Regulation of Claims on Infant Foods in Canada

Margaret C. Cheney and Christina M. Zehaluk

Food Directorate, Health Protection Branch, Ottawa, Ontario, Canada

Because the only infant foods for which claims are made in Canada are infant formulas, I am going to discuss the different types of claims that we are encountering at present, our current regulatory system, and our thoughts on what changes need to be made to this system in the light of new developments in claims. In Canada, manufacturers are now more than ever competing for market share by means of claims. Claims for formulas are directed both to the health worker and to the consumer through a variety of advertising means. The fact that claims are being targeted to consumers indicates that the choice of formula is no longer dictated by the health worker. It is therefore essential that these claims be meaningful to the consumer as well as accurate. The health worker also relies on claims and indications for use when advising mothers on which formulas to use.

It is our experience in Canada that both consumers and health workers assume that the claims made for infant formulas have been validated and approved by the government. Claims for formulas may be divided into four categories.

The first type of claim is a description of the composition of the product, e.g., protein base, absence of lactose, which is useful in guiding health professionals in recommending formulas to mothers and for mothers in choosing formulas; these claims are obviously easy to substantiate and to regulate.

The second type of claim is the statement or claim made for a specific formula but that is applicable to all standard infant formulas by virtue of the basic compositional requirements necessary to sell a formula. We take objection to claims such as "this formula is closest to breast milk" because it is not possible to duplicate the composition of breast milk; instead, it is acceptable to indicate that formulas are modeled after breast milk. When a claim is stated in a manner suggesting that a particular brand of formula is easily digested, and by implication that all other brands are not easy to digest, the claim is considered misleading. These claims can be couched in a manner that is not misleading by making it clear that this brand, like all other infant formulas, is easy to digest. Manufacturers have traditionally not made claims that their formulas contain higher levels of nutrients than other formulas, and we hope that this practice will continue.
The third type of claim is the statement or claim related to dietary management of a disease or condition. These claims have been used for decades for specialized formulas such as those for inborn errors of metabolism and other conditions and for allergies to milk and soy proteins. The data required to substantiate these claims vary depending on the condition. If the principles of dietary management of a condition are well defined, only growth, development, and tolerance studies may be required for the formula. Hypoallergenic claims are acceptable for formulas meeting criteria set up by the Canadian Paediatric Society. Claims for prophylaxis, however, are not as well accepted. In more recent years, we have seen claims related to such conditions as diarrhea or colic, where the data required to substantiate the claims have not been defined either by experience or by expert advice.

The fourth type of claim that is beginning to appear is the claim that the formula will result in superior mental or physical performance or enhanced immune function based on the presence of ingredients that are normally present in breast milk but that have not been traditional ingredients of infant formulas. This is a new dimension of claim that raises a host of issues with respect to substantiation such as the appropriateness of endpoints, meaningfulness, the length of follow-up, and so on.

In 1990, regulations were introduced in Canada requiring manufacturers to notify the Health Protection Branch 90 days before the sale or the advertising for sale of any new infant formula or of an infant formula that had undergone a major change. At that time claims were not an issue. The types of formula on the market were few, and the only claims were those describing the composition of the formula and the well-established indications for the use of special formulas. As a result, the requirements for premarket notification concentrated on the provision of information on the specifications, manufacturing process, quality control procedures, and the other matters considered necessary for safety. When filing a premarket notification, the manufacturer or importer must provide details of the evidence relied on to establish that the new infant formula is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use. The manufacturer or importer must also provide the written text of all labels, including package inserts.

The definition of "major change" is confined to a change of ingredient or in the amount of an ingredient or in the processing or packaging of the human milk substitute, where experience or theory would predict an adverse effect on the levels or availability of nutrients in, or the microbiological or chemical safety of, the formula. Thus, the regulatory requirements for clinical data are confined to the nutritional adequacy or safety of the formula and do not extend to data to substantiate any claims for indications for use. Furthermore, the definition of "major change" does not include changes in labels for new claims or indications for use.

The Health Protection Branch must therefore rely on the general provisions of the Canadian Food and Drugs Act respecting misleading and deceptive labeling practices, which are found in section 5 of the Act, to control claims for infant formulas. At the moment, the onus is on the Health Protection Branch to prove that the claims are misleading or likely to create an erroneous impression as to the value
of the food. In our view, this method of operating is not providing optimal protection to either the mother or the infant.

There has been a proliferation of different types of formula since premarket notification was introduced, competition is becoming fiercer, and with it there is an expansion of claims. We are increasingly being called on to investigate claims after a product is on the market. We feel that infant formulas are too important a class of foods to be treated like ordinary foods when it comes to claims.

Consumers and health workers should have confidence that the claims on an infant formula are justified by appropriate studies in much the same way as they rely on the indications for the use of drugs in Canada. In Canada, the Food and Drugs Act permits the making of regulations respecting the conditions of sale of any food, to prevent a consumer from being misled as to the composition, merit, safety, etc. of the product. Under the authority of this section, it would be possible for us to include in the premarket notification requirements for evidence to substantiate any claims that are made for the benefits of the formula related to health, or for the dietary management of any disease or disorder or condition. It would also be possible to include in the definition of "major change" any change to the label regarding claims for health benefits or dietary management of diseases, and so on. These changes would have the effect of shifting the onus to the manufacturer to justify claims before marketing. Given the increasing sophistication of the claims and their proliferation, we believe that this approach would offer a greater protection to the Canadian public and is worthy of consideration.

