HUMANE SOCIETY INTERNATIONAL
CANADA

June 1, 2011

Carole Swan, President
Canadian Food Inspection Agency
1400 Merivale Road
Ottawa ON K1A 0Y9

Re: Testing methods for the detection of shellfish biotoxins

Dear Ms Swan,

Humane Society International (HSI)/Canada applauds the recent move by the Canadian Food Inspection Agency to institute an innovative new method for the detection of Paralytic Shellfish Poisons (PSPs) that replaces testing on animals.[1]

As alluded to in your agency's recent press release, the classic test for shellfish toxins—the Mouse Bioassay (MBA)—is a more than 30-year-old procedure that involves injecting a shellfish extract into the abdomen of mice and timing how long it takes for them to die.[2-3] Animals in these tests can endure severe, unrelieved suffering, including convulsions and respiratory paralysis, before they die. The MBA has been criticised on scientific, public health and animal welfare grounds[4], having been described by a joint report of the World Health Organisation, United Nations Food and Agriculture Organisation, and the International Oceanographic Commission as having *"severe technical and ethical limitations and generally lack[ing] adequate validation for Codex purposes."*[5] Authorities in New Zealand have remarked that *"the mouse bioassays used to detect and quantify marine biotoxins are non-validated procedures, which are prone to interferences, and entail the use of large numbers of animals,"*[6] and the European Food Safety Authority (EFSA) has concluded that the MBA is "*inappropriate with inherent uncertainty, variability and poor specificity*"[7] for the testing of most biotoxins. As such, continued reliance on this method is highly questionable from a public health standpoint.

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[1] CFIA, *Government of Canada Implements New, Faster Testing Method For Shellfish Toxins,* http://www.inspection.gc.ca/english/corpaffr/newcom/2011/20110525e.shtml
[2] Yasumoto T, Oshima Y & Yamaguchi M. Occurence of a new type of shellfish poisoning in the Tohoku district. *Bulletin of the Japanese Society of Scientific Fisheries* 1978; 46, 1045–1411.
[3] Community Reference Laboratory for Marine Biotoxins. *Standard Operating Procedure for Detection of Okadaic Acid, Dinophysistoxins and Pectenotoxins by Mouse Bioassay*, 2009, http://www.aesan.msc.es/CRLMB/docs/docs /metodos_analiticos_de_desarrollo/Harmonised_EU_MBA_SOP-_version4-April20071.pdf
[4] Hess P, Grune B, Anderson DB, et al. Three Rs approaches in marine biotoxin testing (ECVAM Workshop 54). *Altern Lab Anim*. 2006; 34, 193–224.
[5] FAO/IOC/WHO. *Report of the Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs.* Oslo, Norway: UNESCO, 2004, ftp://ftp.fao.org/es/esn/food/biotoxin_report_en.pdf
[6] Seamer C. Shellfish toxin testing without using animals. *New Zealand Biosecurity Magazine* 2007; 75, 14–15. http://www.biosecurity.govt.nz/files/publications/biosecurity-magazine/issue-75/biosecurity-75.pdf
[7] EFSA CONTAM Panel Scientific Opinions, http://www.efsa.europa.eu/cs/Satellite

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The MBA has also been superseded scientifically by several validated non-animal methods. In addition to the pioneering work by CFIA, other alternative approaches include the "Lawrence Method" of high performance liquid chromatography, which was declared valid by the AOAC in 2005[8] and has since been accepted in the European Union as a full replacement to the MBA for the detection of both PSPs and Amnesiac Shellfish Poisons (ASPs).[9-10] With regard to Diarrhetic Shellfish Poisons (DSPs), the EU has recently enacted a new regulation establishing that *"the EU-RL LC-MS/MS [liquid chromatography-mass spectrometry] method shall be the reference method for the detection of marine toxins."* These non-animal methods have also been recommended in a series of EFSA Scientific Opinions,[11] and are already being used in a number of countries. For example, the German Federal Institute for Risk Assessment and the German National Reference Laboratory for the Control of Marine Biotoxins support the chemico-physical LC-MS/MS test method for toxin testing because "*the physicochemical analytical procedures have proved to be superior to the Mouse-Bioassay and to represent the more appropriate methods for safeguarding consumer protection".*[12]

In light of the foregoing, HSI/Canada would appreciate if you could:

1. Outline, for each class of biotoxin, CFIA's policy regarding the applicability of non-animal test methods as replacements for the *in vivo* bioassay, as well as the Agency's standard approach to testing for toxin detection.
2. Provide statistics concerning the number of animals used by CFIA in bioassays for detection of shellfish toxins for the period 2005 through the present.
3. Outline CFIA's strategy and timetable for achieving full replacement of the *in vivo* bioassay for detection of shellfish toxins.

Thank you in advance for your timely response and for CFIA's continued leadership on this important public health and animal welfare topic.

Yours sincerely,

Troy Seidle
Director of Research & Toxicology

Gemma L Buckland
Science Policy Officer

cc: The Hounourable Gerry Ritz, Minister of Agriculture and Food

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[8] AOAC International. *Lawrence Method Now Official*, 9 June 2005, http://www.aoac.org/marine_toxins/lawrence_method.htm

[9] Commission Regulation (EC) 1664/2006 of 6 November 2006, http://www.aesan.msps.es/CRLMB/docs/docs/legislacion_comunitaria/Amending_Regulation_2074-05.pdf

[10] Commission Regulation (EC) No 2074/2005 of 5 December 2005: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:338:0027:0059:EN:PDF

[11] European Food Safety Authority. EFSA Scientific Documents: Series of CONTAM Panel Scientific Opinions on marine biotoxins and shellfish, 2010: http://www.efsa.europa.eu/cs/Satellite

[12] German Federal Institute of Risk Assessment. *Analysis of Marine Biotoxins - Approaches to Validation and Regulatory Acceptance of the Alternative Methods to the Mouse Bioassay as method of Reference,* http://www.bfr.bund.de/cm/349/position_paper_analysis_of_marine_biotoxins.pdf