‘A NGO AGENDA FOR SUSTAINABLE MICROBIAL PRODUCTION’

Workshop at Genomics Momentum 2004

31 August 2004

Preparation and moderation by:
Piet Schenkelaars, Schenkelaars Biotechnology Consultancy
Huib de Vriend, Foundation Consumer and Biotechnology

Commissioned by:
The Netherlands Genomics Initiative

CONTENT

IS THERE A WAY FORWARD FOR A NGO AGENDA ON SUSTAINABLE MICROBIAL PRODUCTION?

Piet Schenkelaars, Schenkelaars Biotechnology Consultancy
Huib de Vriend, Foundation Consumer & Biotechnology

The initiative to discuss the NGO agenda for sustainable microbial production was a first attempt to explore the opportunities and bottlenecks of a dialogue between environmental and consumer NGOs and technology suppliers, i.e. industry and research institutes, on so-called ‘industrial’ or ‘white’ biotechnology. For several reasons we were interested to contribute to such an initiative.

First of all, we believe that new (bio)technologies should not only serve short-term commercial interests but should also contribute to address societal and environmental problems. Secondly, we sincerely believe that industrial biotechnology has a certain potential to contribute to the development of more sustainable industrial production processes and products. Moreover, in the case of industrial production processes (genetically modified) micro-organisms (GMMs) are generally used under conditions of physical and biological containment, while in many cases the (GM) micro-organisms will probably have great difficulty surviving in the environment after accidental leakage. In our view, the risk debate on the contained use of GMMs therefore essentially differs from the risk debate on field trials and cultivation of GM crops. Since the risks of the contained use of (GM) seem to be better manageable than in the case of environmental releases of GM crops, we believe that a dialogue between NGOs and technology suppliers on the potential risks of industrial biotechnology does not need to be that problematic. We are thus convinced that developments in industrial biotechnology offer opportunities for a constructive dialogue between technology suppliers and other stakeholders, including consumer and environmental NGOs.

The recent communication and lobby activities by industry and research institutes for more co-ordinated government policies at EU and national levels are another reason for our interest. These activities led for example to the establishment of a new European Technology Platform on Sustainable Chemistry in July 2004, a joint initiative by the European chemical industry association Cefic, the European biotechnology industry association EuropaBio and the European Commission Directorate-General Research. While the initiators of this Platform consider industrial biotechnology one of the three key technologies for sustainable chemistry, they also identified several bottlenecks for further development of industrial biotechnology, including the high price of raw materials or feedstock, like sugar, the need for substantial investment and long development times. The Platform further indicated that it would address horizontal issues, such as regulatory safety assessment and the need for effective risk communication. Thereby it was stressed that “*the actual risk form innovative technologies (as opposed to perceived risk) also needs to be effectively communicated to broader society to ensure societal acceptance. Historic failures in this respect have shown that societal acceptance is an effective barrier to innovative technologies. As such this aspect cannot be ignored in any European Platform for Sustainable Chemistry*.”

Also in July 2004 DSM, one of the leading companies in European industrial biotechnology, released a position document with a series of recommendations to the Dutch presidency of the EU in the last six months of 2004. In this position document DSM recommends to allocating research funds for industrial biotechnology within the (next) EU Framework VII, establishing public-private partnerships in research, and implementation of (tax) incentives for start-up companies. DSM further pledges for demonstration projects and communication programs, in order to increase public awareness and (societal) support for industrial biotechnology. A transparent and supportive regulatory framework and the encouragement of competitive prices for sugars within the EU were also recommended.

To us it is as yet not clear what the company means by a ‘transparent and supportive regulatory framework’. Though, recent developments might provide some clues. First of all, most EU Member states so far consider so-called ‘self-cloned’ micro-organisms, i.e. modified by techniques using only DNA from the same species, genetically modified micro-organisms (GMMs) in the meaning of the contained use Directive 90/219/EEC (as amended by Directive 98/81/EC). However, a few Member States exclude the (contained) use of self-cloned GMMs from the Directive. Consequently, there have been discussions between regulators and industry on an EU-wide harmonised exclusion of self-cloned GMMs from the Directive. Such exclusion implies that the EU regulatory framework for industrial biotechnology would no longer require an environmental risk assessment of the contained use of self-cloned GMMs in the EU. Notably, the opinion of 11 December 2003 of the European Food Safety Authority (EFSA) Scientific Panel on GMOs seems to support such an exclusion. At the same time, companies like DSM, Ajinomoto, Danisco and Adisseo, which all develop and use self-cloned, GM micro-organisms for the production of food and feed ingredients, also argue for an exclusion of these products from the GM food and feed European Regulation (EC) No 1829/2003 and the traceability and labelling Regulation 1830 (EC) No 1830/2203.

In our opinion, the proposed exclusion of a wide range of GMMs and products derived thereof from the EU regulatory framework for the food and feed use of genetically modified organisms (GMOs) is typically an issue, which need to be publicly discussed with all interested and concerned parties. Also the proposed increase of governmental spending on (public-private) research programmes and the socio-economic consequences of lowering sugar prices should be subject to public discussions.

At several occasions last year, including the workshop at Genomics Momentum 2004, representatives of industrial biotechnology companies, their associations and (public) research institutions, indicated to be interested in a dialogue with all relevant stakeholders, among which environmental and consumer NGOs. Yet, we learned from the interviews and the workshop that several of these NGOs have serious doubts. Does industry intend to use such a dialogue as a tool to convince other parties? Is such a dialogue an instrument to manage NGOs as a public relations risk? Or is such a dialogue a sincere attempt by industry to be transparent and to take into account societal concerns as expressed by NGOs? And can such a dialogue lead to genuine search for common problem definitions, instead of a one-sided attempt to impose specific technological solutions? Also because of our experience with European and Dutch stakeholder debates on green biotechnology, we believe that current lobby activities by industry, in order to exclude a wide range of (products of) GMMs for food and feed use from the EU GMO legislation, reinforce these doubts at the NGO side.

On the other hand, we are well aware that NGOs have limited staff and financial resources. Most NGOs therefore tend to focus on activities, which aim at influencing rather short-term legislative and policy proposals at national and European level. Also because these organisations have to justify their activities and the results achieved towards their members, their limited resources are often fully adsorbed by these rather short-term activities. Thereby they often have a strong inclination to exclude the potential of innovative (bio)technologies to contribute to more sustainable production and products, while they are also inclined to consider their development risky *per se*. As a consequence, the knowledge-base of many NGOs is usually not well equipped for assessing the potential benefits and risks of new (bio)technologies in a context of future societal and economic developments.

Obviously, this is not a very productive basis for a constructive dialogue between industry, (public) research institutions and NGOs. While the technology supply side seems to be rather eager to have a dialogue, we noted in our report of the workshop that there was hardly any discussion on potential follow-up activities, mainly because of some reluctance at the NGO demand side to engage in a dialogue. Given this state of affairs, the Netherlands Genomics Initiative requested us to reflect on possible ways forward.

As far as we know, the Commission and the European chemical and biotechnology industry association have set up the Technology Platform for sustainable chemistry, including industrial biotechnology, as a way forward. But we are not aware of whether, and, if so, to what extent other interested or concerned parties participate in this Technology Platform. Moreover, we are not aware of public communication programmes set up by individual companies, which might aim at engaging environmental and consumer NGOs and other interested or concerned parties in a stakeholder dialogue on industrial or white biotechnology. Therefore it is difficult for us to assess whether current communication activities by the Commission and the chemical and biotechnology industries associations will contribute to a constructive dialogue between the technology supply side and the NGO demand side. Given these limitations we can only suggest some guidelines for such initiatives:

1. A common basis for dialogue between all parties must be established and potential convergence of specific interests must be identified. For that purpose, specific interests, responsibilities and future (policy) targets of industries, public authorities, research institutions and other interested and concerned parties should be clearly mapped. The report of the workshop and its preparation provides an initial step for the identification of convergent and divergent interests, possibilities and future (policy) targets at the NGO demand side and the technology supply side. A Technology Platform or stakeholder dialogue, which does not recognise the specific

(and potentially diverging) interests of all parties involved, will not lead to a fruitful dialogue;

2. Opportunities should be created to have discussions on further development of industrial biotechnology, which address different policy options concerning safety regulations and consequences for (European) agriculture, industry (sectors), research and public communication in a balanced and holistic way;

3. A dialogue process between parties with converging and diverging interests can be facilitated by (peer-reviewed) societal robust knowledge generated through (scientific) research;

4. National governments and the European Commission, as the guardians of the public interest, should be committed to the outcome of these discussions, i.e. by translating the outcome into concrete policy actions.

While implementation of these guidelines could facilitate a fruitful dialogue between technology suppliers and environmental and consumer NGOs, the level of trust between the parties involved remains decisive for negotiating common problem definitions and (biotechnological and other) solutions.

