Author - Canadian Biotechnology Strategy Taskforce

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THE CANADIAN BIOTECHNOLOGY STRATEGY ONLINE

SECTOR CONSULTATION DOCUMENT: ENVIRONMENT

INTEGRATING BIOTECHNOLOGY INTO THE CANADIAN ECONOMY FOR SUSTAINABLE DEVELOPMENT AND A CLEANER ENVIRONMENT IN THE 21ST CENTURY

CONSULTATION DOCUMENT PREPARED BY:

ENVIRONMENT AND ENVIRONMENTAL INDUSTRIES WORKING GROUP FOR CANADIAN BIOTECHNOLOGY STRATEGY SECTOR CONSULTATIONS

MARCH 30, 1998

Hull, Quebec
K1AOH3

April 6 1998

Dear Members of the Canadian Environmental Biotechnology Community

I am inviting you to participate in a federal government consultation on biotechnology in the Canadian Environment and Environmental Industries sector

The Canadian government is currently considering the renewal of the National Biotechnology Strategy (NBS), a federal initiative established in 1983 to promote the development of biotechnology in Canada. The NBS has played an important role in establishing Canada as a world leader in relevant industrial sectors. In the intervening years however, new challenges and opportunities have arisen that require consideration in the renewed biotechnology strategy. Correspondingly, the renewed strategy is expected to build on current strategy strengths as well as encompass such important considerations as public awareness and involvement, the structure of a national advisory board, and sustainable development.

To garner input to the NBS, the government has initiated a series of Roundtable consultations with stakeholders across Canada in March and April. Three key areas to be addressed are the broad policy framework, the creation of an advisory body on biotechnology, and issues of ongoing public interest. Should you wish to review and comment on these key issues, you will find detailed information on the Internet at ***http://strategis.ic.gc.ca/cbs***

To address matters specific to individual sectors however, the federal government is arranging for parallel consultations in the sectors of mining, forestry, agriculture, health, aquaculture, research, and environment. The Environmental Technologies Advancement Directorate of Environment Canada is leading the consultation for the environment and

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environmental industries sector

Therefore, I would invite you to review the attached sectoral consultation document and to provide your input directly back to Environment Canada by April 27 / 98 via the Internet at ***http://www.ec.gc.ca/biotech*** or by Fax to ***(819) 953-4705***.

Your response will set the stage for the future development and direction of biotechnology in Canada's environmental sector and contribute to the federal government's Biotechnology Task Force's efforts to renew the strategy.

We look forward to receiving your comments and working with you in the development of the renewed National Biotechnology Strategy.

Sincerely,

Mr. P. K. Leung
Deputy Director General
Environmental Technologies Advancement Directorate
Environment Canada

Ce document est aussi disponible en français

CONSULTATION DOCUMENT ON
THE ENVIRONMENT & THE ENVIRONMENTAL INDUSTRIES
AND THE RENEWAL OF
THE CANADIAN BIOTECHNOLOGY[1] STRATEGY

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Footnote :

[1]Biotechnology is the application of science and engineering in the use of living organisms, or parts of such organisms, whether they be natural or modified, to produce goods and services. Biotechnology can benefit the environment directly through applications such as bioremediation of contaminated sites or indirectly through applications which result in cleaner industrial processes and products.
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Environment Consultation Document

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1) Preface

Canada and the world are entering into a new era. It is one in which biotechnology has already begun to enhance our health, environment, and well being. At the same time, it also promises to create more jobs and economic growth as well as contribute to sustainable development. The fast pace of development in the biological and biomedical sciences is yielding an increasing number of new bio-products and bio-processes which are transforming markets and stimulating international competition. This is creating dramatically new opportunities on a global basis.

The Government of Canada is renewing and strengthening its existing biotechnology strategy - a strategy that has been in place since 1983. The purpose of the renewal process is to ensure that biotechnology continues to contribute to our quality of life and deliver economic and social benefits in a way that is ethically and environmentally responsible. The vision for this Canadian biotechnology strategy renewal is that Canada be a world leader in developing and applying biotechnology to enhance the quality of life of its citizens in terms of health, safety, the environment, and economic development. Full achievement of this vision will require the input, participation and endorsation of a wide range of stakeholders in many sectors of the economy.

