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Vol. 145, No. 9 — February 26, 2011

## Regulations Amending the Food and Drug Regulations (1347 — Sulfonamides)

*Statutory authority*

*Food and Drugs Act*

*Sponsoring department*

Department of Health

### REGULATORY IMPACT ANALYSIS STATEMENT

*(This statement is not part of the Regulations.)*

#### ***Issue and objectives***

Under the Canadian *Food and Drug Regulations* (the Regulations), all veterinary drugs must be authorized by Health Canada prior to their sale and administration to prevent and treat diseases in animals. Some drugs are only permitted in certain species not intended to be used for foods while others are used in food-producing animals. These amendments to the Regulations establish safe limits for residues of various sulfonamides in foods originating from animals treated with these particular drugs. These veterinary drugs are an important tool in the production of healthy animals which are destined for use as food.

#### ***Description and rationale***

Acceptable limits of residues of veterinary drugs in food commodities are called maximum residue limits (MRLs). MRLs are the maximum concentrations of residues, expressed in parts per million (p.p.m.) on a fresh weight basis, in edible tissues of food-producing animals as a result of the treatment of those animals with veterinary drugs. An MRL is based on the type and amount of residue considered to pose no adverse health effects if ingested daily by humans over a lifetime. There are a number of MRLs already established in Table III to Division 15 of Part B of the *Food and Drug Regulations*.

In order to determine whether MRLs are safe, scientists at Health Canada review the toxicity and residue depletion data submitted by manufacturers, assess the risks and benefits of the resulting use of the drug and the acceptability of the resulting levels of residues of the drugs that are found in food products. Only when there is sufficient evidence to demonstrate that the residues found will not pose undue risks to consumers can the drug be permitted for administration to food-producing animals and the related food products sold in Canada. Extensive studies have determined that the food commodities containing residues of sulfonamides at levels up to the MRLs listed in the amendments are safe for consumption. These MRLs apply to foods produced domestically or imported into Canada.

A joint Health Canada and Canadian Food Inspection Agency (CFIA) policy regarding the use of administrative MRLs (AMRLs) was established in 2002 as a mechanism for applying limits for authorized drugs prior to their promulgation in the Regulations. In 2004, to further help address this situation, the Veterinary Drugs Directorate (VDD) of Health Canada made a commitment to establish MRLs with every notice of compliance (NOC) for food-producing animal drugs. MRLs and AMRLs enhance health protection by identifying and measuring the risks of veterinary drug residues to the health of consumers and as a result, the appropriate action can be taken to protect Canadians from those risks. MRLs are scientifically equivalent to MRLs, that is, they result from the scientific evaluation process, they differ only in that AMRLs are not yet promulgated. Once the regulatory process is complete, the AMRL is promulgated as an MRL.

The addition of new MRLs for veterinary drugs to Table III to Division 15 of the Regulations can only be accommodated by regulatory amendment. These amendments list the following new individual MRLs for authorized sulfonamide compounds to be used in food-producing animals: sulfabenzamide, sulfacetamide, sulfachlorpyridazine, sulfadiazine, sulfadimethoxine, sulfadoxine, sulfaethoxyypyridazine, sulfaguanidine, sulfamerazine, sulfamethazine, sulfanilamide, sulfanitran, sulfapyridine, sulfaquinoxaline and sulfathiazole. In addition, these amendments propose that sulfonamides may be used singly or in combination. In cases where more than one sulfonamide drug residue is being detected, the combined residues of all sulfonamides listed in the amendments should not exceed 0.1 p.p.m. in edible tissues and 0.01 p.p.m. in milk.

The amendments would permit the regulated sale of food containing residues of veterinary drugs up to the specified level as a result of use of these drugs to prevent and treat diseases in food-producing animals. These amendments benefit both industry and the consumer by reducing potential losses in production, increasing quality of products, improving availability of certain foods, and supporting the trade of safe and high quality products derived from animals.

The MRLs for sulfonamides are aligned with MRLs for these veterinary drugs in tissues and in milk that have already been established by the United States and the European Union. There may be differences in MRLs for specific sulfonamide uses in specific species. However, in the European Union, MRLs (combined residues for all sulfonamides) for both tissues and milk are set at 100 µg/kg (0.1 p.p.m.), in the United States, tolerances MRLs, combined residues for all sulfonamides) are 0.1 p.p.m. for tissues and 0.01 p.p.m. in milk.

There is no anticipated increase in cost to government from the administration of these amendments to the Regulations. Compliance costs would not be a factor as the use of these drugs at the production level is optional.

