

**Bill C-28**  
+  
**Smart\* Regulation**  
=  
**A nasty business**

**A Brief to the Standing Committee on Health, House of Commons**

**on**

**BILL C-28: AN ACT TO AMEND THE FOOD AND DRUGS ACT**

**By**

**Michael McBane**

**Canadian Health Coalition**

**April 11, 2005**

**[www.medicare.ca](http://www.medicare.ca)**

\* **smart** *a. & adv.* **1.** Severe enough to cause pain.  
**2.** Selfishly clever to verge of dishonesty;  
unscrupulously clever;  
(The Concise Oxford Dictionary)

## SUMMARY

Bill C-28 is designed to accelerate the adulteration of Canada's food supply with cancer causing chemicals, pesticides, food additives and veterinary drugs. This legislative proposal would sabotage the health policy objectives of the Government of Canada, including those announced in the Budget Plan 2005, especially investments in healthy living and disease prevention. Bill C-28 must be rejected in its entirety.

\*\*\*\*\*

*Making these decisions is a very nasty piece of business.*

-David Dodge, former Health Canada DM, *Ottawa Citizen*, November 21, 1998

*Smart regulation is market-friendly regulation designed to bring regulatory regimes in line with trade and investment policy.*

-[www.smartregulation.gc.ca](http://www.smartregulation.gc.ca)

*Health Canada and CFIA were able to devise an approach that met the needs of producers, drug manufacturers and veterinarians, and that met the legal obligations of both federal government organizations.*

-*Smart Regulation - Administrative Maximum Residue Levels*, Health Canada, October 2003

*The Department of Health has for too long optimistically assumed that the interests of health and of the industry are as one. This may reflect the fact that the Department sponsors the industry as well as looking after health. The result is that the industry has been left to its own devices for too long. ...The consequences of lax oversight is that the industry's influence has expanded and a number of practices have developed which act against the public interest.*

-House of Commons Health Committee (UK) *The influence of the Pharmaceutical Industry*, 5 April 2005

## INTRODUCTION

The Canadian Health Coalition is a non-partisan advocacy organization founded in 1979 following the SOS Medicare conference attended by Tommy Douglas, Justice Emmett Hall, and Monique Bégin. Membership consists of national organizations representing nurses, seniors, women, anti-poverty, church, and labour movements.

The first goal of the Canadian Health Coalition is: "To create conditions for good health". The statutory duty of the Minister of Health is the protection of Canadians from health hazards and fraud in the sale of food, drugs and health products. The Minister of Health has no duty to promote industry, faster drug approvals, trade, investment or so-called Smart Regulation initiatives. Poor performance of the federal statutory duty to protect health is costing Canadian lives, and threatens the sustainability of the health care system.

The Canadian Health Coalition appeared before this Committee on October 23, 2003 on the need for an inquiry into the predatory practices of the pharmaceutical industry. Since then, this committee issued an excellent report entitled: **Opening the Medicine Cabinet: First Report on the Health Aspects of Prescription Drugs**, April 2004. The direction of Bill C-28 as well as the Government of Canada application of ‘Smart Regulation’ to health products, food and pesticides is the opposite policy direction of your committee’s report.

Bill C-28 is being sold as ‘Smart Regulation’. Agreed. According to the Concise Oxford Dictionary, **smart** means **1.** severe enough to cause pain, and **2.** selfishly clever verging on dishonesty; and unscrupulously clever. Bill C-28 - when examined in terms of its consequences – fits these definitions of **smart**. It would be dishonest to present these legislative changes to Canada’s charter of safety rights, the *Food & Drugs Act*, as merely a technical matter with no impact on safety.

The Canadian Health Coalition’s analysis of this legislation supports the characterization of C-28 as unscrupulous as well as dishonest. Health Canada has issued 82 Notices of Interim Marketing Authority for products that have not completed the regulatory process to assess their safety. This includes food additives for infant formula and genetically modified organisms. As you know, Canada does not even have a scientific methodology to test GMOs for the human and environmental impact. And yet these products are put in our food through this administrative fiat. The Standing Joint Committee on the Scrutiny of Regulations concluded this is illegal.