Therefore, a critical element of the strategy renewal process is establishing an ongoing dialogue with members of the Canadian public who are interested in biotechnology. To do this, the Canadian federal government is conducting two parallel sets of consultations with representatives of industry, academia, environmental non-governmental organisations (ENGOs), provincial governments, and the community at large. The first set of consultations involves five round-table discussions to be held across the country with key stakeholders and members of the community. Participants at these consultations will discuss the strategy's vision, objectives and principles, as well as a broad based advisory body on biotechnology to facilitate public participation and information. To address matters specific to individual sectors, a second set of consultations is also taking place in the following areas: mining, forestry, aquaculture, health, agriculture, R&D (research and development) and finally, **Environment and Environmental Industries** which is the focus of this document.

NOTE: This environment and environmental industries document has evolved from considerable input from an federal government interdepartmental working group. Prior to the commencement of more formal dialogue with the broader environmental biotechnology community, it has been circulated and discussed at an informal workshop held on February 26, 1998 with representatives of the environmental biotechnology community. The following contains a preliminary analysis of those issues identified to date from this initial dialogue on environmental biotechnology in Canada. We would now like to hear your comments and opinions on the material presented in the document.

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2) Objectives of This Environment and Environmental Industries Consultation

1. To initiate and stimulate discussions with Canadians on issues relating to:

- environmental impacts and benefits of biotechnology developments in Canada, and
- environmental applications of biotechnology for sustainable development and improved competitiveness in a number of Canadian industry sectors;

2. To hear from Canadians on what roles the federal government should play relating to:

- opportunities and challenges in applying biotechnology for sustainable development;
- development and advancement of the Canadian environmental bio-industries sector; and,

3. To set the basis for a continuing future dialogue on the federal government's biotechnology strategy and environmental aspects of integrating biotechnology into the Canadian economy in the 21ST century.

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3) Introduction

Over the last fifteen years, Canada has become a major player in research and development relating to biotechnology - which is recognized as one of the most useful enabling technologies ever to be introduced to society. These days, biotechnology is rapidly gaining wide scale attention and capturing the public imagination. This is because of the multifaceted role that it is starting to play in shaping society in a manner just as remarkable as computer and telecommunications technology has already done. Of particular interest are the roles that biotechnology could play relating to national priorities on:

- strategic innovation,
- restoration and rehabilitation of polluted habitats,
- creation of "green" jobs, and
- building a knowledge-based economy which contributes to sustainable development, wealth generation as well as Canada's stewardship responsibilities - nationally and globally.

A recent ruling by the Supreme Court of Canada has stressed the importance of stewardship of the environment as a "fundamental value of our society". It also identified "protection of the environment" as a "major challenge of our time". Biotechnology offers many opportunities for advancing the goals of innovation and sustainable development in the context of environmental stewardship. The challenge is how to develop biotechnology in a responsible manner directly for environmental applications as well as more broadly for enhancing the sustainability and competitiveness of Canadian industry as we move into the 21st century.

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4) Background

a) Status of the Environmental Bio-Industries in Canada

Environmental bio-industries began to develop in Canada during the late 1980's and early 1990's. Environmental biotechnology was estimated to be the third largest creator of biotechnology related jobs in Canada during the early 1990's (after biotechnology in health care and agriculture). During a five year period, approximately 1700 high quality jobs were created in the nascent environmental bio-industry and the average growth rate of employment in that sector was 25% per annum. Current estimates put the number of environmental biotechnology companies in Canada at around 80 with the majority located in Quebec, Ontario, Alberta and British Columbia (Heller 1995[1]) [(KPMG 1996[2]). The current value of environmental biotechnology sales by

Canadian companies is estimated at $80-100 million. The bulk of the sales are in four specific areas including:

- bioremediation,
- biological gas cleaning,
- microbial pest control agents, and
- biological processes and feedstocks for production of industrial chemicals.