1. INTRODUCTION

The five-step approach of this initiative

The Netherlands Genomics Initiative (NGI) commissioned Schenkelaars Biotechnology Consultancy (SBC) and the Foundation Consumer & Biotechnology (C&B) to assist in the preparation of the workshop 'a NGO agenda for sustainable microbial production'. This international workshop was organised at the Genomics Momentum 2004 conference in The Hague, the Netherlands, on 31 August 2004.

Since the NGI recognises that genomics strongly depends on a societal license, it wished to encourage and facilitate active participation by environmental and consumer NGOs. For that purpose SBC and C&B proposed to follow a five-step approach, as they believed that this would provide environmental and consumer NGOs a serious and good opportunity to shape a societal agenda for industrial genomics research.

1. In the first step SBC and C&B drafted a preliminary analysis of sustainability issues in industrial production, which are considered relevant by a number of environmental and consumer NGOs from several European countries – the NGO demand side. In addition, they drafted a preliminary analysis of genomics research in the area of sustainable microbial production – the technological supply side. The findings of both preliminary analyses were reported in a background document and served to structure the interviews with the NGO representatives and with representatives of the technological supply side.
2. In the second step SBC and C&B held interviews with representatives of several environmental and consumer groups at the NGO demand side and research institutions and companies at the technology supply side. The objectives of the interviews were 1) to correct flaws and deepen the preliminary analyses; and 2) to solicit views on the ranking of sustainability issues, potential solutions, and criteria.
3. In the third step SBC and C&B analysed the results of the interviews in terms of convergence and divergence of the NGO demand side and the technology supply side, thereby aiming at identifying problem definitions and solution criteria. The findings thereof are reported in this background paper and serve as a basis for a proposal by SBC and C&B for the workshop's agenda.
4. In the fourth step SBC discussed the proposal for the workshop's agenda with the environmental and consumer NGOs and let them make the ultimate decision on the final agenda of the workshop. This background paper and the agenda will then be made publicly accessible at the website of Genomics 2004.
5. The fifth step consisted of the workshop, which was moderated by SBC and C&B. Basically, the focus of the workshop was on determination of NGO priorities and sustainability criteria for sustainable microbial production and genomics research in this area. Participants were also invited to suggest follow-up initiatives. Finally SBC and C&B reported the workshop's results in a concise document.

In the following chapters of this report SBC and C&B report their findings from the workshop on 31 August 2004, the interviews, and the preliminary analysis. Notably, the speakers at the workshop were asked to answer a number of questions and issues that had resulted from the interviews. These questions and issues are listed in the third chapter of this report.

2. REPORT OF WORKSHOP 'A NGO AGENDA FOR SUSTAINABLE MICROBIAL PRODUCTION'

Workshop at Genomics Momentum, 31 August 2004

Preparation and moderation by:
Piet Schenkelaars, Schenkelaars Biotechnology Consultancy
Huib de Vriend, Foundation Consumer and Biotechnology

2.1 Morning session: Introductions by the participants

Introduction

As start the moderators gave a short introduction on the five-steps, which had been taken to prepare the workshop, including the agenda. Thereby it was pointed out that the speakers had been requested to react to a series of questions, which were listed in the working document for the workshop. This working document also provided the main findings of interviews, which the moderators had held with representatives of NGOs in the Netherlands, the UK, Denmark and 'Brussels' - the NGO demand side - and several companies and research institutions – the technology supply side. Subsequently, representatives of both the NGO demand side and the technology supply side presented their views on the need for a dialogue on (genomics research for) microbial production ('industrial biotechnology') and the issues to be discussed.

Views of the NGO demand side

Sandra Schalk from Greenpeace-Netherlands (an environmental organisation) indicated that the organisation is in principle open for a dialogue. However, not only possible benefits should be on the agenda, potential risks should also be identified before leaping. There is therefore a need to increase scientific knowledge of epigenetics and (microbial) ecology, as well as for cradle-to-grave analyses of industrial biotechnological production processes and products. It was further argued that industry should set up systems for monitoring (accidental) releases of genetically modified micro-organisms (GMMs) from contained use facilities.

According to Camilla Udsen from the Danish Consumer Council (a consumer organisation), dialogues between NGOs and technology suppliers are often rather difficult because both sides do not speak the same language. But this does not mean that NGOs do not have any understanding of a technology. Moreover, since NGOs do not have the responsibility for decision-making on research and development, industry should take the initiative for a dialogue. For such a dialogue on microbial production, as well as with a view to the precautionary principle, full transparency is needed about the potential risks of accidental releases of GMMs, the management of waste from fermentors, and monitoring. Also the availability or development of low-risk alternative technologies should be included in the weighing of the potential benefits and risks of a gene-technological production process, whereby a distinction should be made between potential benefits for society and for the individual consumer. It was further argued that large numbers of consumers find health and environmental impacts more important than economic consequences, while appropriate labelling is needed with a view to freedom of consumer choice.

Becky Price from Genewatch UK (a gene-technology watch organisation) started by referring to ‘ Leaking from the lab’; a report issued by the organisation in 1999. In this report an overview was presented of flaws of governmental oversight and a series of (accidental) releases of GMMs from contained use research facilities in the UK. While the public registers were found merely a work of fiction at that time, industry ignored the exercise. Yet, the organisation has no blanket dislike of the contained use of GMMs and would like to encourage dialogue on decision-making in the area of risk assessment and risk management. It was further argued that current scientific understanding of microbial ecology is rather limited. Moreover, statements by some technology suppliers (in the working document) about ‘zero-emission’ were questioned, as there is no systematic monitoring of (accidental) releases of GMMs and their potential survival outside fermentors.

Views of the technology supply side

Peter Nossin from DSM (Corporate Technology) indicated that from the company’s perspective there is a need for a dialogue with the NGO demand side. On the one hand, because industrial biotechnology could provide sustainable alternatives for several (but not all) chemical synthesis routes. On the other hand, because the company needs a societal license to (further) develop industrial biotechnological alternatives. Thereby it was stressed that Research & Development programmes are in fact continuous learning processes, taking five to ten years, whose outcomes cannot be predicted. There is therefore also a need to involve the NGO demand side in developing methods for measuring sustainability of industrial biotechnological value-chains, in particular for determining the key performance parameters. From this perspective the six case studies commissioned by industry to the German Öko-Institut are considered a good start, also because many (German) NGOs have trust and confidence in this ‘alternative’ research organisation. In addition, there is a need to further integrate industrial biotechnology policy and multi-stakeholder initiatives at the national and European level. A way forward could be the ‘Sustainable Chemistry Platform’, which has recently been established by the European Commission. The NGOs were also invited for a visit and a discussion on the risk assessment and risk management of the contained use of GMMs. Finally it was argued that sustainability is now mainly a discriminator, while the company believes it will be a qualifier in the future.

Ad van Dommelen from the Centre of Environmental Sciences (Dutch acronym: CML) at the University of Leiden, confirmed there is a need for a dialogue and involvement of the NGO demand side in developing methods for measuring sustainability of industrial biotechnological production processes. Thereby it was explained that such involvement of NGOs also is one of the aims of a research project initiated by CML and the Kluyver Centre for Genomics Research. In addition, a series of prerequisites were suggested for a fruitful dialogue between the NGO demand side and the technology supply side. First, such a dialogue needs to be as advanced and sophisticated as the technical research. Second, mechanisms are needed for transparency, mutual trust, learning, bridging divides between stakeholder groups and disciplines from natural and social sciences and assembling of relevant knowledge. It was stressed that dialogue between technology suppliers and NGOs should be considered rather a means towards an end than an objective. Finally, the NGOs were invited to be a partner in the research project carried out by the CML.

2.2 Afternoon session: Discussion on three themes

From the presentations of the morning session the moderators identified three themes, which were further discussed by the speakers and the other attendants at the afternoon session.

Risks

The NGOs had questioned the adequacy of current risk assessment and risk management of contained use of GMMs, and had pointed at limited scientific understanding of microbial ecology and side-effects of genetic engineering and the need for monitoring (accidental) releases. The technology suppliers were therefore asked whether they could show that they know the risks and know how to manage the risks. While some participants argued that risk is a general issue and uncertainty belongs to any activity, others underlined that regulations are in place for the contained use of GMMs. The regulations, it was said, require a risk assessment, including data on survival rates of GMMs compared to corresponding wild-type micro-organisms, while there is also sufficient evidence available, showing that there is no reasons for concern about current risk management practices. Another participant added that GMMs for industrial production purposes are placed in the lowest risk category and there is no reason for concern, as microbial production strains are adapted to fermentor conditions and too 'crippled' for survival in the environment. One technology supplier showed preference for a more pro-active attitude, which implies to continuously address the question 'What could happen, if leakage occurs?', as well as to show the outside world what the company is doing in risk assessment and risk management.
The NGOs were not satisfied by these responses, partly because they considered responses, such as 'everything is risky in life' and 'don't worry; regulations are in place', a standard reflex by industry. One of the NGOs added that official risk assessments hardly address the potential risks of an escape of GMMs into the environment. For a NGO it appears difficult to acquire knowledge about the survivability rates of GMMs outside the fermentor and/or to gain access to studies on such survivability rates. Another felt that proper identification of potential risks and other downsides, as well as the level of 'acceptable' risks were considered essential issues for a dialogue with the technology supply side. It was further argued that after identification of what might happen, in a positive and negative sense, the public should be involved in deciding what should not happen.

