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Vol. 138, No. 40 — October 2, 2004

## Regulations Amending the Food and Drug Regulations (1386 — Kaolin)

*Statutory authority*

*Food and Drugs Act*

*Sponsoring department*

Department of Health



### REGULATORY IMPACT ANALYSIS STATEMENT

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

#### *Description*

Under authority of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) of Health Canada has approved an application for the registration of the pest control product (pesticide) kaolin as an insecticide for the control of a variety of insects on numerous crops. All pest control products that are registered for food uses under the *Pest Control Products Act* are considered agricultural chemicals under the *Food and Drugs Act* and are subject to its provisions regarding residues in food. Under the *Food and Drugs Act*, it is prohibited to sell food containing residues of agricultural chemicals at a level greater than the general Maximum Residue Limit (MRL) of 0.1 parts per million (p.p.m.),

as specified in subsection B.15.002(1) of the *Food and Drug Regulations*, unless a higher MRL has been established in the Regulations or the agricultural chemical has been exempted from subsection B.15.002(1) by listing it in subsection B.15.002(2). This proposed regulatory amendment would list kaolin in subsection B.15.002(2), in order to permit the sale of food containing these residues.

Kaolin is a naturally occurring mineral. It is a soft, white or yellowish white powder with a clay-like taste. Humans consume kaolin in a variety of anti-diarrhea medications. A typical use of these medications includes ingestion of 30 to 60 ml of medication (containing 10 to 20 g of kaolin) following each loose stool defecation. The kaolin adsorbs material and fluid from the gastrointestinal tract and forms a protective coating on the intestinal mucous membrane. Cholera patients have been fed 600 g of kaolin (plus water) over a 12-hour period without ill effects. The acute toxicity of kaolin is limited to its classification as a nuisance dust, which may cause respiratory irritation. Humans are also exposed to kaolin on a daily basis in products such as antiperspirants, toothpaste and cosmetics. In addition, kaolin is used in animal feed as an anti-caking agent in amounts up to 2.5 percent of the finished feed. The use of these products have resulted in chronic oral and dermal exposure of the general population to kaolin, with no adverse effects reported.

Before making a registration decision regarding a new use of a pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. The registration of the pest control product will be amended if the data requirements for assessing value and safety have been adequately addressed, the evaluation indicates that the product has merit and value, and the human health and environmental risks associated with its proposed use are acceptable. In the case of kaolin, waivers were requested and granted for subchronic, chronic, reproductive, developmental and neurological toxicity, based on the long history of use of kaolin without any indication of deleterious effects.

Kaolin is not expected to be absorbed in large quantities from the gastrointestinal tract into the systemic circulation. Based on this information and the absence of any systemic toxicity or other toxicological concerns following oral exposure, no

quantitative dietary risk assessment is needed for kaolin.

After the review of all available information, the PMRA has determined that the proposed domestic use of kaolin on a variety of crops will not pose a risk to any segment of the population, including infants, children, adults and seniors when food is subjected to the normal process of washing or peeling, and cooking for human consumption.

Therefore, it is proposed to amend the *Food and Drug Regulations* to include kaolin in the exemption provisions specified under subsection B.15.002(2).

#### *Alternatives*

Under the *Food and Drugs Act*, it is prohibited to sell food containing residues of agricultural chemicals at a level greater than 0.1 p.p.m. unless a higher MRL has been established in Table II, Division 15, of the *Food and Drug Regulations* or the agricultural chemical has been exempted from subsection B.15.002(1) by listing it in subsection B.15.002(2). In the case of kaolin, exempting kaolin from subsection B.15.002(1) is necessary to support the use of a pest control product which has been shown to be both safe and effective.

#### *Benefits and costs*

The use of kaolin will benefit both the agricultural industry and consumers as a result of improved management of pests and will contribute to a safe, abundant and affordable food supply.

Since this proposed amendment would exempt kaolin from the provisions of B.15.002(1), there would be no costs involved in administering the Regulations.

#### *Consultation*

Registration decisions made by the PMRA are based on internationally recognized risk management principles, which are largely harmonized among member countries of the Organisation for Economic Co-operation and Development.

#### *Compliance and enforcement*

Since kaolin would be exempt from the provisions of subsection B.15.002(1) of the *Food and Drug Regulations*,

compliance monitoring will not be necessary.

*Contact*

Mr. Cameron Laing, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, 2720 Riverside Drive, Address Locator 6607D1, Ottawa, Ontario K1A 0K9, (613) 736-3665 (telephone), (613) 736-3659 (facsimile), [cameron\\_laing@hc-sc.gc.ca](mailto:cameron_laing@hc-sc.gc.ca) (electronic mail).

**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*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1386 — Kaolin)*.

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 Cameron Laing, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Department of Health, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario K1A 0K9 (tel.: (613) 736-3665; fax: (613) 736-3659; e-mail: [cameron\\_laing@hc-sc.gc.ca](mailto:cameron_laing@hc-sc.gc.ca)).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, September 29, 2004

EILEEN BOYD  
*Assistant Clerk of the Privy Council*

**REGULATIONS AMENDING THE FOOD AND DRUG  
REGULATIONS (1386 — KAOLIN)**

## AMENDMENT

1. Subsection B.15.002(2) of the *Food and Drug Regulations* ([see footnote 1](#)) is amended by striking out the word "or" at the end of paragraph (e), by adding the word "or" at the end of paragraph (f) and by adding the following after paragraph (f):

(g) kaolin.

## COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

[40-1-o]

### [Footnote a](#)

S.C. 1999, c. 33, s. 347

### [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 hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



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