It is important for members of the Health Committee to understand why the marketing of chemicals, food additives, veterinary drugs, and pesticides by means of an administrative fiat – Interim Marketing Authority –is illegal. It is illegal because it is unsafe to do so and it exposes Canadians to health hazards. It therefore violates the *Food & Drug Act*. This Act is part of the criminal code. The Parliament of Canada is being asked by the Minister of Health to pass Bill C-28. One of the consequences would be to absolve the Department officials especially the ADM Health Products and Food Branch who issued the 82 illegal notices. Instead of helping to cover their tracks retroactively (as per clause 4 in C-28) and thereby attempt to evade liability for regulatory negligence, the Parliament of Canada must hold these officials to account for failing to uphold the law.

Canadians don’t want their health protection weakened – even if it is done in a smart and unscrupulous manner. They don’t want the *Food & Drug Act* gutted wholesale by means of the Minister’s proposed new Canada Health Protection Act. Nor do Canadians want their safety rights gutted piecemeal with Bill C-28.

## **BACKGROUND TO BILL C-28**

Bill C-28 was introduced in the House of Commons on November 29, 2004 with no advance notice or indication of what it is designed to accomplish. On December 14, 2004, during second reading debate the Parliamentary Secretary to the Minister of Health

explained that this proposed amendment to the *Food & Drugs Act* was drafted in response to concerns expressed by the Standing Joint Committee on the Scrutiny of Regulations.

The amendments to the *Food and Drugs Act and Regulations* that came into effect in July 1997 are unauthorized. Since then, according to the Parliamentary Secretary, 82 pesticides, food additives, and veterinary drugs were let onto the market in Canada without an assessment for safety and without a Notice of Compliance as otherwise required under the Act.

The Parliamentary Secretary explained that the proposed legislation will authorize the Assistant Deputy Minister (ADM) of the Health Products and Food Branch of Health Canada to issue a notice of interim marketing authorization to exempt certain foods from the application, in whole or in part, of the regulations. In other words, the Minister of Health is seeking the legislative authority to allow agricultural chemicals, food additives, pesticides, and veterinary drugs onto the market without a Notice of Compliance or even an assessment verifying that these products are safe.

During second reading debate the Parliamentary Secretary told the House not to worry, the Bill is “not related to food safety” but is a “technical” matter. The Parliamentary Secretary to the Minister of Health added that C-28 is “in line with the ongoing intent of the Government of Canada’s smart regulation initiative and the recommendations from the External Advisory Committee on Smart Regulation”. If that is not enough to reassure public health advocates, he added that Bill C-28 “will support ongoing work under the North American Free Trade Agreement Technical Working Group on pesticides” to harmonize standards down to the U.S. level.

Interim marketing authorization is, to quote the ADM of Health Products and Food Branch, Diane Gorman, “a means to improve the responsiveness of the regulatory system... to permit the immediate sale of ” pesticides, chemicals, food additives and veterinary drugs without bothering to wait for assessment of safety and efficacy and determined to be satisfactory under the *Food & Drugs Act and Regulations* before issuing regulatory approval.

## DESCRIPTION

Clause 1 of this Bill amends section 4 of the *Food and Drugs Act*, which states that contaminated or harmful food cannot be sold. Bill C-28 amends this section with respect to the prohibition on adulteration of food. The original section 4 of the Act is new subsection 4(2) is added that states that **food is not considered as adulterated if it has an interim marketing authorization** and if the substance in question does not exceed the maximum residue limit set out in the authorization. **The substances** renumbered as subsection 4(1), and **for which an authorization can be issued include agricultural chemicals, a veterinary drug or its metabolites, pest control products, or their components, derivatives and metabolites.**

