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Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Veterinary Drugs Directorate
Holland Cross Complex
Ground floor, Suite 14
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Address Locator: 3000A
Ottawa, ON K1A 0K9

File No: 9450-5-20

June 23, 2005

Dear Stakeholder:

The Veterinary Drugs Directorate (VDD) of Health Products and Food Branch, Health Canada, is considering regulatory amendments which may be of interest to your organization. As the designated contact, I would appreciate your collaboration in distributing this information to the attention of all interested parties to solicit their comments.

More specifically, the Veterinary Drugs Directorate is proposing to establish Maximum Residue Limits (MRLs) in Table III to Division 15, Part B of the *Food and Drug Regulations* for Altrenogest (allyl-trenbolone) in edible tissues of food-producing animals as indicated in the following table:

COLUMN I	COLUMN II	COLUMN III	COLUMN IV
COMMON NAME (OR BRAND NAME OF DRUG)	NAME OF SUBSTANCE FOR DRUG ANALYSIS PURPOSES	MRL p.p.m.	FOODS
Altrenogest	Altrenogest	0.001	Liver of swine
		0.002	Kidney of swine

Altrenogest (allyl-trenbolone) is a synthetic trienic C21 steroidal progestomimetic, belonging to the 19-nor-testosterone series. It has a similar structure and function of progesterone. This product is an orally active progestin. Like all steroids, altrenogest acts by its liposolubility by penetrating the target cells where it binds to specific receptors. Altrenogest is used as a veterinary drug in gilts and mares for zootechnical purposes (oestrus synchronization.).

VDD has established an ADI of 1.2 $\mu\text{g}/\text{day}/\text{person}$. The withdrawal period is forty-two (42) days for swine.

The result of our Health Risk Assessment shows that residues at the above noted concentrations will not pose any undue health risk for consumers. These proposed MRLs will be published in the *Canada Gazette*, Part I, after consideration of comments from stakeholders.

I would appreciate receiving your comments on this proposal by September 14, 2005. Comments should be sent to the attention of Marc M Plante, Public Involvement Officer, at the above noted address.

Thank you for your cooperation in this matter.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Kathy Dobbin', with a stylized flourish at the end.

Kathy Dobbin
Acting Director General