Joint Health Canada/Canadian Food Inspection Agency - Policy on Administrative/Maximum Residue Limits and Working Residue Levels for Veterinary Drugs in Food Products.
June 2005

The establishment of Maximum Residues Limits (MRLs) for veterinary drugs in feed products is the legal responsibility of Health Canada's Veterinary Drugs Directorate (VDD). This Directorate is responsible for food safety in relation to foods produced in Canada from food-producing animals treated with veterinary drug products. VDD conducts comprehensive scientific reviews of veterinary drugs before they are approved for sale and subsequent use in Canada.

The Canadian Food Inspection Agency (CFIA) operates a National Chemical Residue Monitoring Program as part of its food safety enforcement and compliance responsibilities. This program relies on information provided by the VDD pertaining to drug residue analytical methodology, marker residues, target tissue(s), health risk assessments and standards for monitoring residues in foods. Ultimately, the VDD, based on a thorough scientific evaluation, will establish a Maximum Residue Limit (MRL) by regulation, an Administrative MRL (AMRL) where the regulatory process for the promulgation of an MRL is not yet complete, or a Working Residue Level (WRL) where there are gaps in the target animal species data package.

It is noted that while the legal status of MRLs and AMRLs differ, there is no difference between an MRL and AMRL in terms of scientific validity. Insofar as WRLs are concerned, a thorough human safety assessment has been conducted based on approval of the drug in other animal species but gaps remain in the target animal species data package which would preclude the establishment of an AMRL/MRL. In the derivation of the WRL, additional safety margins compensate for these gaps. In this way, there is no lessening of food safety controls and in fact, filling the data gaps would be expected to raise (i.e., make less restrictive) the residue level derived in this manner.

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In March 2005, a special "Stakeholder" meeting was held to discuss the derivation and application of WRLs in honey in those instances where neither an AMRL or MRL have been established in this food product, but for which an AMRL or MRL had been established in other food products. As is the case with AMRLs, WRLs will also be posted on HC's VDD website.

Based on the foregoing, there was agreement that WRLs can also be considered as a factor by CFIA, in its deciding on what action is to be taken where the possible contamination of honey is suspected or known.

Establishing WRLs for honey is a pilot project which provides guidance in an exceptional situation and in the interest of public health. While similar steps might be taken in the future under extraordinary circumstances, it should not be interpreted as a policy statement of general application.

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Veterinary Drugs Directorate (VDD)

Date: Sept 9, 2005

Cameron Prince
Executive Director
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Date: Sept 9, 2005