### **Consultation**

Prior to pre-publication in the *Canada Gazette*, Part I, consultations on the MRLs for each veterinary drug included in these amendments were conducted with the following groups: 26 producer associations (e.g. Canadian Cattlemen's Association, Canadian Sheep Federation, Dairy Farmers of Canada, Canadian Pork Council, Aquaculture Association of Canada, Chicken Farmers of Canada), 12 professional associations (e.g. Canadian Veterinary Medical Association), 4 veterinary colleges and universities, 8 federal/provincial/territorial departments and agencies (e.g. Canadian Food Inspection Agency, Agriculture and Agri-food Canada, Fisheries and Oceans Canada, Foreign Affairs and International Trade Canada), 27 members of the drug manufacturing industry (e.g. Canadian Animal Health Institute, Pfizer Canada Inc. Animal Health Group) and 6 other organizations (e.g. Canadian Council on Animal Care, Environmental Defence Canada, Consumer Association of Canada).

There were eleven responses received as a result of the above consultations. Eight letters were supportive of the MRLs with one having a question and one requesting clarification, two letters were neutral and one expressed concerns that Health Canada addressed. Health Canada responded in writing to each of these issues, as indicated in the paragraphs below.

#### MRLs approved for use in certain animals

One stakeholder needed clarification on what constitutes a violation concerning MRLs. Health Canada responded that foods that do not contain more than the proposed MRLs would be exempt from paragraph 4(1)(d) of the *Food and Drugs Act* pursuant to section B.15.003 of Division 15, Part B — Foods in the Regulations. The MRLs are applicable only to residues of the named veterinary drugs authorized in Canada for the food products originating from food-producing animals specified in the Regulations.

#### Combined residues

One stakeholder asked if Health Canada's health risk assessment considered the possible cumulative effects of sulfonamide multi-residues. Health Canada responded that the health risk assessment conducted by our scientists did consider this question. These amendments specify that in cases where more than one sulfonamide drug residue is being detected, the combined residues of sulfonamides listed in the amendments should not exceed 0.1 p.p.m. in edible tissues and 0.01 p.p.m. in milk.

#### Alignment with trading partners and trade implications

One stakeholder commented that it is not anticipated that the MRL amendments would have an impact on Canada's international trade of foods because they are aligned with those adopted by major trading partners. Health Canada responded that while there may be differences in which sulfonamides are used and for which species, in North America, the respective MRLs for edible tissues (0.1 p.p.m.) and milk (0.01 p.p.m.) are the same.

#### Gaps in monitoring capabilities

One stakeholder had concerns on the practicalities of being able to detect sulfonamides drugs at the proposed MRLs. Health Canada discussed the issues raised by the respondent and suggested that he shares his practices and experiences with the CFIA which is responsible for monitoring residues for compliance with the Regulations and with other provinces to improve the methodologies used for testing.

#### ***Implementation, enforcement and service standards***

The CFIA enforces compliance with the MRLs appearing in Table III of Division 15, Part B of the *Food and Drug Regulations*. Where no regulatory MRL has been established, the CFIA may use the AMRL in its monitoring and compliance program so long as the AMRL is in the public domain and has been published on the VDD Web site. By adopting the use of AMRLs, the CFIA is better equipped to focus the risk-based enforcement of efforts regarding these veterinary drugs and thus make a greater contribution to ensuring the safety of food in the Canadian marketplace. Cases where neither an MRL nor an AMRL have been established are individually assessed.

Compliance is monitored by ongoing domestic and import inspection programs conducted by the CFIA. If levels of drug residues in excess of these limits are found in food products derived from food animals intended for human consumption, the product will be considered "adulterated," in accordance with section 4 of the *Food and Drugs Act*. The CFIA is authorized under the *Food and Drugs Act* to take compliance action, when they find violative residues. The CFIA's regulatory activities help to maintain consumer and market confidence in Canada's food supply.

#### **Contact**

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#### **PROPOSED REGULATORY TEXT**

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act* ([see footnote b](#)), proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1347 — Sulfonamides)*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Daniel Chaput, Director General, Veterinary Drugs Directorate, Health Products and Foods Branch, Health Canada, Holland Cross, Ground Floor, Suite 14, Address Locator 3000A, 11 Holland Avenue, Ottawa, Ontario K1A 0K9 (fax: 613-954-5694; e-mail: vetdrugs-medsvet@hc-sc.gc.ca).

