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Trade Team Canada Bio-Industries

Summary Report of the National Functional Food and Nutraceutical Technologies Workshops

Held in March - April 1998

An Overview of the Regulatory Issues Presented By: BIOTECanada

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BIOTECanada

The "Summary Report of the National Functional Food and Nutraceutical Technologies Workshops" is an overview of the proceedings of three one-day national workshops held across Canada in the spring of 1998. The objective of these workshops was to bring together the functional food and nutraceutical community in Canada to identify and resolve the domestic and international business development issues hindering the future development of this emerging sector.

In appreciation for their collaborative support in one or the other phases of the overall project, the following partners are acknowledge BIOTECanada, Agriculture and Agri-Food Canada, Industry Canada (National Biotechnology Sector Team), etc. [As per attached report]

Introduction

Agriculture and Agri-Food Canada, Industry Canada (National Biotechnology Sector Team), BioAgral, BioNova, British Columbia Biotech Alliance, Contact Canada, Department of Western Economic Diversification, Efamol Research/ Scotia Pharmaceutical Ltd., Food Research Development Centre, In*NOVA*corp, National Research Council/ IRAP, Ocean Nutrition Canada Ltd., at the University of Guelph

The domestic and international demand for functional food and nutraceutical products is growing at a phenomenal rate. As functional foods and nutrceuticals become an increasingly important sector of business development, many companies and research organizations are developing new technology-based products to meet the consumer demand. However, the industry is in its infancy. Many issues and barriers to commercialization exist and need to be examined and assessed. Identification, discussion

and resolution of the issues and barriers will promote the development of a strong functional food and nutraceutical industry in Canada

Functional food and nutraceutical companies are increasingly employing biotechnologies to identify, develop and manufacture their products These products tend to occupy an intermediate position with the spectrum defined by the agri-food and health sectors In an effort to better understand this emerging sector, BIOTECanada has developed a series of regional workshops that will focus on the issues facing the industry and highlight the advanced technology components of this sector

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Background on the Status of the Regulatory Framework in Canada

Section 3 of the Canadian Food and Drug Act prohibits the sale or advertising of food that claims to have beneficial health properties It is accepted knowledge that diet affects health and that people consume products to maintain health Health Canada recognizes that the current regulatory framework does not support the labelling and advertising of health benefits to consumers Many nutraceutical products are commercialized without health claims and are regulated as foods but are often used therapeutically

To resolve the current regulatory shortcomings, Health Canada commenced a number of functional food/nutraceutical regulatory initiatives These include setting up internal working groups and external advisory panels, consultations with the Standing Committee on Health, general consultation workshops, and developing a draft policy options analysis paper (1997) The draft policy options analysis paper proposes several options to improve the current regulatory framework One option is to permit, structure function and risk reduction claims for food products, while continuing to regulate therapeutic claims as drugs Another option would be to expand health claims, given appropriate scientific evidence

The advisory panel recommended that safety and quality claims must be regulated, that claims should be divided into three categories (lower/medium/higher risk), that all claims require adequate evidence, that a disclaimer be included on products making no claims, that the notification and submission review process be implemented, that functional foods be considered as food and nutraceuticals as therapeutic products, that Schedule A be removed from the Food and Drug Act, and that a separate structure be developed with appropriate expertise in natural health products and with decision-making authority

For the next steps, Health Canada will monitor the Standing Committee process and finalize the functional food/nutraceutical draft policy options analysis paper, implement regulatory and policy changes, and establish and implement upcoming recommendations in consultation with stakeholders

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Workshop Concept

The workshops were held in Vancouver (March 11th), St-Hyacinthe (April 15th) and Dartmouth (April 28th)

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Key Findings of the National Workshops

The following concerns/issues were identified

Regulatory System

- There was recognition that the current process was not adequately serving their reality of the functional food and nutraceutical industry and resulted in a global competitive

disadvantage when considering product life cycles versus the approval process
- Labelling was identified as the pivotal functional food/nutraceutical industry issue Although Canada has one of the best regulatory systems in the world, the restrictive domestic regulatory environment favours international commercialization at the expense of the domestic market
- Lack of Health Canada resources resulting in a bottle-neck in the approval process
- An issue raised with the current regulatory framework was that it was not the sole factor contributing to holding back the sector The absence of a unified industry position and the lack of sufficient data supporting health claims were also seen as factors
- There is a perception of lack of liaison support by Health Canada, and the need to appear more supportive to firms that have applied for product approval The need for a more supportive attitude and development of some sort of follow-up procedure was suggested

