



**EUROPEAN COMMISSION**

**PROVISION OF SERVICES IN THE SECTOR OF  
COOPERATION RELATED TO:**

**Lot 1: Rural Development and Food Safety**

**Framework Contract N°IB/AMS/451**

**Beneficiary Country : All Countries – All Developing  
Countries**

**Letter of Contract N° 2004/87266**

**Guidelines for Green, White, Blue and Red  
Biotechnologies**

**Final Report**

(Piet Schenkelaars – Edo Lin – Jan Torp Pedersen – Raymond O'Rourke – Patrick Gerin)

**March 2005**

**Consortium**



**AGRIFOR Consult**

Avenue Einstein, 3 – 1300 Wavre – Belgium  
Tél. + 32 – 10.24.50.35 – Fax + 32 – 10.24.50.38  
Email : info@agrifor.be

**JVL (Belgium) – DARUDEC (Denmark) – DFS (Germany)  
JAAKKO PÖYRY (Sweden) – PARDEVO (Belgium) – SNEDE (Portugal)**

The views expressed in this document are those of the Consultant and do not necessarily reflect those of the European Union or the Government of the concerned countries

---

**Table of Content**


---

Phase I : Current Situation and Future of Biotechnologies for the Poor in Developing Countries	2
1. Current situation	2
1.1 Defining biotechnologies	2
1.2 Green biotechnologies	3
1.3 Blue biotechnologies	6
1.4 White biotechnologies	7
1.5 Red biotechnologies	8
2. Potential future of biotechnologies in developing countries	12
Phase II : Current Policy and Strategy Thinking	14
1. Actors, levels and functions	14
2. The roles of the European Union	15
2.1 EU development policy	15
2.2 International co-operation and the life sciences and biotechnology strategy	16
3. Other public and private stakeholders	18
4. Clustering developing countries	20
Phase III : Key Elements of an EU Pro-Poor Biotechnology Strategy	21
1. Purpose of Phase III	21
2. Necessity of pro-poor biotechnology development in developing countries	21
3. Essential features of a pro-poor biotechnology	21
4. Prerequisites and needs for pro-poor biotechnology development	22
5. Present EU policies and strategies relevant to developing countries	25
6. Specific features of clusters of developing countries	26
7. Specific features of green, blue, white and red biotechnologies	30
8. Key elements of an EU pro-poor biotechnology strategy	36
Phase IV : Implementation Modalities	38
1. Introduction	38
2. Step 1: Screening a pro-poor biotechnology proposal against EU guidelines	38
3. Step 2: Detailed assessment of the proposal	38
4. Concluding remarks	41

## **Phase I : Current Situation and Future of Biotechnologies for the Poor in Developing Countries**

### **1. Current situation**

#### **1.1 Defining biotechnologies**

Over the years many definitions have been provided for biotechnology. In the broadest sense biotechnology may be understood to include traditional biological processes as conventional plant and animal breeding and fermentation for beer brewing, bread making or cheese production. In the narrowest sense biotechnology may be taken as a term describing molecular technologies applied for genetic modification (GM) of living organisms. The Convention on Biological Diversity (CBD) defines biotechnology as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or to modify products or processes for specific use”. This very broad definition ensures that virtually all applications that might impact biological diversity are covered by the Convention. As this broad definition does neither exclude any specific modern molecular technology, like genetic modification (GM) or any traditional process, it is the most appropriate definition for developing practical operational guidelines for EU support to pro-poor biotechnologies in developing countries.

As biotechnology can be applied in many different sectors and for many different purposes, it is useful to differentiate between green, blue, white and red biotechnologies. Generally, biotechnologies for agriculture and food production are called green and biotechnologies using aquatic organisms are called blue, while biotechnologies for industrial processes, waste management and soil remediation are called white and biotechnologies in healthcare are called red.

Yet, the boundaries between green, blue, white and red biotechnologies are not always clear or obvious. For instance, animal husbandry is part of agriculture, but the biotechnologies used for animal healthcare, like diagnostic tools and vaccines, are rather red than green. Moreover, fish genetically engineered, in order to function as a living factory for the production of biopharmaceutical proteins, can be called an example of a blue biotechnology applied for the production of ‘red’ molecules. Another example is the application of white biotechnologies to a water sanitation installation, which contributes to the red area of healthcare in terms of disease prevention. Also the production of biopharmaceuticals, like (sub-unit) vaccines through GM fish, or ‘white’ molecules, such as enzymes or biopolymers, through GM plants blur the boundaries between green, red and white biotechnologies.

