MEMORANDUM OF UNDERSTANDING

BETWEEN

Health Policy Branch,
Health Products and Food Branch, and the
Pest Management Regulatory Agency
Health Canada

and

Department of International Trade

and

Regulatory Affairs and Orders-In-Council Secretariat
Privy Council Office

Concerning streamlined processes for regulatory amendments
to Schedule F to the *Food and Drug Regulations*
and to Table II, Division 15, Part B, of the *Food and Drug Regulations*

PREAMBLE

WHEREAS Schedule F of the *Food and Drug Regulations* (hereafter referred to as "Schedule F"), a list of drugs which may only be sold by prescription in Canada, and Table II, Division 15, Part B, of the *Food and Drug Regulations* (hereafter referred to as "Table II"), a table which sets out the maximum residue limits for pesticides in food sold in Canada, may only be amended by a regulation made by the Governor in Council;

WHEREAS consultation with Canadians and international trading partners is an integral part of the Government of Canada Regulatory Policy;

WHEREAS the Government of Canada committed in the Speech from the Throne in September 2002 to bring forward a Smart Regulation strategy "to accelerate reforms in key areas to promote health and sustainability, to contribute to innovation and economic growth, and to reduce the administrative burden on business";

WHEREAS efforts are being made to simplify processes to the extent possible in order to reduce administrative burden and facilitate the adoption of innovative new products while maintaining mechanisms for meaningful consultation;

WHEREAS the processes for regulatory amendments to Schedule F and Table II could be streamlined through implementation of the measures set out in this agreement;

WHEREAS Health Canada is committed to examining its processes in the preparation and approval of regulatory submissions to amend Schedule F and Table II, and to evaluating its performance against benchmarks;

And, WHEREAS the Government of Canada has international notification obligations that are outlined in the World Trade Organization (WTO) Agreement, specifically on notification, publication, provision of information, and treatment of comments under Article 2.9 of the Agreement on Technical Barriers to Trade (TBT Agreement) and Article 7 and Annex B of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement); and the North America Free Trade Agreement (NAFTA), specifically provisions under Article 909 on Standards-Related Measures and Article 718 on Sanitary and Phytosanitary Measures.

THEREFORE, the Health Products and Food Branch (HPFB), the Pest Management Regulatory Agency (PMRA) and the Health Policy Branch (HPB) of Health Canada, the Department of International Trade, and the Regulatory Affairs and Orders in Council Secretariat of the Privy Council Office (collectively known as the Participants) agree to the following modified processes for regulatory amendments to Schedule F and Table II.

A. AMENDMENTS TO SCHEDULE F TO THE *FOOD AND DRUG REGULATIONS*

Background

1. Schedule F is a list of medicinal ingredients which when present in a drug require the drug to be sold only on prescription in Canada. Two distinct processes must be completed to add or remove a medicinal ingredient from Schedule F.

2. The first process is the scientific review of a drug submission by HPFB, in which the Branch evaluates the efficacy, safety and quality of a drug product containing one or more medicinal ingredients. A recommendation to amend Schedule F is then reviewed and approved by an internal drug scheduling committee with scientific expertise.

3. The second process is the regulatory process to amend Schedule F.

Modified Process for Amending Schedule F

4. Once a decision has been made to proceed with an amendment to Schedule F, HPFB will consult with stakeholders by informing them of the proposed change and the Government's intent to amend Schedule F by removing or adding a medicinal ingredient. This will also allow Health Canada to meet the required 75 day comment period stipulated in the Government of Canada Regulatory Policy.

5. Should the amendment involve adding a medicinal ingredient to Schedule F, HPFB will prepare a consultation document in both official languages. The consultation document will address all of the elements required for preparation of the WTO notification as outlined in Appendix A and will be sent to HPFB stakeholders. The consultation document will also be posted in English and French on Health Canada's website at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt (or as amended from time to time), and posted on the Consulting Canadians portal. The consultation document will be sent to the Enquiry Point (currently the Standards Council of Canada under contract to the Department of International Trade) and to the Department of International Trade at least two business days prior to posting on Health Canada's website and the Consulting Canadians portal, for the purposes of complying with Canada's obligations under Article 2.9 of the TBT Agreement.