Approximately 75% of these sales are in the domestic market. While the industry is still in its early stages of development, its potential for growth is strong, given the increasing global awareness that protection of the environment is both a major challenge and priority of our time.

b) Public Perception of Environmental Applications of Biotechnology

The Canadian public is only beginning to become aware of the potential benefits and risks of biotechnology. There is a need for better communication with the public and for better understanding of the issues surrounding public confidence in environmental applications of biotechnology in Canada. Studies which have examined Canadian public opinion on biotechnology indicate that there is a significant level of support for applications aimed at solving environmental problems (Environment Canada 1996).[3] It is expected that greater support will require the public to have confidence:

- that the regulatory system adequately protects human health and the environment, and
- that those developing and applying biotechnology for environmental purposes set high technical and ethical standards for membership in their community.

The public also has raised specific questions relating to the application of environmental biotechnology in Canada. They include questions about:

- its effectiveness and reliability;
- possible failure scenarios and associated contingency planning;
- the range of potential risks and benefits, particularly involving the use of recombinant organisms;[4]
- any possible human health consequences;
- provisions for public involvement in setting standards and codes of practice; and,
- its cost effectiveness compared to conventional technology.

c) Government regulatory oversight of biotechnology

In 1993 the Canadian federal government established a regulatory framework for biotechnology products in Canada. In 1997, New Substances Notification Regulations for biotechnology products came into force under the *Canadian Environmental Protection Act* (CEPA). The Framework and the Notification Regulations have clarified the regulatory requirements which must be fulfilled prior to importation or manufacture of a biotechnology product in Canada.

Through the OECD, Canada is involved with international efforts to harmonize regulatory oversight of biotechnology. For example, international consensus documents have been developed to provide a collaborative and harmonized approach for evaluation of the health and environmental risks associated with environmental release of certain microorganisms. These represent very concrete evidence of international cooperation that directly benefits industry.

Canada is also a signatory to the convention on Biological Diversity and, in 1998, is participating in negotiations under the convention on a "Biosafety Protocol". The Protocol will establish ground rules that will govern international movement of "living modified organisms" including information requirements, a mechanism for "advanced informed assent", and obligations for exporters.

In addition to regulations at the federal level, there are cases where provincial and municipal regulations must be met before a biotechnology product can be used in the environment. However, the federal government is actively involved in reducing duplication and enhancing harmonization with the provinces through the Canadian Council of Ministers of the Environment and through direct dialogue with the provincial government officials. In addition, municipalities may have by-laws which cover environmental applications of organisms, (e.g. wastewater treatment organisms or bioremediation organisms).

The science underpinning biotechnology is developing and evolving at an ever-increasing pace. A number of countries, most notably the US, Germany and Australia, have made strides to keep their regulatory policies and practices abreast of changes in the understanding of the science. Canada needs to maintain its monitoring and analysis of these developments and continue to evolve its regulatory system to ensure that it is responsive for the dual purposes of:

- protecting Canadians from newly identified risks, and
- reducing unnecessary regulatory burdens on Canadian industry.

d) Contribution of Environmental Biotechnology Sustainable Development

Environmental biotechnology offers the potential for:

- *in-situ* biology based techniques which offer options for restoration of contaminated habitats and which are less disruptive and less resource intensive than conventional approaches;
- new techniques to address recalcitrant environmental pollutants (e.g., PCB's, metals); and,
- environmentally friendly and "green" industrial processes in a number of sectors which use less energy and produce not only less waste but also waste which is less toxic than conventional chemical processes per unit of product manufactured.

In the future, environmental biotechnology is expected to contribute improved methods for:

- assessing the health of ecosystems (biosensors, bio-indicator organisms);
- making more efficient use of non-renewable resources (e.g., microbial enhanced oil recovery, microbial desulfurization of heavy oil and coal);
- environmentally friendly biological alternatives to chemicals for control of diseases, pests, and weeds in agriculture, aquaculture, and forestry;
- conversion of agricultural, forestry and other organic wastes to bio-fuels or valuable industrial specialty chemicals replacing fossil fuel feedstocks; and,
- trapping and recycling of green house gases such as CO_2 into industrial chemical feedstocks using microorganisms such as single-cell algae.