---

## 1.2 Green biotechnologies

---

The UN Food and Agriculture Organisation (FAO) in a recent account emphasised that green biotechnologies can complement but not substitute for research in other areas such as plant breeding, integrated pest and nutrient management, livestock breeding, feeding and disease management systems. Accordingly, green pro-poor biotechnologies should form part of an integrated development programme that gives priority to the problems of the poor. Modern biotechnology must be incorporated into mainstream agricultural research and development programmes, not as stand-alone technologies. However, there are no major public or private sector programs to tackle the critical problems of the poor or targeting crops and animals that they rely on. Concerted international efforts are therefore required to ensure that the technology needs of the poor are addressed and that barriers to access are overcome. While some of the challenges to promote agricultural growth might be more difficult for biotechnology than for other technologies, others might be less difficult. Technologies that are embodied in seed, such as GM insect resistance, might be easier to adopt for small-scale, resource-poor farmers than more complicated crop cultivation technologies that require substantial investment or complex management strategies. Though, it should also be noted that in many developing countries there are as yet no suitable seed distribution mechanisms to reach the farmers.

Thus far, a few public-private partnerships between actors from private and public sectors in the North and from public sectors in the South have mainly focused on crops, like maize, soybean and cotton, which are often grown for domestic urban and/or export markets in the North. As cultivation of these crops mostly takes place with a high-input of agro-chemicals at large-scale mono-cultural settings, green biotechnologies have the potential to decrease inputs of agro-chemicals and/or to increase yields. In the case of insect-resistant GM Bt cotton for instance, there is mounting peer-reviewed evidence that its cultivation brings socio-economic and environmental benefits to large-scale cotton growers in the USA, as well as to small-scale farmers in South Africa, India and China. By contrast, there are an increasing number of reports on the cultivation of herbicide-tolerant GM soybean, which suggest that it only brought some economic gains and environmental benefits to large-scale farmers in the USA and Argentina during the first couple of years of its adoption. The main reason for further adoption by other (large-scale) farmers is the ease and flexibility of weed management, which is particularly relevant when labour (costs) are constraining profitability.

Some actors from the public sector and the civil society have doubts on whether public-private partnerships, which involve large international biotechnology and seed companies, are eventually beneficial for resource-poor farmers and other poor people in the developing world, given their current focus on GM crops. However, it can be argued that the adoption

of GM crops by several developing countries through such partnerships might at least have contributed to further macro-economic development and integration into the global markets. But until now the number of such public-private partnerships in this area has been very limited. It should thereby be noted that developing countries have so far hardly forged South-to-South collaboration among themselves, although it could create efficiencies by sharing knowledge on specific crops and traits and (regulatory) data.

Notably, a few examples of so-called participatory ('bottom-up') approaches, i.e. engagement of resource-poor farmers in setting biotechnology R&D priorities and arrangements for the adoption of R&D results, show that they do not necessarily exclude GM technology. As the case study on the Netherlands support programme in India showed, it is possible to engage resource-poor farmers in developing countries to establish priorities for biotechnology R&D focussed on local crops and not on crops for export markets. The local crops included, sorghum, millet, cassava etc., which are mostly grown under marginal conditions, like drought or salinity. There are also examples of biotechnology development programmes, resulting in local entrepreneurs using rather simple green biotechnologies, like tissue culture, for the supply of disease-free planting materials for resource-poor farmers or large-scale producers of flowers for export markets, or for the production of biological pesticides from local plant species.

Public research institutions, sometimes with private sector actors, have so far conducted the largest proportion of GM plant breeding research in developing countries. Of 201 GM plants developed in 15 developing countries (Africa 4; Asia 7; Latin America 4), 35 GM plants contain insect-resistance as a trait, which could help reduce the use of conventional insecticides, thereby yielding environmental and human health benefits. Reduction of the use of other pesticides and yield increase could be achieved by 84 other GM plants, which have been made resistant to virus, fungus or other diseases. 11 GM plants have been developed with tolerances to abiotic stress, such as drought and salinity, in order to be grown under marginal conditions. Of 15 GM plants being developed for product qualities, 5 are in the area of nutritional enhancement and 6 are to prolong shelf life. The other 4 are for product characteristics, such as increased sucrose content. Finally, 9 GM plants are being developed for plant-based vaccine-deployment.

The technologies required to produce GM crops have developed rapidly during the last decade, and time and cost of making new gene constructs have decreased considerably. In stark contrast, during the same period the time and costs for testing the efficiency and safety of new GM crops have increased significantly. Estimates indicate that the costs involved in developing, approving and marketing a new GM crop have actually doubled and now approaches the costs of developing a new pharmaceutical.