6. Should the amendment involve removing a medicinal ingredient from Schedule F, HPFB will publish a Notice of Intent, containing the information outlined in Appendix A, in the Canada Gazette, Part I. The Notice of Intent will also be posted in English and French on Health Canada's website at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt (or as amended from time to time), posted on the Consulting Canadians portal and sent to HPFB stakeholders. The Notice of Intent will be signed by the Assistant Deputy Minister of HPFB, and will be sent in both official languages by HPFB to the Enquiry Point (currently the Standards Council of Canada under contract to the Department of

International Trade) and the Department of International Trade at least two business days prior to publication in Canada Gazette, Part I.

7. Following the comment period, the Minister of Health will prepare a regulatory submission and seek the support of PCO in requesting Treasury Board's consideration for an exemption from pre-publication of the regulation in Canada Gazette, Part I, and approval to publish the amendment in Canada Gazette, Part II. The submission will take into account comments received during the consultation period.

8. When informing stakeholders of the publication of the final change to Schedule F in Canada Gazette, Part II, HPFB will also inform the Department of International Trade, and the Enquiry Point, so that this information can be made available to international trading partners.

9. The publication of the regulation in Canada Gazette, Part II must contain references to the date of the original consultation letter or the date of the original Notice of Intent, and the date of the notification to Department of International Trade and to the Enquiry Point.

B. AMENDMENTS TO TABLE II, DIVISION 15, PART B, OF THE *FOOD AND DRUG REGULATIONS*

Background

1. Before registering a pesticide under the Pest Control Products Act (PCPA) for use in Canada on crops or food-producing animals, the PMRA must determine that the amount of residue likely to remain in food when the pesticide is used according to label directions will not pose an unacceptable health risk to consumers. This amount is then legally established as a maximum residue limit (MRL) in Table II. This applies whether or not the pesticide is already registered for other food or non-food uses. MRLs are also established for pesticides not registered in Canada that may be found as residues in imported food. If residues exceeding the MRLs remain in a food at the point of sale, the item is considered to be adulterated under the Food and Drugs Act and prohibited from sale in Canada.

2. As part of ongoing work under the North American Free Trade Agreement Technical Working Group on Pesticides, the PMRA and the United States Environmental Protection Agency (EPA) have accelerated bilateral harmonization in the regulation of pesticides in order to provide faster and simultaneous access to a wider range of newer safer pest management tools in both countries.

3. While pesticide registration decisions are often taken in both countries at the same time, the benefits to Canada of harmonization are being diminished because of the length of time it takes to establish an MRL in Canada, as compared to in the United States (U.S). In the U.S., a pesticide tolerance (as MRLs are called in the U.S.) can be established

many months before a Canadian MRL; this puts Canadian growers at a competitive disadvantage and hinders the Canadian economy. It is also delaying replacement of older pesticides by newer, safer ones and the resulting benefits to human health and the environment.

4. The proposed modified process is based on the process used by the U.S. EPA to establish pesticide tolerances.

Modified Process for Amending Table II

5. Upon receipt of an application for registration or establishment of an import MRL, the PMRA will publish summary information about the proposed MRL, as outlined in Appendix B, in Canada Gazette, Part I. The publication would appear as a Notice of Intent signed by the Chief Registrar, PMRA, and would clearly indicate the Government's intent to amend Table II, and establish an MRL, should the application be approved. The Notice of Intent would have a 75 day comment period, based on the day of publication, as required by the Government of Canada Regulatory Policy. The PMRA will also establish a link from its website to the Canada Gazette website and the Notice of Intent will also be posted on the Consulting Canadians portal.