In 1992, the Health Protection Branch established an ad hoc expert consultation to advise on the composition and testing of formulas for preterm infants. Their report was published in 1995 and provides valuable guidance to us in the evaluation of preterm formulas. In the future our branch and other regulatory bodies will need advice and guidance from experts on the types and designs of clinical studies required to support the various types of claims.

DISCUSSION

Dr. Utaa: What claims have there been in Canada recently that you are concerned may be misleading?

Dr. Cheney: We have seen claims for colic and claims for dietary management of diarrhea in particular.

Dr. Yolken: I understand from your presentation that you would not accept the claim that formula X is closer to breast milk than formula Y. But I have seen advertising along those lines from Canada. Do you not have the ability to control this, or is some other mechanism involved?

Dr. Cheney: In Canada, if those claims are deemed misleading, action is taken after the fact.

Dr. Aggett: I understand that people can make claims, and then, only if somebody raises an objection can you actually examine the claim and its veracity?

Dr. Cheney: No. In Canada, claims are brought to our attention either through trade complaints or by our finding them.
Dr. Agget: So people don’t come to you before making a claim; they make the claim and may get away with it. Is that the situation?

Dr. Cheney: This is why we are proposing a change.

Dr. Agget: So if you do catch up with them, can you actually stop them continuing with the claims?

Dr. Cheney: Yes, but you then get into the “is it false, misleading, or deceptive” situation, and if you end up arguing under those conditions, it becomes extremely time-consuming, involves a lot of expert testimony, and is ultimately dependent on a judge’s decision. This is not a good way to resolve these issues.

Dr. Clarke: To stand in solidarity with my two colleagues, because I do a very similar job in the United Kingdom, I should say that not only is the whole issue a gray area, but it also becomes highly emotive because the primary objective is benefit, and the safety issue is often forgotten or swept to one side. I am sure that the three of us have been in a similar position where it has been said that we are denying infants the benefits of having particular products in infant formulas. It is a thankless task to withhold permission on the basis of safety, but I would remind everyone that regulations are designed not to hinder progress but to protect and benefit the population.

Dr. Przyrembel: This is, in fact, why in Germany—in addition to the seven claims that European regulations allow—manufacturers may also list what they have added to a formula, but not why. Thus, they may add LC-PUFAs and state so on the label but not say why they have added them. It is for informed people to make their choice.

Dr. Uauy: If you start putting things on the label that the public cannot clearly interpret, it is potentially misleading. The regulatory agencies should be concerned with what the public reaction will be. I would like to know what the public reaction is in Canada or in Germany to this sort of claim. Are people calling up and asking the regulatory agency about it? Who is orienting the public?

Dr. Cheney: I would admit that claims on the label, such as “contains added nucleotides,” may not mean very much to consumers, and this is why there is a temptation to go beyond that and to start explaining what the benefits are of those particular added ingredients. In Canada, the only issue that periodically comes up in the media is “Why don’t Canadian formulas contain DHA?”

Dr. Przyrembel: So far as the German situation is concerned, I think the motivation of the government in passing this law was to encourage manufacturers to do more research, not to stop with the composition regulations that the European Commission had set up. It is up to the physician, to the pediatrician, to read about the subject and to form his own opinion.

Dr. Steenhout: I agree with your comment that the pediatrician must offer an intellectual reflection on what is on the label. However, I had a lot of experience in private practice before joining Nestlé, and I can tell you that when mothers see this sort of advertising on the label, they are attracted by it, and if you prescribe a formula from another company without any advertising, you get asked why. I think we must be very careful with this sort of legislation; good science must come before pure marketing.

Dr. Lucas: In the past, proper efficacy and safety studies have been very rare, and when they have been done, they have not been done well, and many of the claims that have been made have been misleading and unacceptable. It is becoming clear now that we are moving into a new area of research, where claims will be supported by the medical profession as a whole in a proper way, that is, after properly randomized long-term efficacy studies with proper safety and numbers, more than one study, and so on, and if we have all those things, then it seems to me extremely important that regulatory bodies are able to respond by allowing
legitimate and medically supported claims to be made. I believe this for two reasons: one is that it is informative for the public; the other is that because a large amount of funding for research comes from industry, there is very little incentive for industry to support really important outcome research if they are unable to make any kind of claim for the health benefits at the end, even if they have been legitimately proven. So my concern is that the foundations are laid down by regulatory bodies so that they can respond to what is going to be a new wave of research in the next few years.

Dr. Cheney: I think that is a very good point; it would be most unfortunate if a regulatory structure were set up that discouraged developments. That would be an extremely negative outcome. There is a need for consumer protection and also for the protection of companies that do the research, so that they themselves get the benefits of it as well.

Dr. Guesry: Do you think that the interpretation of the rules has changed recently? I see differences between the situation 10 years ago and that now. Ten years ago, the addition of taurine was accepted purely on the basis that it was present in human milk, even though no effect whatsoever on the health of the baby had been proven. Now, we have the nucleotide issue, which is comparable: no effect has been demonstrated in infants, but nucleotides are present in human milk. However, the addition of nucleotides is banned by most of the regulatory bodies. So do you think there has been an evolution of the rules, so that the fact that a compound is present in human milk is now insufficient to support a claim for its inclusion in an infant formula?

Dr. Cheney: Yes. There are now safety issues involving not only the novel ingredient but also its source. Safety has to be established for both.