Technology-oriented approach versus problem-oriented approach

The moderators suggested that the NGO demand side has a strong preference for a problem-oriented approach, whereas the technology supply side follows a technology-oriented approach. There was hardly any disagreement with this analysis. A few technology suppliers subsequently started arguing hat 'economics' decide in the end whether and when new technologies will be deployed. Potential environmental and/or social benefits hardly play a role. One technology supplier pointed out that not only 'economics' will be decisive. In the US for instance, an important aim is to decrease the country's dependency on imports of oil, while also agricultural organisations supported further development of industrial biotechnology.

The NGOs commented that the dominance of short-term economic interests in developing and shaping new technologies not always leads to the best solutions from a social and environmental point of view. Moreover, as one of the NGOs argued, society must look at different routes to find solutions but has hardly any mechanism in place for rewarding organisations and individuals looking for alternative options.
One of the attendants recognised that technology suppliers are inclined to have a ‘technological fix’, which as such is understandable and justifiable, but precisely for this reason there is a need to involve various stakeholders and disciplines from natural and social sciences, who might suggest alternatives options. Scientists therefore needed to learn how to communicate.

Need and urgency for a dialogue

There was agreement that trust between parties is an essential prerequisite to start a dialogue. While the technology supply side more or less unanimously felt a need to engage in a dialogue process, it (only) expected openness, fairness and trust from the NGO demand side. By contrast, the NGOs showed some suspicion about the seriousness of industry and its commitment to use the outcome of a dialogue to induce change of its practices. Moreover, one NGO said it sometimes felt perceived by industry as a communication risk to be managed. Therefore, the main prerequisite for a dialogue is that it is not a public relations exercise. Another NGO argued that the problem-oriented approach preferred by NGOs could lead to alternative solutions, which needed to be included in the sustainability measurement but might not be of (commercial) interest to the industrial biotechnology supply side.

Follow-up activities?

Mainly because of some reluctance at the NGO demand side to engage in a dialogue, there was hardly any discussion on potential follow-up activities. According to the moderators, this workshop should be considered an initial and small step in the exploration of opportunities and bottlenecks for a dialogue between the NGO demand side and the technology supply side on (genomics research for) industrial biotechnology and the potential to contribute to a sustainable microbial production.

3. QUESTIONS AND ISSUES TO BE DISCUSSED

3.1 The urgency and need from a NGO perspective for a dialogue on sustainable microbial production between the NGO demand side and technology supply side

Is there, from a NGO perspective, a need for a dialogue between the NGO demand side and technology supply side on sustainable microbial production? If so, how urgent do the NGOs view such a dialogue? And which role, if any, do the NGOs wish to play in a (societal) dialogue on sustainable microbial production?

Is there, from a technology supply side perspective, a need for a dialogue between the NGO demand side and technology supply side on sustainable microbial production? If so, how urgent do the technology suppliers view such a dialogue? And which role, if any, do the technology suppliers wish to play in a (societal) dialogue on sustainable microbial production?

Which are, both from the NGO demand side and the technology supply side perspective, essential prerequisites for a dialogue? What do NGOs expect from technology suppliers and what do technology suppliers expect from NGOs?

3.2 The need and urgency from a NGO perspective for a clarification of the problem solving capacity of industrial biotechnology and the risk assessment and risk management of the (contained) use of (GM) micro-organisms and the production, use and disposal of new (nano-bio) materials and particles

Is there, from a NGO perspective, a need for a clarification of the problem solving capacity of microbial production for industrial purposes? If so, how urgent do the NGOs view such a clarification, and which elements should be included? Which problems could serve for a case study? And which role, if any, do the NGOs wish to play therein?

Is there, from a NGO perspective, a need for the development and establishment of general conditions, principles, prerequisites, and sustainability indicators for the use of (GM) micro-organisms for industrial production purposes? What is necessary for the development and establishment of such conditions, principles, prerequisites, and sustainability indicators?

Is there, from a NGO perspective, a need for a clarification of the risk assessment and risk management of the (contained) use of (GM) micro-organisms for industrial production? If so, how urgent do the NGOs view such a clarification?

If any, which areas of (genomics) research for sustainable microbial production should have priority?

Is there, both from a NGO and a technology supplier perspective, a need for a societal debate on nano-biotechnology and a scientific assessment of potentially novel risks and benefits to the environment and human health of the production, use and disposal of new nano-bio particles? If so, which role, if any, do the NGOs wish to play therein?

3.3 The need and urgency, from a technology supply side perspective, to involve the NGO demand side in the further development of methods for measuring the sustainability of microbial production for industrial purposes and the risk assessment and risk management of the (contained) use of (GM) micro-organisms

Is there, from a NGO demand side and/or technology supply side perspective, a need for an overview of (policy) initiatives, technical and societal research programmes and (technology) platforms at EU-level and national level in areas, like 'white biotechnology', 'sustainable industrial chemistry', 'bio-fuels', 'renewable materials', 'industrial genomics', etc.? Would it be useful and feasible to further integrate these European and national initiatives?

Is there, from a technology supply side perspective, a need to involve the NGO demand side in the further development of methods for measuring the sustainability of microbial production for industrial purposes? If so, how urgent do technology suppliers view the involvement of NGOs? Which role, if any, do technology suppliers wish to play in the involvement of NGOs? Which industrial microbial processes or products could serve as case studies?

Is there, from a technology supply side perspective, a need to involve the NGO demand side in (the further development of) the risk assessment and the risk management[1] of the (contained) use of GM-micro-organisms?

[1] includes the identification, measurement, control, and minimization of risks to a level commensurate with the value of the assets protected, i.e. the definition of 'acceptable risk'.

4. MAIN FINDINGS FROM THE INTERVIEWS

4.1 This initiative

All interviewees at the NGO demand side stressed their organisations had not (yet) developed a formal position on the contained use of (genetically modified, GM) micro-organisms for industrial production purposes. Also because, as one NGO interviewee phrased, 'it is not clear what is in it for us'. One of main problems for most NGOs is the availability of resources to become engaged in the area of industrial biotechnology (IB) and genomics research. Several interviewees indicated that the staff of their organisations, in particularly at the EU-level, is mostly focussed on and adsorbed by short-term legislative proposals. Issues involved in IB and genomics research are considered more of longer term. One interviewee further pointed out that this problem could not be solved on an *ad hoc* basis. Even in case of a longer-term project, whereby one person would be responsible to several NGOs and who would be funded from other sources, NGO staff would still need to spend time to discuss and provide feedback to this person.

While most interviewees at the NGO demand side underlined that issues involved in (genomics research for) IB are not high on their agendas, they also indicated that they lacked knowledge for the development of a coherent view on the use of (GM) micro-organisms for industrial production. They were therefore not yet prepared to publicly debate the use of GMMs in a qualified way. Though most of them did not seem to have fundamental objections, as long as GMMs are kept in strict containment. But they are critical about developments controlled by large industrial corporations. Most of the interviewees stressed that their organisations were not willing to engage in a dialogue on technical details. One interviewee therefore believed that at this stage only a dialogue on principles might be possible, while another interviewee from an organisation, specifically focusing on the risks and societal impacts of genetic technologies, confirmed this view by indicating that this organisation is not specialised in more general environmental issues. This seemingly paradox probably emerges due to IB's capacity to crosscut several industrial sectors and NGO campaigning areas.

Most interviewees at the technology supply side indicated to attach (high) importance to well-prepared and well-informed discussions on the societal impacts of IB. In general most of them endorsed this initiative. Yet, one technology supplier expressed serious concerns about this particular initiative, as there are several European and Dutch (policy) initiatives, technical and societal research programmes and (technology) platforms in areas like 'white biotechnology', 'sustainable industrial chemistry', 'bio-fuels', 'renewable materials', and 'genomics & society', which are being run too much in parallel. From a company perspective, it would be better to effectively co-ordinate all these parallel initiatives at the European and national level.

In several instances interviewees at the technology supply side suggested that if 'we' wait too long and neglect or reject innovation, investments in white biotechnology will move from Europe to the US and Asia, which will in the end results in Europe as buyer of white biotechnology (products). From their perspective, the European Commission, national governments and NGOs do not seem to share this sense of urgency.

4.2 Issues at the NGO demand side

Three thematic areas: hazardous substances, climate change/energy, and waste

The interviewees at the NGO demand side confirmed that their organisations are involved in campaigns in the three areas identified by the background document: 1) hazardous substances; 2) climate change, and 3) (toxic) waste. The priorities set in each of these areas widely differ among the organisations. While the environmental and consumer NGOs regularly co-operate and have a certain division of labour in many cases, they can nonetheless take different positions on issues because of a different focus. The environmental NGOs focus more on production processes and related problems, like for instance greenhouse gas emissions in relation to climate change, whereas the consumer NGOs tend to focus more on products, which makes the issue of hazardous substances particularly relevant for them.