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5) Environmental Bio-industries: Strengths, Weaknesses, Opportunities & Threats

Strengths

The environmental bio-industry in Canada has a number of key strengths:

- a highly entrepreneurial culture with the ability to move rapidly to address new market opportunities;
- regulatory certainty under the Canadian Environmental Protection Act for importation and manufacture of

organisms employed in environmental applications of biotechnology

- technical expertise in bioremediation and wastewater treatment under widely varying field conditions across Canada's geographical and climatic regions; and
- established technical capabilities in areas (e.g. petroleum hydrocarbon remediation) relevant to expanding environmental markets in the US, Mexico, and South America.

In addition, Canadian companies and research organizations are:

- recognized internationally as leaders in improving the performance of bioremediation (e.g. bioremediation methods for polyaromatic hydrocarbons, energetic materials, and weathered hydrocarbons);
- leaders in identifying indigenous plants which are hyperaccumulators of metals or which play a role in the degradation of organic substances in contaminated soils;
- actively involved in world-class collaborative projects demonstrating effectiveness in the field of bioremediation for cleanup of toxic organic substances such as PCB's and of phytoremediation for accumulation and removal of toxic heavy metals; and,
- beginning to develop and utilize biotechnology not just for 'end-of-pipe' solutions but also for cleaner industrial products and processes (e.g. bio-pulping and bio-bleaching in pulp and paper manufacture, enzymes for processing textiles, microorganisms for oil desulfurization);

Weaknesses

Sector weaknesses include the following:

- the perceived high cost of regulation and technology demonstration projects related to commercializing a novel biotechnology in Canada;
- lack of formal mechanisms (e.g. Centres of Excellence or research consortia) in Canada for exchange of scientific information and technology transfer within the university and government research community and also between the research community and the industry;
- environmental bio-industries lack an overall sense of cohesiveness and the ability to organize and advocate a position to government (e.g. on further evolution of biotechnology regulations under the Canadian Environmental Protection Act);
- companies in the environmental bio-industries are largely project driven and, as a result, the sector has been slow to evolve due to a lack of strategic alliance activity;
- biotechnology is not yet recognized or understood as an important factor for differentiating company capabilities in the overall environmental industries sector (in this respect the Canadian industry lags its U.S. counterpart); and,
- limited development of the fundamental science underpinning certain areas of environmental microbiology (e.g. related to: the role of microorganisms in their habitat, predicting the behavior of detoxifying microorganisms, estimating bioavailability of toxic substances in different media and bioremediation techniques for inorganics).

Threats

A number of factors have been identified which threaten the ability of the Canadian environmental bio-industry to achieve its growth potential:

- the perception that regulation of naturally occurring microorganisms occurs in Canada but not in the US (this permits US companies to demonstrate, at lower cost, technologies based on these organisms);
- entry of larger US competitors into the Canadian market;

- a major culture gap between biological scientists in the environmental biotechnology community and engineers in user industries (i.e. resource companies);
- continued loss of skilled human resources to the US and a limited capacity to train or retrain human resources, especially those bridging the biology-engineering culture gap;
- lack of centrally located technology demonstration facilities and lack of scientifically validated protocols to determine product efficacy and quality;
- lack of market incentives for key industry sectors to adopt cleaner products and processes;
- lack of government investment to support fundamental research and strategic R&D networks in the fields of environmental biotechnology and microbial ecology;
- lack of private sector investment capital to support industrial innovation and growth.

