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Stéphane Dupont

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Aller au sommaire du numéro

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Stéphane Dupont

Executive Director, BioProducts Centre Inc. Saskatoon, Canada

THE CANADIAN ENVIRONMENT

Canada's size, climate and natural resources are well known around the world. With a land surface area of 9.2 M km^2 and a population of 30.3 M people, Canadians are used to wide open spaces. The forest land accounts for 4.2 M km^2, a sizeable 10% of the world's forests. Canada is the world's largest exporter of timber products, commercially exploiting 28% of its forests. Annually, 128,000 km^2 of forests are affected by defoliating insects and 66,000 km^2 are lost to fires.

Farmland represents 680,000 km^2, which combines with the small population to make Canada a major exporter of agricultural commodities. Over half of our exports go to the U.S., while the rest goes around the world, with Japan, the E.U. and China as the next major clients. Table 1 shows an overview of the Canadian agricultural commodities usually targeted for biocontrol.

The growing season is short and farming often involves large areas managed with minimum tillage and inputs, resulting in relatively low yields compared to many other OECD countries. This is especially true of wheat farming in the prairies and has certain implications for biological control since the cost of production of biologicals usually puts these products well above what the farmer can afford. Timber, as a crop, is akin to wheat, with very low margins and inputs. Oilseed production is represented mainly by canola in the prairie provinces. Canola oil is a premium product and the better margins make biocontrol a potentially more viable option. Fruits and vegetables tend to be more propitious crops for commercial biocontrol products, as in most other countries. The Canadian livestock industry is also very interested in using biocontrol products against both insect pests of cattle and noxious weeds of pasture and rangeland.

Canada's rigorous winter has a major impact on both pests and the biocontrol options available to manage them. We tend to have fewer pests, especially diseases and, to a certain extent, insects. With fewer pest generations per year, resistance appears more slowly. Winter can also play a signifi-

Table 1: Market Value of Canadian Agricultural Production (Cdn $ B)

Commodities	British Columbia	Prairie Provinces	Ontario & Québec	Maritime Provinces	Canada
Grains	0.02	5.14	0.83	0.02	6.01
Oilseeds	0.01	2.24	0.89	<0.01	3.14
Fruits & Veg.	0.30	0.08	1.05	0.09	1.52
Other Crops	0.42	1.18	1.63	0.32	3.55
Red meats	0.29	4.60	2.91	0.18	7.98

cant role in preventing or delaying the long-term establishment of a new biocontrol agent. This may be desirable for an inundative agent used outside of its natural range or undesirable for a classical agent.

INDUSTRY PERSPECTIVE

Canada has traditionally been at the forefront of biocontrol research and there is a large biocontrol scientific community in Universities and government institutions (mainly the research centres of Agriculture and Agri-Food Canada and the Canadian Forest Service). Unfortunately, this has not resulted in the development of a large private sector. This sector is made up of two distinct types of companies. On the one hand, there are the large crop protection multinationals, whose interest in biological control is increasingly directed at pest resistant transgenic crops, and on the other, about 15 small to very small companies involved in the development and manufacture of other biocontrol products (mainly microbials and a few insect agents). A few other companies distribute products manufactured abroad in addition to having limited R&D activities. The case of *Bt* is a telling example of the gulf between public research and commercialisation. A large amount of R&D work has been carried out in Canada on all aspects of this type of product, from fundamental biochemistry to forestry and agriculture applications, but there is no Canadian manufacturer and Canada must import the products from the U.S.

All the Canadian biocontrol company contacts identified were sent a list of questions. These aimed to determine the main issues regarding the commercial development of safe new biocontrol products and the companies' recommendations for research priorities. About two-thirds of those contacted provided feedback. Most of the respondents felt that the Canadian registration requirements are quite stringent and comprehensive in addressing the potential risks associated with usage of new, non-modified, microbial biocontrol products. A minority felt that the authorities are focusing too much on selected non-target species, to the detriment of a more ecological approach assessing long-term impact on the biodiversity of the various eco-regions. It was suggested that microbial biodiversity banks representative of the many Canadian agro-eco-regions could be established as a safeguard against unforeseen effects. However, the above suggestions would represent a major, if not insurmountable, logistical, financial and scientific challenge.

Most of the respondents from the small companies expressed some degree of unease regarding the use of transgenic microorganisms. This was often based on the belief that only a small fraction of microorganisms are known (an estimated 1%) and that our knowledge of microbial ecology, and especially, lateral gene transfer mechanisms among microbes, is thought to be very limited. Another concern is that transgenic organisms relying on a single mechanism of action are more likely to induce resistance in the target pests. Similarly, non-modified organisms also relying on simple mechanisms are considered more "resistance-prone" than those deploying more complex mechanisms. Some expressed the opinion that, by placing a greater emphasis on the design of appropriate screening procedures, natural microorganisms with the desired profiles can be found without having to resort to genetic engineering.

In addition to the safety issues discussed above, most respondents commented on other aspects of the Canadian regulatory framework for biocontrol agents. This framework is structured as follows: microbial pest control agents (as well as synthetic and natural chemical pesticides) are regulated by the Pest Management Regulatory Agency (Health Canada). Growth promoting inoculants, macro-invertebrates and transgenic crops are reviewed by the Canadian Food Inspection Agency (now independent but formerly within Agriculture and Agri-Food Canada). All biocontrol agents produced or under development by the respondents fall

within the mandate of one of these two agencies. A third organisation, the Canadian Environmental Protection Agency, deals with all other new biological products. Unless specified otherwise, (Canadian regulatory) "agencies" will be used here in reference to the PMRA and the CFIA.