For most NGO interviewees the problem solving capacity of industrial biotechnology (IB) in these three areas was far from clear and not obvious at all, and was in some cases even considered as overstated. One interviewee believed that current (industrial) genomics research is rather driven by the desire to innovate and to establish a knowledge-economy than by sustainability considerations. If sustainable development would be really the objective instead of economic innovation, the research objectives would be quite different, argued a couple of interviewees. From their perspective, the funds spent on research at the genomic level should rather be used for research at the ecosystem level. Knowledge of the functioning of ecosystems is considered far more relevant for sustainable development, environmental protection and nature conservation. Only for a few exceptional cases in the area of nature conservation, according to one interviewee, it might be relevant to increase understanding at the genomic level. So, if research money must be spent at the genomic level, the organisation would spend it on the population genetics of some endangered species, eventually for their captive breeding, taxonomy of (rare and endangered) (sub)species, links between wildlife issues and infectious diseases, like Ebola and SARS, and the nexus animal health and natural resource management.

Although the NGO interviewees did not have fundamental reasons for opposition against the (contained) use of (GM) micro-organisms for industrial production, several interviewees were concerned that IB would be just another technological fix, which only perpetuates existing problems. Most of them therefore argued that one of the issues on a NGO agenda should be the problem solving capacity of IB, which should be analysed by using some benchmark for sustainability. Life Cycle Analysis (LCA) methods were generally considered a rather adequate tool, as long as the method is scientifically transparent, documents well the assumptions it makes and the boundaries it sets, is calculated on the basis of energy balance instead of economic value, and comparisons to alternative solutions are made. One interviewee warned for the rather limited robustness of the outcome of very global LCAs because of the roughness of estimations of data and low precision of boundaries. Though some interviewees also pointed at several methodological problems of LCA-approaches and the choice of sustainability indicators. One interviewee also strongly criticised the (potential) application of LCA methods as a policy decision-making tool (but not as a decision support tool), as policy can better be steered by hierarchies of principles.

Two interviewees mentioned the importance of local realities that should be taken into account (systems may not work to the same extent in different places). One interviewee clearly expressed preference for local production systems, which are simple to manage and easily adaptable to people's local situation. Related to current trends in production distribution (and transport), another interviewee emphasized the relevance of the proximity principle. A few other NGOs also stressed that consumers' needs and the sustainability impact of changes in consumer behaviour that result from the introduction of new products should also be considered.

A few NGO interviewees also argued that the scope of industrial or white biotechnology goes far beyond industrial production with the aid of (GM) micro-organisms. Also the use of GM crops for the production of (building blocks for) pharmaceuticals, (fine) chemicals and bio-polymers is considered white biotechnology. In that case they expressed serious concern that the food supply and wild relatives would be contaminated by transgenes from such GM crops. Therefore, they considered cultivation of such GM crops in the open air for the production of chemicals and pharmaceuticals irresponsible from an environmental and human health perspective.

For the area of '(toxic) waste' most NGO interviewees attached high importance to a certain hierarchy of principles, which was specified by one of them as: 1) prevention; 2) re-use; 3) recycling (material recovery); 4) disposal with energy recovery incineration & landfill, and; 5) disposal with no energy recovery incineration & landfill. From such a perspective, another interviewee therefore argued that a combination of intelligent product design, for instance by limiting the number of different compounds, and the use of recyclable materials and integration of recycling in cascading production processes would contribute more to the sustainability of products than 'bio-degradability'. Another interviewee expressed concerns about the promotion by some producers of biodegradable bio-plastics as an 'anti-litter' solution, because it would continue a wasteful social practice, while the social conscious should be "You don't throw away, you conserve".

For the area of 'hazardous substances' most NGO interviewees indicated to support to EU REACH policy to a large extent, although there is still disagreement over the assessment criteria and the categories of hazardous substances, which should be banned. Moreover, they mostly confirmed that five categories of hazardous substances identified by preliminary analysis of the NGO demand side in the background document, e.g. phtalates and PVC, alkylphenols, halogenated flame retardants and organotin compounds, should be substituted. Some added that linear alkylbenzene sulphonates (LAS), EDTA and 'hazardous' fragrances should no longer be used in detergents, while two interviewees argued that EU legislation on detergents should not only cover surfactants but also all other ingredients, like builders, enzymes, enzyme stabilisers, solvents, dispersants, dye transfer inhibitors, preservatives and perfumes. Given the lack of governmental policies, according to one NGO interviewee, substitution of the five categories of hazardous substances by already existing alternatives heavily relies on whether companies are confronted with societal pressure, while investments in existing production processes constitutes another major bottleneck.

For the area of 'climate change/energy' most NGO interviewees pointed out that energy use could also be minimised by energy saving measures and eco-efficient technologies, as well as by reducing waste and mobility. With a view to fossil fuels they generally advocate their replacement by renewable energy technologies, powered by the sun, streams, wind, tides, biogas and clean biomass. From their perspective, the use of annual crops as biomass for the production of bio-fuels does not seem to be an effective solution for the reduction of emissions of carbon dioxide and other greenhouse gases. ‘Sugar-bio-ethanol’ produced from wheat or maize, as well as ‘fatty acid methyl esters’ (FAME) produced from oilseed rape were mainly viewed as a short-sighted solution, resulting from a political desire to solve economic problems of current high-input agriculture in the EU. Several NGOs criticised these applications for their impact on land use and its potential consequences for nature conservation. By contrast, many held (slightly) more favourable views on the use of agricultural waste and multi-annual (woody) crops for direct energy production (heat) or ‘cellulose-bio-ethanol’. Some indicated that implications for land use, biodiversity and pressures on the conversion of tropical forests should be important parameters in the sustainability assessment of biomass-based energy. One interviewee further added to be more interested in hydrogen as an energy source, as this would contribute to achieve low levels of carbon transport.

Risk management of GMMs and nano-bio materials and particles

None of the interviewees at the NGO demand side had principal objections against the use of GMMs, as long as they are kept in strict containment. The reliability of the inactivation methods for GMM-sludge/waste from industrial production facilities was therefore one of the main concerns shared by several of the NGO interviewees. Some further pointed out that knowledge of microbial ecology and horizontal gene transfer, especially the take-up of naked DNA, is still very limited, whereby, contrary to the situation for chemicals, there is no validated set of empirical tests for predicting the presence or absence of risks. It was therefore also argued that (accidental) releases of GMMs from contained industrial production facilities should be adequately monitored.

Some NGO interviewees associated industrial microbial production with new developments in nano-biotechnology[2]. They believed that a careful scientific assessment of potentially novel environmental and human health risks of the production, use and disposal of new nano-bio particles and materials is urgently needed, in particular with a view to potentially new biological properties and their biological persistency. One of the interviewees also pointed at the need to enhance societal debate in relation to these issues.

4.3 Issues at the technology supply side

Societal dialogue

Most interviewees at the technology supply side endorsed the five-step approach. According to one interviewee, industry had in the mean time learned that it is better to have discussions with NGOs on the societal prerequisites before starting its operations than afterwards. Another interviewee hoped that it would lead to a consensus about the problems, which need to be tackled, and the conditions for a societal successful development of industrial biotechnology (IB). One technology supplier showed strong reservations about the flexibility of the approach with a view to a proper identification of

[2] For instance: The assembly of 3-dimensional architectures of bio-engineered nanocrystals that provides potentially new materials for electronics and sensing applications.

the issues, which are relevant for a dialogue between the NGO demand side and technology supply side. For example, issues related to GM crops for the production of chemicals and pharmaceuticals and silicon-biotechnology should not be put on the agenda of the workshop. It was further argued that the pharmaceutical industry should also have been approached, as it also benefits from IB in replacing chemical synthesis routes by biotechnological routes using GMMs for the production of complex molecules, thereby suggesting to focus the workshop on concrete examples and available case studies.

Several technology suppliers somehow argued that if one believes IB could contribute to resolve problems of economic innovation and environmental issues associated with petrochemicals, one should realise that the introduction of IB requires a major societal transition. Yet, the issue was not whether such a transition would take place. The issue at stake was how to manage and control its pace, as different parties have different short-term interests and priorities. Some also pointed out that genomics research and IB applications are still in their infancy, while a few criticised the false impression that many problems could already be tackled by IB today. Others stressed that IB is an alternative tool but it will never be able to make all existing chemical production processes fully obsolete, also because existing chemical production can be (made) sufficiently sustainable. According to one of the technology suppliers, innovation usually consists of a long and complex route with an uncertain outcome, also because non-technological factors might hinder commercialisation of research findings. Another interviewee pointed out that interaction and exchange between the NGO demand side and the technology supply side are extremely complicated processes, and believed that current spokespersons for IB might be too enthusiastic, as this could trigger scepticism and suspicion of NGOs and the public.