6. At least two days before the Notice of Intent is published in Canada Gazette, Part I, the PMRA will send a completed WTO Notification Form (see Appendix C) in both official languages to the Department of International Trade and to the Enquiry Point (currently the Standards Council of Canada under contract by Department of International Trade), for the purpose of complying with Canada's obligations under Article 7 and Annex B of the SPS agreement.

7. Once the PMRA has made a decision on the application, the Minister of Health will prepare a regulatory submission and seek the support of PCO in requesting Treasury Board's consideration for an exemption from pre-publication of the regulation in Canada Gazette, Part I, and for approval to publish the final MRL in Canada Gazette, Part II. The submission will take into account any comments received during the consultation period. When the final regulation is published in Canada Gazette Part II, the PMRA will send the Canada Gazette, Part II publication date to the Enquiry Point with a reference to the date of the Canada Gazette, Part I Notice of Intent.

8. Should the final MRL determined by PMRA be higher than that proposed in the Part I Notice of Intent, PMRA will publish a second Notice of Intent signed by the Chief Registrar, PMRA in Canada Gazette, Part I at the time that preparation of the regulatory submission is initiated. This will afford an opportunity for the public to provide additional comments. The publication of the final MRL in Canada Gazette, Part II will reference the date of publication of the original Notice of Intent in Canada Gazette, Part I, and the original date of the notification to Department of International Trade and to the Enquiry Point (currently the Standards Council of Canada, under contract to the

Department of International Trade).

C. EVALUATION

1. The Participants agree that an evaluation of this agreement will examine the extent to which its objectives and terms have been met, including:

   a) the effect of the modified processes on Canada's ability to comply with its international obligations, including those outlined in the WTO Agreement, Article 2.9 of the TBT Agreement, Article 7 and Annex B of the SPS Agreement, and Article 909 on Standards-Related Measures and Article 718 on Sanitary and Phytosanitary Measures in NAFTA; in all cases, this includes notifying Member Countries of intent to introduce a proposed technical regulation, providing a 60 day comment period to Members, and taking comments into account whenever possible;

   b) the net gain in terms of the time required to complete these regulatory amendments, and

   c) the impact of the modified processes on resources within both Health Canada and the Department of International Trade.

2. The evaluation will be led by Health Policy Branch, Health Canada, in consultation with PMRA and HPFB, PCO and the Department of International Trade.

D. DURATION

1. For therapeutic products, the Participants agree to evaluate, per Part C of this agreement, the modified process as described in Part A of this agreement, 30 months from the date of commencement of this MOU.

2. For pesticides, the Participants agree to evaluate, per Part C of this agreement, the modified process as described in Part B of this agreement, 30 months from the date of commencement of this MOU.

E. COMMENCEMENT AND TERMINATION

1. This MOU will commence on the day on which it is signed by the last Participant.

2. Any Participant may request that either Part A or Part B of the agreement, or the agreement in its entirety, be terminated if it considers that the terms or objectives of the agreement are not being met, or the agreement is no longer necessary. Such a request to terminate must be effected in writing and must follow consultation with the other Participants.

F. PRIVY COUNCIL OFFICE UNDERTAKING

1. The Privy Council Office (Regulatory Affairs and Orders in Council Secretariat) agrees to brief members of the Treasury Board on the terms of the proposed agreement.

2. Implementation of the modified processes will be contingent on Treasury Board agreement in principle to exempt from pre-publication the types of regulatory submissions outlined above.

3. Such agreement in principle will not preclude requiring the pre-publication of any specific regulatory submission in *Canada Gazette, Part I*, if the Treasury Board deems it necessary.

Signed this day, on the 23rd day of February 2005.