Opportunities

Applications of biotechnology for environmental restoration and rehabilitation, pollution abatement, and pollution prevention are expected to become substantial future growth markets. Environmental applications of biotechnology are also expected to significantly enhance the sustainability and competitiveness of a number of major industry sectors in Canada. This is based on experiences where biotechnology has already revolutionized existing approaches to increasing process efficiency and pollution prevention, for example:

- **value added processes** which can either detoxify or convert traditional products or waste streams into more valuable new products and by products (e.g. biological systems for absorbing and recycling CO_2; fine chemicals produced from food processing wastes; biological removal of sulfur from heavy oil and coal);
- **chemicals and materials from biomass** (e.g bio-ethanol from pulp and paper wastewater; bio-diesel, bio-plastics) that will reduce reliance on fossil fuels and other non renewable resources as well as reduce their contribution to global warming, and adverse climate change;
- **biocatalysts** (e.g. enzymes and microorganisms) for industrial processes which require less energy and produce less waste and less toxic waste per unit of product manufactured (e.g. biological bleaching of wood pulp for paper making, biological leaching of minerals for metal recovery, microbial enhanced oil recovery, biodegradable degreasing compounds);
- **innovative cleanup processes** for destruction, reduction, or stabilization of long standing and recalcitrant pollutants throughout the Canadian environment; (e.g. novel approaches using microorganisms or plants for cleanup of toxic materials and habitat restoration) and,
- **pollution detection and biological monitoring techniques** which offer greater precision and accuracy at lower cost for improved maintenance of environmental quality (e.g. biosensors, bio-indicator organisms) (OECD 1998)[5]

In addition to these growth markets, other opportunities have been identified:

- the growing interest in Latin America related to biotechnology based solutions to environmental problems and a mechanism (CAMBiotec) for identifying strategic alliances;
- increased coordination and organization of the industry to advocate its position and concerns to government;
- development of Canadian consortia for penetrating export markets and for undertaking generic research;
- cooperation among industry, the research community and government to ensure that Canadian regulatory policies and practices are responsive to changes in understanding of the science and are harmonized with those of our major trading partners.

6) International Competitiveness of the Sector

The above analysis of strengths, weaknesses, opportunities and threats indicates that the Canadian environmental bio-industries have some key technical strengths but must overcome a number of major barriers in order to grow. They will be successful if they can make the case to investors, user industries, the government and the public that biotechnology, as embodied in their products and services, is a powerful tool to change the paradigm that industrial growth always occurs at the expense of the environment. To succeed in international markets [6], they will have to be able to make this case more effectively than their competitors in other countries.

The potential for biotechnology to fulfill the needs of sustainable development has not been lost on governments in a number of Canada's major trading partners (e.g. USA, Germany, Japan, Netherlands – see OECD 1998[7]). In addition, industry associations such as the US Bioindustry Organization (BIO) are reorienting their business plans to include environmental biotechnology as an important focus for future efforts. Consequently, governments in these countries are making significant new investments in R&D relating to environmental applications of biotechnology. In the United States, Germany and the Netherlands for example, at least five major initiatives (each drawing on resources of more than $20 million) have been established with specific focus on the demonstration of environmental applications of biotechnology.

In the US, progress towards commercialization of environmental biotechnology is ahead of that in Canada for three key reasons:

- the majority of environmental biotechnology R&D has been carried out in the USA, with the EPA playing an active role in developing R&D consortia and demonstration projects with industry;
- the enforcement of US environmental law exceeds that of other nations and has driven the growth of markets for environmental cleanup and cleaner industrial processes;
- the public acceptance of environmental biotechnology in the US has been spurred on by considerable success stories realized from the use of the technology at Superfund sites and more recently in major Brownfield initiatives supported by a number of states.

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7) Sector Information Gaps and Research Opportunities

The following areas have been identified by the environmental biotechnology community as important information gaps and corresponding opportunities for further research or data gathering. (The public's information requests on biotechnology have been outlined in section 4c.)

a) Information required by the environmental bio-industries

In order to grow and develop, the environmental bio-industries need information on:

- **markets** which are the most promising for them to penetrate and strategies or mechanisms (e.g. export consortia or international strategic alliances) to increase sales of their products and services in those markets;
- **trends in markets and scientific advances** which will drive improvement of existing technology or lead to the next generation of environmental biotechnologies (and where they should focus their investments in R&D);
- **provincial government and foreign regulations**, their detailed requirements as well as strategies to minimize the costs of fulfilling those requirements; and,
- **codes of practice**, (e.g. the Responsible Care Program for chemicals) which can help provide effective voluntary alternatives to regulation for achieving environmental objectives.