Measuring sustainability

While almost every technology supplier believed that risk-benefit analyses of new technologies and comparisons with traditional processes are required, they also recognised that there is a need for scientifically validated techniques for measuring the overall sustainability of IB processes. Several technology suppliers are therefore co-operating in research initiatives for a further development of Life Cycle Analysis (LCA) approaches. In addition, many argued that potential impacts on the environment, land use, employment, occupational safety, competitiveness of European industry and agriculture and the long-term effects of a decreasing dependency on fossil fuels should be included in the comparisons of IB production processes and traditional (petro-chemical) productions processes. Yet, one of the interviewees expressed serious concerns about the position of scientific knowledge on several sides of societal debates on science and technology, including IB. Although societal debate and decision-making should not rely on technical science as the sole source of information, science is an indispensable tool to clarify what we know and what we do not know. According to another interviewee, findings from LCA studies could be used in scenario planning by the government or industry, but so far there were only a few consistent LCA studies available with a sufficiently transparent database. While companies might in principle be willing to share detailed information about their production processes with government officials, researchers and NGOs, they generally do not want to share such information with their competitors. Moreover, one interviewee indicated to consider LCA methods rather expensive and time-consuming, thereby also pointing at the new concept of 'bio-indicators' as an alternative to LCA methods. Within the OECD task force on IB the US delegation in particular is now working on this concept. Basically not every single product would then need to be specifically measured. Instead, key areas would be identified for measuring impacts of the production process of the product, such as carbon dioxide emission, employment of (certain) industrial sectors, land use, etc. Notably, One of the interviewees argued that it would probably be more convincing for consumers if there were some kind of independent assessment and/or (legally) binding guidelines, which foresee how sustainability should be measured, instead of believing what a company tells.

Finally, there was a divergence of views among the technology suppliers on whether it would be necessary and desirable to increase the productivity of annual (food) crops and multi-annual (woody) crops by using genetic modification techniques.

Bio-based sustainable chemistry, renewable materials and bio-fuels

Several technology suppliers indicated that the main rationale behind (joint) public and private industry programmes for (genomics research for) further development of IB was not ‘sustainability’ as such. Main reason for (government) funding is the importance for the (Dutch) (chemical) industry to remain economically competitive, whereby a decrease of its environmental impacts is a precondition, as one interviewee phrased. Notably, many of these research & development activities at European and national level do not take place under the heading of ‘industrial biotechnology’ but under headings, like ‘bio-based sustainable chemistry’, ‘biomass-based energy’, and ‘renewable materials’, etc.

Many technology suppliers commented that their activities were not specifically focused on the three NGO thematic areas, ‘hazardous substances’, ‘climate change’ and ‘waste’, On the other hand, they generally believed that (genomics research for) IB could contribute to solve several of problems in each of these thematic areas. For replacing fossil fuels by alternatives most interviewees mentioned ‘sugar-bio-ethanol’ from wheat or corn and ‘bio-diesel’ from oilseed rape, ‘cellulose-bio-ethanol’ from agricultural ‘waste’ and multi-annual (woody) crops, and bio-hydrogen. In addition, they mentioned a wide range of opportunities for microbial production as an alternative to chemical synthesis of materials, like polyesters (like poly lactic acid, PLA), polyamides, polyethene, a microbial protein as alternative to organotin compounds, and other polypeptides with novel functionalities. However, for several reasons hardly one of these microbial routes seems as yet to be able to compete with (petro) chemically based production processes. In many cases the research is still at its infancy and major technological breakthroughs are needed. In addition, current prices for sugar (and maize starch) are considered too high due to current EU agricultural policies and because microbial production routes have the potential of disruption of existing (infrastructures and investments in) chemical production routes.

With a view to the NGO thematic areas of ‘hazardous substances’ and ‘waste’ and the technology supply side for ‘renewable materials’ and ‘bio-based sustainable chemistry’ some further argued that the starting point for the use of new materials in products should be their functionality. The answer to this question defines the choice between reusable, recyclable and biodegradable.

With a view to the NGO thematic area of ‘climate change/energy’, most technology suppliers confirmed that the effectiveness of ‘sugar-bio-ethanol’ from wheat or corn or bio-diesel from oilseed rape for decreasing emissions of carbon dioxide and other greenhouse gases is rather modest. Some also estimated that large-scale application of bio-fuels from annual crops would have enormous implications for land use in the EU. A few also pointed out that ‘sugar-bio-ethanol’ and fatty acid methyl esters are so far the main bio-fuels available on the market, while at the same time these bio-fuels are commercially worthwhile only because of tax incentives. Several interviewees therefore considered these bio-fuels a first step towards more efficient microbial routes for the production of ‘cellulose-bio-ethanol’ from agricultural waste (maize stalks, straw, etc.), which does at present have hardly any economic value, and multi-annual (woody) crops. One of the interviewees argued that incineration of ‘residual’ biomass mainly results in their loss. Similar to present re-use practices in the paper industry, it would be better to first convert residual biomass into cascade-usage of raw materials in recyclable products to the extent possible, before nothing else can be done than burning. Since cellulosic biomass essentially consists of C5-sugars and C6-sugars and yeast can only grow on C6-sugars, as many interviewees pointed out, genetic modification is inevitable, so as to enable yeast to grow on C5-sugars. Many interviewees believed that major technological breakthroughs are right now taking place, in particular for the utilisation of ‘agricultural waste’ as feedstock for IB-based production processes. Although companies generally do not view tax incentives as a solid basis for long-term planning, one interviewee suggested to include ‘cellulosic-bio-ethanol’ from ‘agriculture waste’ into the EU tax regulations, which are now only applicable to ‘bio-ethanol’ from wheat or corn and ‘bio-diesel’ from oilseed rape. In addition, with a view to a reduction of carbon dioxide emission, it would be better if such tax regulations would discriminate between ‘cellulose based bio-ethanol’ and ‘sugar based bio-ethanol’.

Safety of the contained use of GMMs and zero-emission

While genomics research yields understanding of industrial production strains of micro-organisms, technology suppliers generally confirmed that many applications of IB require genetic adaptation of micro-organisms by using genetic modification techniques. There is a strong preference for the use of so-called Generally Recognised As Safe (GRAS) micro-organisms, which are placed in the safest (or lowest risk) category of contained use of GMMs.

In many cases EU regulations not only foresee physical and/or biological containment but can also require inactivation. And if regulatory authorities do not require inactivation, most companies do inactivate. Not for safety reasons, but because ‘zero-emission’ of GMMs into the environment is also a way to protect intellectual property rights, as one interviewee phrased. Accidental leakage of GMMs from industrial production facilities does occur once in a while, but such incidents do not lead to safety problems, incidentally only to a ‘smell’ issue.

Several interviewees further indicated that inactivated sludge of the fermentors can be incinerated for direct energy production, but it can also be used as compost, which would be more sustainable, as this contributes to prevent soil depletion by crop cultivation. One interviewee stressed that this recycling of bio-mass is not a deliberate release of GMOs into the environment, as there are no viable GMMs present in the compost from the inactivated sludge.

5. LIST OF INTERVIEWEES

Lucas Reijnders, Netherlands Society for Nature and Environment

Martin Rocholl and Geert Ritsema, Friends of the Earth Europe

Melissa Shin, European Environmental Bureau

Doug Parr, Greenpeace (United Kingdom)

Sandra Schalk, Greenpeace (Netherlands)

Camilla Udsen, Danish Consumer Council

Becky Price, Genewatch (United Kingdom)

Melanie Peters, Consumentenbond (Netherlands)

Miriam van Gool, World Wildlife Fund (Netherlands)

Minke Noordermeer, Shell Global Solutions

Luuk van der Wielen, Bio-Based Industrial Chemistry (Kluyver Centre)

Ad van Dommelen, Centre for Environmental Sciences, University of Leiden

Huub Scheres, Ana-Maria Bravo, Frances Stalder, Genencor International

Peter Nossin, DSM Corporate Technology

Gerrit Eggink, Agrotechnology and Food Innovations Institute

Douwe van den Berg, Biomass Technology Group

6. PRELIMINARY ANALYSIS

In a wide range of industrial sectors, like pharmaceuticals, fine chemicals, bulk chemicals, food and feed, textiles, pulp and paper, minerals and energy, there is an increasing tendency to develop innovative production processes, which aim at contributing at the so-called Triple P bottom-line of sustainability – People, Planet and Profit. In nearly all these industrial sectors stakeholders are now engaged in dialogues as well as controversies over what Triple P sustainability means in practice. Stakeholders in these debates typically include the commercial operators in a certain production and distribution chain as well as consumer and environmental groups and, occasionally, other civil society organisations. Also governments and public research institutes are seeking ways to contribute to sustainable development, for example by developing regulatory and fiscal policies, producing scientific knowledge and supporting technological innovations. In this context several industries, governments and research institutions have advocated the further development and application of (white) biotechnology and industrial genomics to microbial processes as one of the means for sustainable production.[3]

In 2001 the Netherlands Genomics Initiative (NGI) started an extensive genomics research programme and on 30 August – 1 September 2004 the NGI organises the fourth Genomics Momentum congress. Since the NGI recognises that genomics research strongly depends on a societal license, it has agreed with the preparation of a NGO workshop on sustainability and microbial production. This workshop will offer environmental and consumer NGOs from several European countries the opportunity to explore and discuss the potential and priorities of white biotechnology and industrial genomics for contributing to solve issues, for which the NGOs are campaigning.