Ottawa, February 10, 2011

JURICA ČAPKUN  
*Assistant Clerk of the Privy Council*

**REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1347 —  
 SULFONAMIDES)  
 AMENDMENTS**

**1. Table III to Division 15 of Part B of the *Food and Drug Regulations* ([see footnote 1](#)) is amended by adding the following after item S.2:**

<b>Item No.</b>	<b>Column I Common Name (or Brand Name) of Drug</b>	<b>Column II Name of substance for Drug Analysis Purposes</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
S.2.1	sulfabenzamide	sulfabenzamide	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
			0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle and sheep
S.2.2	sulfacetamide	sulfacetamide	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
			0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle and sheep

**2. The portion of item S.3 of Table III to Division 15 of Part B of the Regulations in column III is replaced by the following:**

<b>Column III</b>	
<b>Item No.</b>	<b>Maximum Residue Limit p.p.m.</b>
<b>S.3</b>	0.1 — singly or in combination with other sulfonamides listed in this Table

**3. The portion of item S.3.1 of Table III to Division 15 of Part B of the Regulations in columns III and IV is replaced by the following:**

<b>Item No.</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
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**S.3.1** 0.1 — singly or in combination with other sulfonamides listed in this Table Edible tissue of cattle, horses, sheep and swine; muscle of salmonids

**4. The portion of item S.4 of Table III to Division 15 of Part B of the Regulations in columns III and IV is replaced by the following:**

<b>Item No.</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
<b>S.4</b>	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
	0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle, chickens, horses, swine and turkeys; muscle of salmonids

**5. Table III to Division 15 of Part B of the Regulations is amended by adding the following after item S.4:**

<b>Item No.</b>	<b>Column I Common Name (or Brand Name) of Drug</b>	<b>Column II Name of substance for Drug Analysis Purposes</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
S.4.1	sulfadoxine	sulfadoxine	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
			0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle and swine

**6. The portion of item S.5 of Table III to Division 15 of Part B of the Regulations in columns III and IV is replaced by the following:**

<b>Item No.</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
<b>S.5</b>	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk

0.1 — singly or in combination with other sulfonamides listed in this Table

Edible tissue of cattle and swine

**7. Table III to Division 15 of Part B of the Regulations is amended by adding the following after item S.5:**

<b>Item No.</b>	<b>Column I Common Name (or Brand Name) of Drug</b>	<b>Column II Name of substance for Drug Analysis Purposes</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
S.5.1	sulfaguanidine	sulfaguanidine	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
			0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle, horses, rabbits, sheep and swine
S.5.2	sulfamerazine	sulfamerazine	0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle, sheep and swine

**8. The portion of item S.6 of Table III to Division 15 of Part B of the Regulations in columns III and IV is replaced by the following:**

<b>Item No.</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
<b>S.6</b>	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
	0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle, chickens, ducks, geese, goats, horses, sheep, swine and turkeys

**9. Table III to Division 15 of Part B of the Regulations is amended by adding the following after item S.6:**

<b>Column I Common Name</b>	<b>Column II Name of substance for</b>	<b>Column III</b>	<b>Column IV</b>
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<b>Item (or Brand Name) No.</b>	<b>(or Brand Name) of Drug</b>	<b>Drug Analysis Purposes</b>	<b>Maximum Residue Limit p.p.m.</b>	<b>Foods</b>
S.6.1	sulfanilamide	sulfanilamide	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
			0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle, sheep and swine
S.6.2	sulfanitran	sulfanitran	0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of chickens and turkeys
S.6.3	sulfapyridine	sulfapyridine	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
			0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle and swine
S.6.4	sulfaquinoxaline	sulfaquinoxaline	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk
			0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle, chickens, rabbits, sheep and turkeys

**10. The portion of item S.7 of Table III to Division 15 of Part B of the Regulations in columns III and IV is replaced by the following:**

<b>Item No.</b>	<b>Column III Maximum Residue Limit p.p.m.</b>	<b>Column IV Foods</b>
<b>S.7</b>	0.01 — singly or in combination with other sulfonamides listed in this Table	Milk

0.1 — singly or in combination with other sulfonamides listed in this Table	Edible tissue of cattle, chickens, ducks, geese, goats, horses, sheep, swine and turkeys
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### COMING INTO FORCE

#### **11. These Regulations come into force on the day on which they are registered.**

[9-1-o]

[Footnote a](#)

S.C. 2005, c. 42, s. 2

[Footnote b](#)

R.S., c. F-27

[Footnote 1](#)

C.R.C., c. 870

**NOTICE:**

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

Date Modified: 2011-04-06