidal Products Directive 98/8/EC with a new Biocidal Products Regulation cited above. Among other changes, the information requirements specified in Annexes II and III for registration of new active ingredients and formulated products have been substantially amended to reflect scientific best practices in the toxicology and ecotoxicology based on the latest test guidelines and guidance promulgated by the Organization for Economic Cooperation and Development (OECD) and others. These regulatory amendments allow for a more flexible and efficient approach to safety testing that reduces both economic costs to industry and welfare costs to animals while maintaining a high level of regulatory scrutiny for the protection of human health and the environment. A cursory overview of changes to specific regulatory endpoints is provided below and at *http://eusaat.org/images/2012/presentations/seidle_troy_2012_09_07_pesticide_regulation_eusaat_2012.pdf*: 1. Acute systemic toxicity, through conditional waiving of the dermal route for active substances and formulations 2. Carcinogenicity, through the conditional waiving of the mouse bioassay 3. Subchronic toxicity, through inclusion of micronucleus assessments in lieu of standalone *in vivo* testing for this genotoxicity endpoint 4. Calculation approaches for hazard classification of finished products based on the properties of their constituent ingredients 5. Skin sensitization, through acceptance of the reduced local lymph node assay where an assessment of potency is not required 6. Fish acute toxicity, through use of the threshold approach/tiered strategy 7. Reproductive toxicity, through the adoption of the new OECD extended 1-generation study 8. Developmental toxicity, through the conditional waiving of the rat teratogenicity study where the rabbit study and a generational rodent reproductive toxicity study reveal no signs of adverse effects on fertility or development 9. Avian reproduction, through waiving of the study requirement	

	when the dietary LC_{50} is in excess of 2000 mg/kg. In the best-case scenario, these amendments could reduce animal testing by approximately 40%, with substantial cost savings as well. However, such savings can only be realized if regulations in other major markets are aligned with the EU's revised data requirements. In the worst case, if there is no move toward alignment with new EU requirements, industry could be forced to double-test in some instances, e.g., non-animal test for the EU market and the conventional animal test for the US, leading to a relative escalation in testing costs.
Possible solutions	In the interests of minimizing redundant testing and preventing undue costs, market access delays and animal use, we urge the US to act swiftly to bring its registration data requirements into alignment with the new state-of-the-art embodied in the EU biocides regulation. We understand from bilateral discussions with EPA's Office of Pesticide Programs that the 158W rulemaking for antimicrobial pesticides has not yet been finalized, thus providing the US with an ideal route for enhancing regulatory alignment with the EU in a manner that will benefit all concerned stakeholders.

2. FOOD-USE PESTICIDES / PLANT PROTECTION PRODUCTS

	European Union	United States
Agency / Directorate General	DG Health & Consumers (SANCO) European Food Safety Authority	Environmental Protection Agency
Relevant regulatory / statutory provisions	Regulation (EC) No. 544/2011 & Regulation (EC) No. 545/2011 to be amended in 2013 by SANCO/11802/2010 Rev. 7 (POOL/E3/2010/11802/11802R7-EN.doc)	40 CFR § 158
Regulatory differences & their negative effects on stakeholders	The EU is currently in the advanced stages of revising its data requirements for plant protection products, i.e., food-use pesticides. In July of this year, we were informed that the revised requirements detailed in the above mentioned SANCO document were received favorably by the EU Member State Standing Committee on the Food Chain and Animal Health, and have now moved forward in the political process for scrutiny by the European Parliament. Once this process is complete, the new data requirements for pesticide active ingredients and formulated products will be adopted as separate regulations, repealing those referenced above. The anticipated amendments are substantially similar to those outlined above for biocides, as are the benefits of regulatory alignment and drawbacks of divergences.	
Possible solutions	40 CFR Part 158 was revised in 2007 and EPA has indicated that it does not intend to embark on additional rulemaking in the foreseeable future. However, another option could be the issuance of science-policies that would authorize departures from Part 158 requirements under well-defined circumstances.	

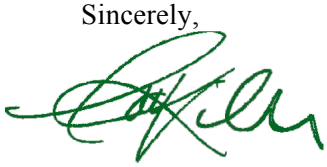
3. CLASSIFICATION AND LABELLING OF CHEMICALS AND MIXTURES

	European Union	United States
Agency / Directorate General	DG Enterprise and Industry	Environmental Protection Agency
Relevant regulatory / statutory provisions	Regulation (EC) No. 1272/2008	40 CFR § 156
Regulatory differences & their negative effects on stakeholders	In 2008 the EU repealed Directives 67/548/EEC and 1999/45/EC and replaced them with the above-mentioned regulation with a view to implementing the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and facilitating worldwide trade through harmonized criteria for classification and labeling. More recently the US Occupational Safety and Health Agency has aligned its Hazard Communication Standard with the GHS; however, EPA's Office of Pesticide Programs, despite many years of discussion with stakeholders, has yet to take similar action in relation to its Label Review Manual and regulations. Although classification and labeling (C&L) criteria are often said to be "test method neutral," meaning that the results of any internationally accepted test could in theory be used as a basis for C&L, some authorities and companies cite divergent C&L criteria as a basis for, e.g., not utilizing available 3R alternative methods. Practical examples of divergences between EU and US C&L criteria include: 1. Acute oral/dermal toxicity limit dose of 2000 mg/kg in the EU and 5,000 mg/kg in the US. The GHS discourages the higher limit dose on both practical and animal welfare grounds, yet this higher dose level is still retained by EPA (but not OSHA). This divergence could lead EU companies with products tested at the 2000 mg/kg limit dose to repeat one or more acute toxicity studies to satisfy US C&L requirements. 2. A single "irritant" category for skin and eye irritation in the EU vs. two irritant categories (severe / moderate) in the US. OECD-accepted *in vitro* skin irritation test methods are currently validated to distinguish between irritants and non-irritants, but do not support sub-classification. The US EPA (but not OSHA) requirement for sub-classification of skin and eye irritants has been cited as the major barrier to the widespread use of these non-animal test methods in the US.	
Possible solutions	EPA has indicated that it does not intend to embark on additional rulemaking in the foreseeable future. However, another option could be the issuance of science-policies that would authorize departures from classification criteria specified in § 156.	

We believe these points are responsive to the High-Level Regulatory Cooperation Forum's objectives of reducing excessive regulatory costs, unjustified regulatory differences, and unnecessary red tape while respecting each other's right to protect public health, safety, welfare and the environment.

Thank you for your consideration of this submission. Please direct any questions to the undersigned.

Sincerely,



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