## ANALYSIS

The effect of this clause is to create the legal fiction that a food is not adulterated with a pesticide, chemical, or veterinary drug (and its metabolites) if the ADM issues an interim marketing authorization. *Hocus-pocus*, adulteration is not adulteration. No evidence of safety is required. No Notice of Compliance for the new drug is required before it is put into our food supply. In effect, C-28 paves the way for a chemical ‘free for all’. Hazardous drugs are let on the market without first establishing the safety of the product. Once these products are on the market, it is falsely assumed that their safety was established by Health Canada. In fact, the interim marketing authority has already been used many times to let drugs on the market for which there may or may not be a methodology for testing for residues. The real purpose of C-28 is to provide the legal basis for this reckless regulatory practice.

## DESCRIPTION

Clause 2 amends the Regulations section (section 30) of the *Food and Drugs Act* by adding two new regulation-making powers for the Governor in Council. These include: regulations defining “agricultural chemical,” “food additive,” “mineral nutrient,” “veterinary drug” and “vitamin” for the purposes of the Act; and regulations regarding interim marketing authorizations.

Clause 3 adds new subsection 30.2 to section 30 of the *Food and Drugs Act*. **The new subsection gives the Minister of Health the authority to issue an interim marketing authorization** and outlines the authorization’s types and limitations. **The Minister has the authority to issue an interim marketing authorization if he or she determines that the food would not be harmful to the health of the purchaser or consumer.** An authorization may cover an agricultural chemical, a veterinary drug and its metabolites, a food additive, a vitamin, a mineral nutrient or an amino acid.

As well, the authorization may provide for a maximum residue limit for agricultural chemicals or veterinary drugs, or a maximum level of use for food additives, only if those substances are already allowed under the regulations, and **the authorization would permit a level higher than is currently allowed under the regulations, or would permit the substance, singly or in any combination, to be present in, or used on or in, a different food.** Subsection 30.2(4) states that **the Minister may apply any terms and conditions to the authorization.** The provisions of clause 3 essentially move regulatory powers currently in section B.01.056 of the *Food and Drug Regulations* into the Act itself.

## ANALYSIS

This clause would gut the Minister of Health’s current statutory duty to protect the public from health hazards and fraud. Interim marketing authority would give the Minister of Health the legal authority to expose Canadians to chemicals, food additives, pesticides and veterinary drugs that are known carcinogens and that cause DNA damage to children.

How can the Minister of Health authorize the marketing of a drug or chemical without first receiving sufficient scientific data to assess the safety and effectiveness of the new drug?

Why would the Minister of Health, Ujjal Dosanjh, seek interim marketing authority for products that are known to be hazardous to human health? Why would Canadians give this power to their Minister of Health?

How many Canadians have to die from diet related cancer before Health Canada stops the adulteration of the food supply with known carcinogens?

#### DESCRIPTION

**Clause 4 is a deeming provision that allows any Notice of Interim Marketing Authorization issued under section B.01.056 of the *Food and Drug Regulations* prior to the coming into force of clause 4 to be deemed an interim marketing authorization issued under the amended Act.**

#### ANALYSIS

This clause would legalize retroactively the current notices of interim marketing that were issued without valid legal authority. This clause is an admission that the products issued since 1997 under these notices have no legal basis to be on the market and present in our food as residues.

#### DESCRIPTION

**Clause 5(1) provides that if an agricultural chemical is a pest control product, then the maximum residue limit established under the *Food and Drug Regulations* as read immediately before the coming into force of clause 5(1) is deemed to be the maximum residue limit as set out in the *Pest Control Products Act*. Clause 5(2) states that clause 5(1) comes into effect once both section 89 of the *Pest Control Products Act* and clauses 1 through 4 of this Act have come into force.**

#### ANALYSIS

According to Health Canada's Health Products and Food Branch, Veterinary Drugs Directorate, a maximum residue limit (MRL) is: "an amount of residue that could remain in the tissue or food product derived from a food-producing animal that has been treated with a veterinary drug. This residue is considered to pose no adverse health effects if ingested daily by humans over a lifetime".

