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Regulatory Discretion

Why soft law can be hard to take for food companies

Most food law is made by public servants, not law makers. Sure, legislation goes to legislatures and regulations go to Cabinets for decision, but guidelines, directives, interpretations, certifications, pre-market approvals, letters of no objection, waivers, decisions to prosecute, detention orders, product seizures, recalls, HACCP approvals and withdrawals, advisories, border controls, warnings, rulings, etc. – these all come from your friendly food regulator. These rules are often called soft laws in the sense that they are not the direct products of lawmakers or elected officials. But if you're on the wrong side of the bureaucratic decision, they can feel pretty hard.

Broad bureaucratic discretion is necessary in food law for many reasons. Legislation is necessarily general and often the bureaucratic decision is essential to provide prior guidance on interpretation or to implement general provisions. For example, Section 5 of the *Food and Drugs Act* provides that it is a criminal offence to "label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety." The Canadian Food Inspection Agency (CFIA) has kindly published the *2003 Guide to Food Labelling and Advertising*, featuring 15 chapters and hundreds of pages of guidance interpreting Section 5 and other related regulatory provisions.

Section 3 of the *Food and Drugs Act* defines a drug to include "any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms…or restoring, correcting or modifying a body function or the body structure of human-beings." If a food makes such a claim, it becomes a drug. There are now dozens of pages of rulings "clarifying" these general words. So, for example, Health Canada issued Information Letter No. 793 in 1991 setting out detailed rules for foods represented for use in weight maintenance and making it clear that any food that purports to promote weight-reduction would be a drug and would require a formal DIN number. The CFIA has further determined that a food cannot advertise that it can help "manage" your weight, but it can claim to help you "maintain" your weight. We have also been advised that while "foods" can claim to help achieve and maintain a healthy body weight, ingredients cannot. We have also been told that in their opinion it is a criminal offence to say that a food can help to "manage hunger," but it is perfectly legal to say that the food can help to "satisfy hunger." There is not enough room in this column to set out the convoluted reasoning for this distinction.

Sometimes, in an effort to clarify the law, the regulator actually creates more confusion when it releases a new interpretation (for example, the new draft *Highlighted Ingredients Directive*), or issues a "clarification" that is actually a new policy (for example, the CFIA memo of April 2007 regarding labelling on sandwiches). Sometimes the interpretations become completely out of date, and while they could easily be updated to reflect new science without the necessity of regulatory change, they can become rigid "law." So, for example, in spite of many bureaucratic promises to modernize and clarify the rules on novel fibres, Guideline No. 9 issued by Health Canada in November 1997 is beginning to look like a permanent fixture of Canadian food law.

Sometimes the industry craves interpretation so that there can be certainty and a level playing field. For example, the current lack of a policy to determine when an item is a food or a natural health product has resulted in mixed messages and major confusion in the industry. And sometimes inadequate or spotty enforcement can have the effect of changing the effective law. For example, it seems quite clear that if a food claims that it can strengthen one's immunity, such a claim would be an offence under Section 3. By not taking enforcement action, it appears that regulators now consider such claims to be legal.

For reasons of public health, trade and consumer protection, the food industry is perhaps the most highly regulated industry in the country. The hundreds of pages of legislation and formal regulation do not even begin to capture the weight of the hand of government, a hand that is mostly thumbs with few fingers. Success in the food industry requires a good relationship with your regulator and a working knowledge of soft law.

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