Health Claims

- It was mentioned that if firms are to make claims, than they should be willing to provide the data and assume the expense
- Discussion on the high cost of gathering health claim information suggested to lower the cost and relax regulatory requirements by decreasing the depth of information required relative to drugs, and sharing the costs among all stakeholders It was suggested to use existing scientific information instead of developing new and costly information
- Researchers indicated that the need to meet public demand for functional food/nutraceuticals must also be balanced by the requirement that products be safe and effective for consumption

Quality Control

- It was mentioned that even if firms could provide researcher/scientist data on health claims, it would still be difficult to accept a product under the current regulatory framework It was suggested that a low/medium/high risk mechanism be introduced
- The need for clinical studies was raised in the context of labelling of supplements Health claims must be supported by clinical studies The nature of the ingredients, source, concentration and possible synergistic effects are all aspects that need to be considered Analytical tools are necessary to isolate and identify the active ingredients, since many commercialized products are actually mixtures Currently, there are no standard good manufacturing practices (GMPs) and there may be a need to establish universal standards in the industry
- Industry indicated there is a need for regulating products since many products on the shelves are not quality controlled In addition, functional food/nutraceutical products are now available via direct mail and electronic commerce and foreign products are sold domestically
- A need exists to deliver quality product information and to determine how to deliver the message to the consumer Industry favours some form of self-regulation and quality standards (i e veterinary association responsible for regulating the quality of pet food)
- A quality assurance process would ensure that products get to market more quickly, although the GMP process to acquire a license would represent an additional delay

R&D Efforts

- With the decreasing government funding must be allocated towards research into evaluating plants and their phytochemical compositions The Standing Committee was aware that more research funding is necessary Currently, most of the regulatory process is under cost recovery, and the possibility that more funding could be leveraged out of other organizations was suggested

- The need to focus the R&D effort and standardization of manufacturing practices were identified

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Key Recommendations

Several organizations including Health Canada indicated that the regulatory process is moving forward and appeared more flexible that in the past There appeared to be some desire to try to find additional flexibility in the regulatory process The notion that perhaps clinical trials are not necessary, based on certain available evidence was advanced Unfortunately, the issue of making health claims cannot be addressed until a final decision on the regulatory issue is made by government and until then, the industry perceived that Health Canada's current approach represented a good first step A continued consultation with the industry is required prior to changing regulatory policy

Canada has already achieved success in the biotechnology industry, but must leverage its successes and do more to remain a world leader The pharmaceutical, drug and agri-food sectors should be bridged, which will result in new market opportunities The Canadian regulatory system should be in harmony with the global regulatory system A bridge between the regulation of food and drugs should be sought instead of applying the current regulatory process to each Both government and industry must increase their R&D effort for funtional foods/nutraceuticals to gain economic benefit from the products of that research Otherwise we will continue to be an importer of the products with all the economic benefit accruing abroad Finally, more resources must be invested in the development of managers and entrepreneurs, and more venture capital is necessary for the industry

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Conclusion

The functional food/nutraceutical industry is young and fragmented, reminiscent fo the biotechnology sector a decade ago Based on the experience of the biotechnology sector, it is important to network and coordinate the functional food/nutraceutical industry at a national level to ensure a leadership role for Canada The Saskatchewan Nutraceutical Network was identified as the lead organization in the west of Canada and acts as the focal point of communication for the industry A number of other regional organizaitons have shown their interest such as BioAgral (Québec), University of Guelph (Ontario), University of Manitoba, Department of Food and Nutrition (Manitoba), University of Alberta, Department of Agriculture of Foods and Nutrition (Alberta), and BioNova (Nova Scotia) The Ontario Agri-Food Technologies (OAFT) has also indicated its intention to co-host a similar workshop in early fall in Guelph

The functional food/nutraceutical industry in Canada is primarily a niche with an increasing opportunity for growth The use of biotechnologies, such as genetic engineering, is increasing and will represent a major activity of this new business sector over the next few years

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