Yet according to the U.K. Food Standards Agency, a maximum residue level (MRL) is defined as "a legal limit... it is not a safety limit".

## QUESTIONS FOR HEALTH CANADA

1. Why is Health Canada regulating on the basis of a “maximum residue limit” and not on the basis of human health and safety?
2. How can a “maximum residue limit” and “administrative maximum residue limits” be “deemed” in the absence of scientific data establishing safety?
3. If there is no science and no legal basis for Health Canada’s regulation of pesticides, veterinary drugs, and food additives, why has the Health Products and Food Branch ADM issued 82 Interim Marketing Authorizations?
4. How can you establish a ‘maximum residue level’ for carcinogens, genotoxic carcinogens, and for genotoxic mutagenic carcinogens (e.g. Estradiol used as a growth promoter in Canadian beef but banned in the EU)?
5. When Health Canada established an “administrative” MRL for Estradiol, what level of breast and prostate cancer did it deem acceptable as a consequence?
6. How does Health Canada establish a safe level for substances in food of which one single molecule can cause a mutation leading to cancer?
7. Why is Health Canada approving drugs in food producing animals without, in some cases, a method to test for residues?
8. Why is Health Canada approving the non-therapeutic use of antibiotics in food-producing animals resulting in antimicrobial resistance and approving the use of animal protein in feed - a known means of BSE transmission?
9. Where is Health Canada’s methodology for assessing GMOs or the toxicology of mixtures including carcinogenicity, reproductive and developmental toxicology, endocrine disruption, immunotoxicity, genotoxicity and other effects *in vitro*?
10. In the absence of any of this scientific capacity at Health Canada, how can the Department establish so-called “safe levels”; issue MRL’s, “administrative” MRLs or notices of interim marketing authority?
11. Why were the scientists in the Veterinary Drugs Directorate who refused to issue MRLs for drugs whose safety could not be established as required by law, fired (July 2004) and how many MRLs were issued after they were relieved of their duties?
12. How can Health Canada’s Veterinary Drugs Directorate, The Pest Management Regulatory Agency, the Therapeutics Products Directorate, and the Food Program conduct independent risk assessments in the public interest when they are funded by drug manufacturers?

## CONCLUSION

As the Joint Committee for the Scrutiny of Regulations has pointed out, Health Canada’s current approval of chemicals, pesticides and veterinary drugs through an interim marketing authority is illegal. It must remain illegal because it is unsafe and violates the *Food & Drugs Act*. The Canadian Health Coalition considers this practice, and the proposal to legalize it with Bill C-28, a major threat to food safety and the health of Canadians.

The statutory duty of the Minister of Health is and must remain the protection of the health and safety of all Canadians – especially the children. The Minister has no legal basis to permit the marketing of health hazards and then manage the damage after people become ill and die prematurely. Parliament must not give the Minister of Health what he is asking for in Bill C-28 – the power to expose Canadians to known carcinogens by “deeming” these hazards to be safe – no evidence required. Canadians want health regulation based on the Precautionary Principle, where one always errors on the side of safety and not on the side of the risk.

## **RECOMMENDATIONS**

The Canadian Health Coalition recommends the following:

### **Recommendation 1:**

That Bill C-28 be rejected in its entirety.

### **Recommendation 2:**

That the Minister of Health terminate the use of interim marketing authority and return to performing his legal duties in the *Food & Drugs Act*.

### **Recommendation 3:**

That the Minister of Health acknowledge the inconsistency between the Government of Canada’s Smart Regulation initiative, with its stated objective of bringing Canada’s health protection regulations in line with trade and investment policy, and his statutory duty in the *Food & Drugs Act* to protect Canadians from health hazards and fraud.

### **Recommendation 4:**

That the Health Committee examine the circumstances surrounding the firing of three Health Canada scientists from the Veterinary Drugs Directorate immediately prior to the drafting of this proposed legislation and conduct an independent review of Health Canada’s drug approval system for human as well as animal drugs.