While in general environmental and consumer NGOs have been campaigning for sustainable development in various areas of food and non-food production and consumption over many years, their campaigns in non-food areas now focus on the presence of hazardous chemicals in daily products, climate change and waste management. This backgrounder provides a preliminary analysis of the NGO or societal demand-side, as well as a preliminary analysis of the technological supply-side (in the Netherlands). Information and data for these preliminary analyses have been obtained by visiting the websites of the organisations listed below.

On the basis of the outcome of these preliminary analyses a series of interviews will be held with representatives of several environmental and consumers organisations from the Netherlands and abroad, as well as with representatives of research institutions and (white biotechnology) companies. The interviews with these representatives will be

[3] In this backgrounder the term 'white biotechnology' is used to describe the application of biotechnology to industrial production processes, while the term 'industrial genomics' is used to describe the scientific research, which could lead to improvement of industrial microbial strains and (white) biotechnological production process conditions. In an interview published by the NGI newsletter (Vol. 2 – No. 4) Mr Sijbesma, member of the DSM Board of Directors and the Supervisory Board of the NGI and chair of the European biotechnology interest organisation EuropaBio, did not differentiate between both terms but referred to 'genomics technologies'.

structured in accordance with the preliminary analyses of the NGO demand side and the technological supply side.

Greenpeace (NL, UK)	Kluyver Laboratory of the Technical University Delft (NL)
Friends of the Earth (FoE) Europe	DSM
European Environmental Bureau (EEB)	Genencor
Netherlands Society for Nature and Environment (SNM) (NL) (member of EEB)	Cargill Dow
GeneWatch (UK)	Shell
Bureau Européen des Unions des Consommateurs (BEUC)	AFI – Biobased Products
Consumentenbond (CB) (NL)	Dutch Polymer Institute
Goede Waar & Co (GW) (NL)	BTG Biomass Technology Group BV
Verbraucherzentrale Bundesverband (VB) (G)	Centre for Genomics and Society (NL)
	Centre for BioSystems Genomics (NL)

6.1 Issues at the NGO demand side

Hazardous chemicals

In November 1998 the European Commission reached the conclusion that present regulatory systems for chemicals showed serious flaws. An integrated and coherent approach to a new EU Chemicals Policy was therefore needed, which reflects the precautionary principle and the principle of sustainability. Consequently, in February 2001 the European Commission adopted a White Paper, introducing the Registration Evaluation and Authorisation of Chemicals (REACH). In this context the EEB, FoE, World Wildlife Fund (WWF), BEUC and many other environmental and consumer organisations developed a series of key demands:

- A full right to know, including which chemicals are present in products.
- A deadline by which all chemicals on the market must have their safety independently assessed.
- A commitment to stop all environmental releases of hazardous substances by 2020.
- A phase-out of persistent or bio-accumulative chemicals.
- A requirement to substitute less safe chemicals with safer alternatives.

According to a joint discussion paper by the EEB and WWF of 2003, the REACH system would create markets for safer products that substitute hazardous substances, as well as new markets for innovative safety testing and risk assessment tools.[4] Given the debate

[4] A new chemicals policy in Europe – new opportunities for industry; a discussion paper from WWF European Toxics Programme and the European Environmental Bureau, January 2003.

on the potential economic costs and the use of test animals for additional safety testing for those chemicals that have little or no safety data available, the paper further referred to suggestions by FoE and animal welfare and animal rights groups to develop alternative non-animal tests. As a consequence, at the European and national level major environmental and consumer NGOs are now campaigning to phase-out or ban halogenated flame retardants, phtalates, organotin compounds, alkylphenols and synthetic musk compounds, and to substitute these hazardous substances by harmless alternatives.[5]

Moreover, in March 2004 BEUC issued a study on less hazardous chemicals in everyday consumer products, thereby linking the EU chemicals policy and the EU Eco-label scheme.[6] Although the Eco-label was originally conceived to reward products having a reduced environmental impact, the study included potential health impacts as an important dimension. A total number of twenty eco-labelled product groups were studied, among which bed mattresses, copying paper, detergents, textiles, paints, dishwashers, refrigerators, vacuum cleaners, computers and washing machines.

Hazardous substance	Alternatives
Halogenated flame retardants	Replacement by phosphorous esters without halogens, magnesium hydroxid and aluminum trihydrate
Phtalates (for softening PVC)	Replacement of PVC by other materials, like polypropylene
Organotin compounds (tributylin (TBT), triphenyltin (TPT) and mono- and di-octyltins as stabilisers in PVC)	Replacement of TBT-containing paints and replacement of PVC
Alkylphenols (AP) for production of alkylphenol ethoxylates (APEO)	Replacement of APEOs by linear alcohol ethoxylates
Synthetic musk compounds	Replacement by natural fragrances.

Climate change

Environmental organisations, like Greenpeace, FoE, EEB and World Wildlife Fund (WWF), believe that societies should take drastic steps toward reducing energy use. In their view, climate change is not an issue that can be dealt with through ‘technological fixes’, although eco-efficiency should remain a top priority. According to these organisations, the Kyoto Protocol has presented the EU with the challenging task of reducing greenhouse gases in the atmosphere by 8 % over the next decade. This would represent a strong incentive for a shift in energy policies: from supply security to demand side management, from fossil fuels to renewable and safe energy systems. In April 2004 FoE, WWF and Greenpeace sent a joint letter to the European Commission, in which

[5] Gif –bloedlink; het verhaal dat niemand wil horen, Stichting Greenpeace Nederland, Amsterdam, april 2004 (see www.lichaamzondergif.nl); Groen & Geel, Stichting Natuur en Milieu, Utrecht, special juni 2003.
[6] The EU Eco-label; less hazardous chemicals in everyday consumer products, BEUC, Brussels, March 2004.

they criticised for not setting a new target for boosting the share of renewable energy used in Europe to 25 % by the year 2020.[7] As substitutes for fossil fuel these organisations generally advocate renewable energy technologies, powered by the sun, streams, wind, waves, tides, (clean) biomass and biogas[8].

Proposals by the European Commission for the promotion of biofuels (for transport) in 2002 were however not appreciated by the EEB, in particular as the Commission favoured mostly those fuels, which are usually produced from intensively farmed annual crops, such as oilseed rape, sugar beet and wheat.[9] According to estimates by the Commission, 8 percent of the fuel market could be substituted by biofuels when 10 percent of the agricultural area of the EU, about 14 million hectares, would be dedicated to the cultivation of biofuel crops. The EEB however felt that the use of such an enormous amount of land for biofuel production could not be justified. In its view, there were many better uses of this land, such as fodder production for the EU's livestock to improve food safety, the extensification of agricultural productions, or even the production of biomass for the generation of heat and power. The EEB thereby stressed that biomass production for the purpose of incineration for heat and power would have to meet certain requirements concerning species (no exotic plants), pest management and fertiliser use. Multi-annual biomass crops would also give wildlife a better chance of survival and existence than annual biomass crops, provided insecticide use is kept low or at zero.

In the view of the EEB, the production and use of biofuels from conventional crops would have undesirable consequences from an environmental point of view. The most widely used biofuel, Rapeseed Methyl Ester (RME), needs one unit of fossil fuel in order to produce 2.5 to 3 units of biofuel. Compared to biofuels produced from tree residues, this is very inefficient, as up to 17 units of biofuels can be produced from tree residues with one unit of fossil fuel. Moreover, estimations of the savings in greenhouse gas emissions vary widely. CO_2 savings lie in the range of 25 to 80 percent for RME. The Commission's estimate of 70 percent savings was therefore viewed as being rather on the optimistic side. But besides CO_2, another greenhouse gas, N_2O, is emitted in the biofuel cycle, due to the application of nitrogen fertiliser. N_2O has a high potential factor for global warming, about 270 times higher than CO_2, and its emissions are highest for biofuel production from rapeseed, because of the relatively high use of nitrogen fertiliser in rapeseed production. For RME, N_2O emissions result in a loss of about 10 to 15 percent of the equivalent CO_2 savings. Moreover, estimates of the reduction costs per ton of CO_2 vary widely from 37 to 235 euros per ton, while the reduction costs for other biofuels, like bio-ethanol, are even higher. Consequently, the loss in state income might be significant. The money that consumers (taxpayers) spend on achieving CO_2 savings must be used to fund measures, which achieve the best possible results. However, CO_2 savings are too costly in the case of biofuels, while the reduction in state revenue from mineral oil taxes caused by tax-breaks on biofuels would also be very costly. In conclusion, the

[7] Letter to all Commissioners, dated 21 April 2004, Friends of the Earth Europe, Greenpeace and World Wildlife Fund: www.foeeurope.org/press/2004/letter_EC_renewable_energy.pdf
[8] Power to tackle poverty; gettiing renewable energy to the world's poor, Greenpeace & The Body Shop, June 2001.
[9] Biofuels not as green as they sound, EEB position paper on the Draft Directive on the promotion of the use of biofuels for transport and the Draft Directive amending Directive 92/81/EEC with regard to the possibility of applying a reduced rate of excise duty on certain mineral oils containing biofuels and on biofuels, COM (2001)547, European Environmental Bureau, Brussels, May 2002.