Additional scrutiny of GM crops and GM food in the EU due to ethical, environmental and consumer safety concerns has led to stringent and increased authorisation costs for such products. As a result, the EU regulatory framework for the use of GM crops from farm to fork also requires traceability and labelling of lots of GM seeds and of GM food and feed (ingredients), in addition to thresholds being set for the adventitious presence of GM material. Consequently, the production and distribution of non-GM seeds, GM crops and GM foods and feeds need co-existence management of GM and non-GM crops and (logistical and administrative) measures for segregation of harvest, transportation, storage and processing. For developing countries importing food or exporting agricultural commodities to the EU, the compliance costs and liability risks involved in co-existence and segregation are significant, while it is difficult to estimate the distribution costs across supply chains and commodities and among various importers and different exporters. As the case study on Egypt demonstrated, this country has a GM consumption potato ready for commercialisation, but it has so far not applied for regulatory clearance by the EU and not implemented co-existence and segregation measures. In addition, this situation also has the potential to jeopardise the usual export of non-GM consumption potatoes to Europe.

Finally, as patents protect many of the GM tools, their use for plant breeding research and commercial purposes requires a license from the patent holder. In many instances the patent holder will be an actor from the private sector, which holds the dominant position over public institutions in filing patent claims for DNA sequences as well as for patents for basic biotechnology processes ('enabling patents'). Between 1980 and 1996, 48% of the patent claims for DNA sequences derived from 78 plant species of economic or scientific importance were made by 14 multinational companies alone. In a fundamental way, this demonstrates a worrying trend that threatens to hinder progress of life sciences and biotechnology development. Access to key data and research tools has become increasingly limited. The proliferation of patent rights can impede or effectively preclude the use of research tools altogether. Some studies indicate that researchers have circumvented the patent system, in order to carry out their work.

The complexity of the patent landscape has thus created both real and perceived obstacles to the effective use of many research tools for green biotechnologies by many public and private organisations worldwide. As a response, alternative GM technologies have recently been developed and have been made available and accessible to the international community in a 'protected technology commons'. The open-source-modelled licenses for these GM technologies are characterised by having no commercial restrictions other than covenants for sharing of improvement, relevant safety information and regulatory data and for preserving the opportunity for others to freely improve and use the GM technologies.

---

### 1.3 Blue biotechnologies

---

Compared to green biotechnologies, the potential of blue biotechnologies seems to have attracted much less (policy) attention, at least in the EU. As many developing countries have long coastal lines, rivers and/or lakes, development and usage of blue biotechnologies for high-input and low-input aquacultural systems could be beneficial in terms of local food security and macro-economic development, when applied for instance to the production of food for domestic urban and export markets.

According to the case study, tilapia, which is a robust fish with low demands for water quality and feed compared to carnivorous fish species, blue biotechnologies hold the promise for improvement of small-scale fish production. This could be directly beneficial to poor people, as tilapia farming has a long history in the developing world and exists as an extensive low-input farming system in many cases. It provides households with food security and improved nutrition, while surpluses are marketed and generate additional income. Over the last decade demand for tilapia has substantially grown in export markets, first in North America and Japan and now also in Europe. As a consequence, tilapia is increasingly farmed in high-intensive systems. The use of selective breeding techniques and the (potential) use of locally available waste, like for example coffee pulp, for low-cost feed could help to further improve the productivity of tilapia farming and lower its environmental burden. Moreover, an increased demand for tilapia will also require a continuous supply of fry and fingerlings, which could be met by small-scale hatcheries as an income generating activity.

Shrimp farming is another important activity in many developing countries, which could benefit from the advancement of blue biotechnologies. At the moment several multinational companies run large vertically integrated operation, but most shrimp farming is still mainly an activity of small-scale farmers. Traditionally, shrimp farming was based on post larvae in coastal waters caught by resource-poor coastal fishers. However, by-catches and the introduction of pathogens combined with seasonal fluctuations have prompted the development of hatcheries to supply post larvae to shrimp farmers. As shrimp is susceptible to a large number of pathogens, molecular tools are increasingly being used for its genetic improvement and for early diagnosis of potential health/zoonoses diseases.

Presently, several fish species, like salmon and rohu, an Indian fish species, have been genetically modified with for instance (foreign) genes for growth hormone to increase their growth. As in the case of GM crops, GM fish need to meet the same requirements for safety, traceability and labelling as specified in EU regulations on GM food and feed, before a developing country can export it to the European market. Further demands in

export markets also include compliance with international standards for food safety in fish production and post-harvest technology.