The following opportunity areas were identified with regard to scientific research which would support continued development of the industry:

- microbial ecology and environmental microbiology to improve understanding of natural microbial communities and how their responses to natural and man-made factors can be managed;
- microbial genetics and taxonomy to improve understanding of characteristics of natural organisms and how they can be used to degrade pollutants or contribute to cleaner industrial processes;
- ecotoxicology to improve understanding of environmental bioavailability of contaminants and how to do better risk evaluation to permit more informed choice of which environmental biotechnologies are appropriate to employ under what circumstances;
- biosensor technologies to provide more specific, accurate and lower cost analyses of chemicals and their bioavailability in the environment; and,
- analysis by industry sector of which existing process technologies are the most harmful to the environment and the potential for replacing these processes with cleaner ones based on biotechnology (i.e. a technology roadmap).

b) Information required by the research community

The research community needs information to help focus its research and to help it transfer its knowledge and technologies to industry, for example, better information on:

- Canadian companies which are active in the field of environmental biotechnology and what are their research needs (see section 7a for details);
- human resource training needs of the sector; and,
- opportunities for international collaboration in the areas of science and technology which support development of environmental biotechnology.

c) Information required by government

The federal government needs information to support development of its policies and programs with respect to biotechnology and the environmental bio-industries. Specifically it needs information on:

- the percent penetration of user industries by biotechnology, especially for cleaner processes and products;
- the size and performance (sales, job creation, exports, etc.) of the commercial bio-industries sector;
- the relative expenditures of industry, universities and government in Canada on R&D in key areas of science underpinning environmental biotechnology and how these compare to those of other major trading partners;
- the needs of the sector for demonstration of innovative technologies and for internationally harmonized technology verification protocols; and,
- major developments in the science base or in regulations in other countries which may require a response to maintain Canada's competitive position or to continue Canada's high level of protection for human health and the environment.

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8) Some Key Issues

- Regulation of biotechnology products in Canada including:
  - confidence in the regulatory system to adequately protect human health and the environment;
  - improving dialog with industry and the public on the existing regulatory system and its evolution in future;

- resolving differences in regulatory approach between Canada and major trading partners and the need for greater clarification of which biotechnology products are covered by what regulations particularly for those products not regulated by traditional regulatory departments;

- Addressing public interests, awareness, and concerns relating to the development of biotechnology in Canada;

- Identifying research needs and priorities relating to environmental applications of biotechnology in Canada;

- Improving public and private sector support to the scientific research base which underpins

  - An effective biotechnology regulatory system to safeguard Canadians, and

  - A biotechnology innovation system to create jobs and wealth for Canadians as well as to commercialize products and services which contribute to quality of life;

- Facilitating innovation as well as demonstration and application in Canada of environmental technologies derived through biotechnology;

- Ensuring international market access for environmental products and services derived from biotechnology;

- Clarifying the roles of organizations with an interest in environmental applications of biotechnology and identifying opportunities for the establishment of partnerships; and

- Identifying the information needs of the sector.

Footnotes :

[1] Heller, J.G. 1995. *Background Economic Study of Biotechnology in Canada.*
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[2] KPMG, 1996
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[3] Environment Canada. 1996. *Public awareness and acceptance of environmental biotechnology Draft Study*
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[4] Note that the current focus of the Canadian environmental bio-industry is almost exclusively on naturally occurring organisms for site specific applications such as bioremediation and phytoremediation. In addition, a number of industrial processes utilize genetically engineered organisms in contained facilities to produce products such as enzymes or fine chemicals.
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[5]OECD, 1998. *OECD Working Party on Biotechnology: Biotechnology for clean industrial products and processes.*
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[6] The OECD predicts that the total global market for environmental products and services will grow at an annual rate of 20% to $500 billion by the year 2000.
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[7]OECD, 1998. *OECD Working Party on Biotechnology: Biotechnology for clean industrial products and processes.*
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