FOR THE PRIVY COUNCIL OFFICE

Jody Aylard — 23 February 2005

Jody Aylard
Director of Operations,
Office of Assistant Secretary
Regulatory Affairs and Orders in Council Secretariat

Date

FOR THE DEPARTMENT OF INTERNATIONAL TRADE

23 02 05

Paul Martin
Director,
Technical Barriers and Regulations Division

Date

FOR HEALTH CANADA

Caroline Weber — 23 feb. 05

Caroline Weber
Director-General,
Policy Planning and Priorities Directorate
Health Policy Branch

Date

23 Feb. 05

Trish MacQuarrie
Director,
Alternative Strategies and Regulatory Affairs Division
Pest Management Regulatory Agency

Date

23 Feb 05

Robert Asare-Danso
A/ Director-General,
Office of Regulatory and International Affairs
Health Products and Food Branch

Date

APPENDIX A

Health Canada Consultation Letter/ Notice of Intent for Schedule F Amendments

The consultation letter is intended to outline the proposal to amend Schedule F by the addition of one or more medicinal ingredients. A Notice of Intent will be prepared in cases when the proposal is to amend Schedule F by removing a medicinal ingredient.

Consultation letters and Notices of Intent will be prepared in both official languages.

The consultation letter/ Notice of Intent will contain the following information:

- Brief description of Schedule F and the internal process leading to a recommendation for Schedule F status.
- Identification of the medicinal ingredient(s):
    - which are proposed to be added to or removed from Schedule F, and
    - listed as they are proposed to appear in the regulatory amendment: using the approved and translated International Nonproprietary Name and any phrases that would qualify the listing.
- Description of each medicinal ingredient and rationale for the proposed amendment.
- Statement regarding the proposed timing for coming into force of the amendment (i.e., whether immediately upon registration or with a delayed implementation)
- Statement re the approximate timeframe from the date of the letter to publication in the *Canada Gazette*, Part II.
- Outline of the rationale for this degree of regulatory control and any alternatives which were considered.
- Description of prior consultation concerning these proposed amendments.
- Outline of the costs and benefits to stakeholders.
- Statement of the impact of the amendment on compliance mechanisms.
- Identification of the responsible policy analyst /regulatory officer including mailing address, fax number and email address.
- Invitation to comment.
- Statement of the time period to submit comments:
    - in the case of an addition, the 75-day comment period will be linked to the date that the letter was signed, or
    - in the case of a removal, the 75-day comment period will be linked to the date of publication of the Notice of Intent in Canada Gazette Part I.

APPENDIX B

Initial Notice of Intent for Pesticide MRLs to be Published in Canada Gazette, Part I

The following summary information about proposed MRLs will be included in the Notice of Intent (see Part B, Clause 5) published by PMRA:

I. General Information
- Purpose of document
- Disclaimer with respect to government review of summary
- Action to be taken by PMRA with respect to applicant's submission
- How, when and to whom to submit comments

II. Applicant's Summary of Application
- Residue chemistry
- Toxicological profile
- Aggregate exposure
- Cumulative effects
- Safety determination
- International tolerances

APPENDIX C

WORLD TRADE ORGANIZATION

G/SPS/N/COUNTRY/
date of distribution
(##-####)

Committee on Sanitary and Phytosanitary Measures Original:

NOTIFICATION

1.	**Member to Agreement notifying:** **If applicable, name of local government involved:**
2.	**Agency responsible:**
3.	**Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):**
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:**
5.	**Title, language and number of pages of the notified document:**
6.	**Description of content:**
7.	**Objective and rationale: [ ] food safety, [ ] animal health, [ ] plant protection,** **[ ] protect humans from animal/plant pest or disease,** **[ ] protect territory from other damage from pests**
8.	**International standard, guideline or recommendation:** **[ ] Codex Alimentarius Commission, [ ] World Organization of Animal Health,** **[ ] International Plant Protection Convention, [ ] None** **If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:**
9.	**Relevant documents and language(s) in which these are available:**
10.	**Proposed date of adoption:**
11.	**Proposed date of entry into force:**
12.	**Final date for comments:** **Agency or authority designated to handle comments: [ ] National notification authority, [ ] National enquiry point, or address, fax number and E-mail address (if available) of other body:**
13.	**Texts available from: [ ] National notification authority, [ ] National enquiry point, or address, fax number and E-mail address (if available) of other body:**