EEB's argued against mandatory replacement of fossil fuels through biofuels and for national tax exemptions because:

- It would be destructive for biodiversity.
- It does little to save CO_2.
- It makes no economic sense.
- It might miss the target for supporting EU farmers.
- It does not significantly contribute to the reduction of noxious emissions.
- It is not a sustainable element for the reform of the Common Agricultural Policy.

Besides promotion of public transport and insulation of buildings and houses, the EEB therefore believed that it would be more rational to promote innovative technologies to convert organic waste from the agriculture and forestry production chain into biofuels, rather than to rely on biofuels from intensively farmed crops. Moreover, the Life Cycle Assessment of biogas suggested that this would have a more positive net result, as well as liquid fuel production derived from wood products or biomass (ligno-cellulosic or thermo-chemical conversion), but it was uncertain whether these could economically compete with other processes.

Waste management

Waste issues are also considered a top priority by environmental and consumer organisations, while these organisation also link this issue to the increasing use of non-sustainable packaging materials. In a position paper of 2003 the EEB indicated to believe that the 6th Environmental Action Programme (EAP) and the Integrated Product Policy (IPP) could offer new opportunities to considerably reduce the quantity and harmfulness of waste.[10] The 6th EAP established four major priorities, among which ensuring the sustainable management of natural resources and wastes. In this context the EEB insisted on the adoption of Directives regarding priority waste streams, among which the Biodegradable Waste Directive.

Moreover, the consumer organisation BEUC believed that consumers would like to see packaging made from materials, which present a less negative environmental impact, from cradle to grave.[11] In this context the BEUC acknowledged a problem in the different types and difficulties involved in recycling plastics, while for detergents BEUC pledged that they should be able to biodegrade, so as to avoid health implications through food and water sources.[12]

Environmental risks

Genomics research on industrial micro-organisms generally focus on a better understanding of their performance under industrial fermentation conditions, as this would enable improvement of process conditions and/or microbial strains via (high-throughput) mutation and selection techniques or via genetic modification.

The so-called 'contained use' of genetically modified micro-organisms (GMMs) in research laboratories and commercial production facilities is regulated under EU

[10] Towards waste prevention and steering of waste streams: position paper on the Communication from the European Commission COM(2003)301 final, EEB, Brussels, 2004.
[11] Letter sent to Mr Krämer – DG Environment on the revision of the packaging and packaging waste, BEUC/X/158/2000, Brussels.
[12] Detergents regulation: BEUC position, Brussels, BEUC/X/004/2003.

Directive 98/81/EC. This Directive specifies the degree to which a GMM should be prevented from escaping to the environment (its containment level). This depends on an assessment of whether the GMM poses a low or higher risk to human health and the environment (Group I or II), together with the scale of its use (Type A or B). The Directive foresees four different risk categories to establish containment levels. Nonetheless, contained use GMMs can also be discharged into the environment either through the breakdown of containment facilities, or through routine discharges if the GMM is deemed 'safe' and is considered to have a limited ability to survive in the environment (Group I organism).

In July 1999 the UK-based organisation GeneWatch issued a report on what was known about the use of GMMs in the UK and whether existing safety systems were adequate.[13] A main finding was that there was no overall picture of the use of GMMs, where they might have been accidentally or intentionally released, and what products were being developed from them. Yet, regulators and scientific advisors were confident that their risk classifications were accurate and correct. The report further found the absence of independent monitoring a serious shortcoming. In contrast to the regulation of chemical discharges from factories, there was no requirement either for the user or the competent authorities to monitor releases, which was often justified by the circular argument that because the GMM is safe, there is no need to monitor. But although waste from (large-scale) facilities might be treated by heat or chemicals before its disposal, there was no requirement for this and no independent verification that this was undertaken. Since GMMs are living organisms and mistakes would not be rectifiable once any harmful effects have become apparent, the organisation recommended setting standards and release limits for GMMs with the default level being zero.

At the end of 1999 GeneWatch commissioned a public survey to MORI, which led to the general conclusion that the vast majority of the British public support tightening the control of waste and disposal from laboratories and factories using GMMs. While 83 % believed that limits should be set on the releases of GMMs, only 3 % disagreed. In addition, 88 % believed that waste and disposals from laboratories and factories should be monitored, whereas only 2 % disagreed.[14]

Social constitution of a technology

In the foreword of a report commissioned by Greenpeace in 2003 on nanotechnology and other emerging technologies, the organisation explained in detail its interest in new technologies.[15] While the organisation campaigned against GM crop technology and nuclear power because of their negative environmental impacts, it also had the view that some new technologies might be an integral part of solutions to environmental problems. The organisation pointed at examples, like renewable energy technologies (solar, wind and wave power) and waste treatment technologies (mechanical-biological treatment). It further suggested that the 'social constitution' of a technology appears key to its acceptability, if it provides the answers to questions, such as:

[13] Leaking from the Lab? The 'Contained Use' of Genetically Modified Micro-organisms in the UK, GeneWatch, July 1999 (See also www.genewatch.org)
[14] Press release: Massive public support for tighter control of GM waste, GeneWatch, 10 January 2000; see www.genewatch.org.
[15] Future Technologies, Today's Choices, Nanotechnology, Artificial Intelligence and Robotics: A technical, political and institutional map of emerging technologies, A report for the Greenpeace Environment Trust, July 2003 (see www.greenpeace.co.uk)

- Who is in control?
- Where can I get information that I trust?
- On what terms is the technology being introduced?
- What risks apply, with what certainty, and to whom?
- Where do the benefits fall?
- Do the risks and benefits fall to the same people?
- Who takes responsibility for resulting problems?

6.2 Issues at the technology supply side

Studies by OECD and EuropaBio

While some of the industrial production processes are currently based on the use of microbes or enzymes, other industrial production processes are based on petrol and chemical technologies. Application of new bio-molecular technologies, like genetic modification, protein engineering and functional genomics, could lead to innovations of both these types of industrial production processes. Recently, the term 'white biotechnology' has been coined for the use of micro-organisms like moulds, yeasts or bacteria and enzymes in industrial production of antibiotics, vitamins, detergents, bio-fuels, bio-plastics and new textile fibres. According to studies commissioned by the OECD[16] in 2001 and EuropaBio[17] in 2003, the application of (white) biotechnology to industrial processes could contribute to sustainability. In addition, enzyme producers have also initiated research into the use of GM crops for the production of (industrial) enzymes, while at the same time pharmaceutical, chemical, energy and (green) biotechnology companies are developing GM crops for the production of (building blocks for) pharmaceuticals, (fine) chemicals, bio-polymers and bio-fuels.

The OECD report of 2001 drew on twenty-one case studies from a wide range of industrial sectors: pharmaceuticals, fine chemicals, bulk chemicals, food and feed, textiles, pulp and paper, minerals and energy. Findings from these case studies made clear that biotechnology does not necessarily always offer the single, best route. Sometimes it may be effectively used a one of a series of tools or integrated in other processes. However, the case studies also showed that application of biotechnology led to a reduction of either operating costs or capital costs or both. It also led to a more sustainable process, a lowered ecological footprint in the widest sense, by reducing some or all energy use, water use, waste water or greenhouse gas production. The case studies further suggested that (industrial) decision-makers regarded environmental friendliness as secondary to cost consideration. Though it is sometimes difficult to separate the two, as the reduction of inputs usually means a reduction in costs as well. According to the OECD, all the case studies pointed to a future in which the use of renewable resources and biotechnology, including genetic modification, functional genomics and pathway engineering, will enable the manufacture of materials, (fine) chemicals and fuels in cheaper and more environmentally friendly ways. The OECD's main conclusion was that industrial sustainability and quality of life in general would

[16] The Application of Biotechnology to Industrial Sustainability, Organisation for Economic Co-operation and Development (OECD), Paris, 2001.
[17] White Biotechnology (bioprocesses): a gateway to a more sustainable future, studies say, EuropaBio, Press Release, Lyon, 10 April 2003.

improve. But, according to the OECD, one limiting factor for confirming the potential of biotechnology was the absence of a scientifically validated technique for measuring its overall long-term sustainability. Joint government-industry action to this need was essential to encourage consumer and public confidence in bio-based and cleaner industrial processes and products.

On 10 April 2003 EuropaBio presented six case studies, which all showed environmental benefits, be it in reducing water or energy use or carbon dioxide. Five case studies also scored high on economic value. According to EuropaBio, white biotechnology could contribute to all aspects of the Triple P bottom-line of sustainability – People, Planet, and Profit. Further, to capture the potential of white biotechnology a Technology Platform with all stakeholders present should be set up. According to EuropaBio, there was a need to develop a vision and roadmap, to work on financial incentives, to have a supportive regulatory framework in place and to reduce prices of biological raw materials, like (maize) starch or oil.