Several respondents indicated that minimal risks are sometimes given much more weight than they deserve by reviewers while the benefits of introducing a safe and effective alternative to chemical pesticides are not valued highly enough. In this context, the issue of commercial development of products containing ubiquitous, normally harmless, microorganisms, which may become opportunistic pathogens in individuals with severely depressed immunity, is of concern. Since these products normally pass stringent safety tests, it was felt that potential health problems, which might occur in very uncommon situations, should not lead to the rejection of the application when they could be safely addressed with appropriate delivery systems, use patterns and precautionary statements.

Most companies wish for improvements in the time taken to clarify final data requirements and complete the submission reviews. Any speeding up of registration and streamlining of associated bureaucratic processes will reduce development costs, which is especially important for the small companies. The fact that PMRA reviewers often appear more accustomed to dealing with chemical pesticides than microbials was also mentioned. New chemical pesticides usually have no health or environmental history whereas considerable information is often available on microbial agents. Solid expertise in the ecology, biology, mode of action and benefits of microbial control agents is needed on the part of both registrants and reviewers to evaluate all existing relevant information. This information should be taken into account when determining the registration requirements. Some companies have also expressed the wish that agencies show more flexibility in considering their prior registration data when reviewing new submissions for similar products (e.g. same organism, different formulation; or very similar agent for the same target application). Finally, when only limited information exists in the literature about a new agent, it is often indicative of a species with no history of pathogenicity. The lack of prior information should, therefore, not raise undue concerns with reviewers.

Both agencies have established new registration guidelines over the past few years, which are generally highly regarded. The registrant-agency consultations in advance of the final submissions are greatly appreciated by all respondents but especially by the small companies who lack the resources to employ full-time registration personnel and for whom an early definition of the studies required (i.e. registration R&D costs) is extremely useful.

Commercial development issues are at the forefront of industry concerns in Canada, as they are elsewhere. There are many go/no-go decision points in the commercial development of a biocontrol product. Efficacy and cost of the final products are the main factors governing their adoption by the users. Biologicals are often associated with high production costs; low, slow or inconsistent efficacy; and short shelf lives. These concerns are most commonly cited by the respondents as obstacles to the successful commercialisation of new biological products. Companies, large and small, usually see addressing these issues as their responsibility and best done on a product by product basis. Other issues include the investment and expertise needed to develop high performance Quality Assurance assays and formulations, and effectively market the new products. Various aspects of the commercial development issues mentioned above greatly benefit from collaborations with experts in the public sector. The maintenance and expansion of the matching public funding options for these collaborations is strongly encouraged. Finally, Canada currently lacks scale-up facilities for fermentation, downstream processing and formulation. Developing these is a major challenge and would

strongly benefit from a concerted approach between the government(s) and the private sector.

Several respondents also indicated that applied public research in inundative biocontrol (i.e. work aiming for the eventual widespread use of a product) should, like industry, take economic viability into consideration as early as possible. Even for products developed on a "public good" basis (high user or public need but no interest or possibility for the private sector to invest heavily in the commercial development), the economic feasibility must still be realistically evaluated. The total cost to complete the proof of concept work on economic, regulatory and technical feasibility is usually about Cdn $ 0.4 to 0.8 M. A further $ 2 to 5 M is then needed to complete the efficacy, registration and process R&D work, without including the cost of the production facility or marketing the product. This emphasises the need for effective collaborations between the public and private research sectors, and the importance of flexible funding options for the inherently riskier commercial proof of concept phase of a project.

MAIN RECOMMENDATIONS AND OUTLOOK

Various suggestions deemed helpful by the Canadian industrial biocontrol sector have been made so far. However, the recommendations respondents were most eager to put forward as priority areas for a concerted effort of the various biocontrol sectors were: a) support for basic research in microbiology and b) information of the public and potential users. Advances in the fields of microbial/soil ecology, biochemistry, physiology, molecular microbiology, etc. would have a major long-term impact on most aspects of safety and commercial development of new agents. In addition there is an increasing realisation that, for any new products to be used in the environment and/or the food chain, using the best possible science to ensure the best possible risk/benefit ratio is no longer enough. Effectively communicating accurate information about the products, their risks and benefits to the public is equally indispensable. Past and current experiences with public debate and perception of chemical pesticides and transgenic crops in Canada and abroad have demonstrated the need for effective communications. The confidence of the Canadian public in the regulatory authorities to ensure safety of new products with respect to the food chain and the environment remains generally high but cannot be taken for granted.

Over the past few years, Canada has developed a mechanism to fund high profile networks in areas where coordination of the research among scientists and with the private sector will result in maximum benefits for Canadian society. This is the Networks of Centres of Excellence Program and a funding application for a Biocontrol Network was submitted in May 1998. Producing the complex application document was the first time that representatives of all the different fields of biocontrol research in Canada worked together for a common goal. Research on products with a high potential for commercial success, in collaboration with the private sector, is a major priority of this network. However, other aspects discussed above are also featured prominently, such as basic science and improved communications among all biocontrol stakeholders and with the general public. The network will have a strong IPM component to ensure optimum long-term efficacy of the new products when used with each other and with existing pest management products and methods. The main targets are insect pests, diseases, and weeds in forestry, canola, fruits and vegetables, as well as insects and weeds of concern to the livestock industry. The Biocontrol Network will be ideally placed to coordinate research and other activities in the priority areas most relevant for Canada.