Noteworthy, both the studies commissioned by the OECD and EuropaBio pointed at a need to reduce the prices for biological raw materials (feed stocks), because white biotechnology would then better be able to compete against production processes based on petrochemicals.

EuropaBio case studies (2003)

- Vitamin B2 is traditionally produced using a complex eight-step chemical process. BASF's new biotechnology process reduces production to a one-step fermentation process, leading to a reduction of overall costs up to 40 %, CO_2 emissions by 30 %, resource consumption by 60 %, and of waste by 95 %.

- The antibiotic cephalexin is traditionally produced using a ten-step (bio)chemical process. A new biotechnological process developed by DSM reduces overall costs up to 50 % and saves both materials input and energy consumption by 65 %.

- Traditional scouring of textiles involves the use of relatively harsh chemical solutions, like for example a hot alkaline treatment. In textile industries scouring enzymes developed by Novozymes can lead to a cost reduction of 20 % and saves energy consumption by 25 % and emissions into water by 60 %.

- Bio-based polymers made by Cargill Dow (and Genencor) from maize require 17 to 55 % less fossil inputs.

- In the future the use of renewable biomass in large-volume (bulk) production of chemicals and fuels could contribute to reduction of CO_2 emissions. Relative to traditional counterparts bio-ethylene production would reduce CO_2 emissions by 106 %, while the reduction in the case of bio-ethanol would amount to 108 %. But companies need to have access to cheap biological feedstocks, which further depends on the cost-effective conversion of biomass, like straw or maize stover, to sugars, the raw material for fermentation processes. Technologies for such biomass conversion are under development.

Finally, in its second progress report on Life Sciences and Biotechnology of April 2004 the European Commission recognised the potential of white biotechnology in terms of competitiveness, growth and environmental sustainability.[18] But it was also noted that large-scale practical application of white biotechnology in Europe seemed to be limited, while in the US and Japan a strategic agenda for its development had been formulated. Moreover, the second progress reports also referred to the European Commission's Communication on 'Environmental Technology Action Plan' (ETAP), which highlighted the importance of white biotechnology for sustainable development.

Renewable raw materials

In 2002 the EU/RRM (Renewable Raw Materials) committee, chaired by the European Commission DG Enterprise and co-ordinated by the European Renewable Resources & Materials Association (ERRMA) under the European Climate Change Programme (ECCP), issued a report on crop-derived materials. According to the report, RRMs do not only have the potential for a modest reduction in greenhouse gas emissions by the replacement of non-renewable, primarily mineral oil-derived products. RRMs would also have the potential to improve the economic competitiveness of EU industry and agriculture by giving incentives to the most advanced technologies, especially biotechnology. RRM would also provide social benefits by rejuvenating rural communities and enhance further environmental protection by improving soil, air and water quality. In this context ERRMA believes there is a role for (white) biotechnology as a tool for products based on RRMs and will have the following benefits:[19]

- Reduced use of water and traditional chemicals.
- Reduced use of energy, and thus lower levels of fossil-fuel derived CO_2 emissions.
- Increased use of renewable resources, as chemical feed stocks and for energy production (through electricity generation and in the form of biofuels). Growing crops rather than extracting finite mineral reserves will reduce the use of fossil fuels and is also carbon-neutral.
- Production of new materials. Cell cultures are unique in their capacity to make new pharmaceuticals and vaccines.
- Cost effective production of materials with less waste.

ERRMA also believes that the increased use of RRM based materials, be it by biotechnology or bio-synthesis is fully consistent with the 6th EAP. As regards climate change, the increased use of RRM would lead to primary and secondary savings of CO_2 emissions, while the introduction of alternative, non-food crops into agriculture would increase on-farm biodiversity. There would also be benefits for both health and environment from an increased use of non-food crops and in the area of natural resource and waste management benefits would relate to the security of supply of raw materials and biodegradability.

---

[18] Report from the Commission to the European Parliament, the Council and the European Economic and Social, Life Sciences and Biotechnology – A strategy for Europe: Second progress report and future orientations, Brussles, 07.04.2004, COM(2004) 250 final.
[19] ERRMA position to proposal of EuropaBio 'Preparing a technology platform for white biotechnology', Dietrich Wittmeyer, 26.09.2003.

Enzyme producers

In 2000 the Association of Manufacturers of Fermentation Enzyme Products (AMFEP) issued a policy statement on the use of genetic modification for the development of improved enzyme-producing micro-organisms.[20] This policy statement indicated that microbial enzymes produced by AMFEP members are used in a wide variety of industrial applications and the application of modern biotechnology, e.g. genetic modification, could offer the following advantages in the production and/or quality of these enzymes:

- Higher production efficiency and thus less use of energy and raw materials, and less waste.
- Availability of enzyme products, which for economic, occupational or environmental reasons would not be available, enabling new applications.
- Technical improvement through higher specificity and purity of enzyme products.

AMFEP further felt that the consumer's right to know and right of choice should be respected and that an open dialogue would be the approach to gain confidence in the use of modern biotechnology.

Silicon biotechnology

The term 'silicon biotechnology' has recently been introduced for developments at the interface between bio- and nanotechnology. Proteins, viruses and DNA appear to be very suitable for the production of inorganic materials, like semi-conductors and magnetic materials. Current manufacturing routes for micro- and nano-structures require complex manufacturing processes, often in vacuum under controlled temperature conditions in large chips-factories. By contrast, micro-organisms are capable to build very complex silicon-oxides structures with limited means and under a variety of conditions. Research in this area can therefore lead to modified micro-organisms and proteins with new bio-catalytic properties for faster, easier and more environmentally friendly production of silicon chips and other nano-structures.[21] Although current research in silicon biotechnology largely takes place at public research institutions, several private companies also see opportunities at the interface of bio- and nano-technology. For example, Dow Corning with its expertise in silicon chemistry and Genencor with its protein expertise have recently formed an alliance with the aim to apply biotechnology for a more environmentally friendly production of silicon.[22]

NGI supported genomics research at the Kluyver Centre

The Kluyver Centre of the Technical University of Delft is one of the leading research institutions on microbial production systems in the Netherlands and it collaborates with a number of major fermentation industries, including DSM, Tate & Lyle, Heineken and Nedalco.[23] Besides a generic 'Genomics Tools' programme with an emphasis on quantitative proteomics, metabolomics and high-throughput screening techniques, the genomics research focuses on the following micro-organisms:

Saccharomyces *cerevisiae* is considered of great importance for the (Dutch) fermentation industry; production of bakers' yeast, yeast extracts, heterologous proteins,

[20] AMFEP Policy Statement on Modern Biotechnology, Amfep/95/21 rev. May 2000.
[21] See for example http://www.twanetwerk.nl/default.ashx?DocumentID=1532.
[22] See http://www.cargilldow.com and http://www.genencor.com
[23] See www.kluyvercentre.nl (visited in May 2004)

ethanol, beer and fine chemicals. It is considered an excellent model organism for studying fundamental scientific aspects and novel concepts in genomics-driven innovation of industrial processes. Genomics has the potential for improving process conditions and it can be used for direct microbial strain improvement via high-throughput mutation and selection or via targeted genetic modification. In addition, the research will act as a stepping stone for implementing genomics approaches to other industrially relevant eukaryotic cell factories, such as *Penicillium chrysogenum*, *Aspergillus niger*, *Kluyveromyces lactis* and *Phaffia rhodozyme*.

Aspergillus niger is used as a filamentous fungi cell factory for the production of proteins and peptides (mostly enzymes). The genomics research here focuses on clarifying folding and secretion of homologous and heterologous protein at the intracellular level, the cellular level and the reactor level. The aim is improvement of protein production processes.

Pseudomonas putida strains, which are tolerant to organic solvents, like toluene, can be used in biotransformation processes for the production of fine chemicals. The overall target of the genomic research here is to further optimise this bacterium as a host in the production of (fine) chemicals.

6.3 Preliminary conclusions

From the preliminary analyses of the NGO demand side and the technological supply side our suggestion for the interviews is to further explore and reflect on the sustainability potential of industrial genomics and white biotechnology in the following areas:

- Replacement of PVC (in packaging materials) by recyclable or biodegradable biopolymers.
- Replacement of synthetic musk compounds by natural fragrances.
- Replacement of chemical treatments in production of paper, textiles and leather by enzymes.
- Replacement of fossil fuels by liquid fuels derived from wood products or multi-annual crops.
- Replacement of APEOs by linear alcohol ethoxylates or microbially produced surfactants.
- Biodegradable detergents.
- Nanobiotechnology for silicon production.

For the interviews we further suggest to solicit views on the following issues:

- The absence of scientifically validated technique for measuring the overall long-term sustainability of white biotechnology applications; the divergence in views on the sustainability of biofuels from annual crops could serve as a case.
- The social constitution of industrial genomics and nanobiotechnology.