#### **1.4 White biotechnologies**

---

Historically, the chemical industry was developed on the basis of exploiting coal and oil reserves. These fossil resources, which originally originated from biomass, were and are 'only' converted by the chemical industry. As these fossil resources are becoming scarce and often exploited in an unsustainable way, white (or industrial) biotechnology research and development has been initiated (in the North) for a 'bio-based' economy with a more sustainable (chemical) industry. Such an economy will be based on renewable resources, i.e. biomass, which, owing to photosynthesis, is the major and primary producer of renewable chemical 'building blocks' in the biosphere. Biomass is available almost everywhere in the world. Provided it is managed, cropped and harvested properly, biomass could contribute to the sustainable development of both developed and developing countries. Local or regional conversion of biomass into useful products (by biorefineries) could thereby lead to local or regional economic development, while it reduces the need for transportation of raw materials as only lower volumes of (semi-) final products have to be transported over longer distances.

In comparison to the USA the development of white biotechnologies for the production of bulk and fine chemicals, biofuels, and enzymes for industrial and food/feed purposes, started attracting only very recently policy attention in the EU. In addition, the USA is spending nearly ten times as much as the EU on research on white biotechnologies. Important obstacles for further development of white biotechnologies in the EU are high prices of raw materials ('feedstock'), like sugar, glucose, starch and vegetable oils, which are needed for the bioprocesses and the large investments needed for research combined with the long development times for enzymes needed to convert biomass.

Given the limited availability or affordability of energy sources in many developing countries, biogas technology has the potential to exploit organic waste and biomass for methane-rich biogas production in both small and large-scale scenarios. Millions of families in rural India and China already possess anaerobic digesters for biogas, which can be used for heating, cooking and the production of electricity, enabling access to education, media, etc., better storage of pharmaceutical and the improvement of working conditions. If managed in a sustainable way, further development of biogas production at local and community level could contribute to protecting forests, which are now over-exploited for fire-wood, prevent desertification, while the residues of anaerobic digestion can be used as fertiliser to improve crop yields.

On the other hand, according to the case study included in this study, it has been noted that while the introduction of biogas technology in India has been successful, its integration into the livelihood of the end-users, mainly women, has been far less successful. Issues, like a rural energy crisis and a need for decreasing the import of oil and chemical fertiliser, are issues that are mainly conceived by politicians and not by the people who are the users of the technology. There is for example little evidence that the rural energy crisis is something that women, if comparing to other needs, prioritise. Lack of education and safe drinking water are normally seen more acutely than lack of energy. Many features of biogas technology could be attained through other solutions, such as improved cooking stoves and photovoltaic systems for light. The strategy to let the users clearly define their problem in a specific context, and thereafter to ascertain if technological solutions are available to meet the identified needs has not been applied with sufficient rigour in the past. However, the Indian government today does work towards creating an end-use strategy.

Organic household wastes or agricultural wastes, like straw and coffee pulp, are now also increasingly being considered biomass. At the same time many (developing) countries have introduced environmental regulations to limit the environmental impact of such wastes. In many coffee-producing countries and because of very low coffee prices in the world market, biotechnologies are therefore being researched and applied to use coffee pulp for the production of feed, bioenergy or as substrate for mushroom cultivation.

Developing countries with the capacity to produce biomass may have opportunities in providing domestic and export markets with biofuels, 'green' chemicals and high-value enzymes. In order to increase biomass production in a sustainable way, appropriate application of green biotechnologies to annual crops, like sugar cane, maize, etc., or multi-annual woody crops and trees, is thereby probably indispensable for generating cheap feedstock for white biotechnologies. Developing countries could also use white biotechnologies for adapting and improving indigenous fermentation biotechnologies for traditional foods and beverages, in order to enhance their safety and nutritional quality. This may also help to increase opportunities on domestic urban markets and possibly even export markets in the North, where consumers might be interested in something 'exotic', provided it is safe and tasty.

## **1.5 Red biotechnologies**

---

Several developing countries, such as China, India, Cuba and Brazil, not only have superior research capabilities in green and other biotechnologies but also in red biotechnologies, while they also have many large and small domestic pharmaceutical companies. These developing countries are increasingly using and developing novel molecular tools for creating and manufacturing diagnostic tools, GM vaccines and biopharmaceuticals. Several

of these developing countries are engaged in South-South export of products of red biotechnologies.

Nonetheless, there is still a huge gap in health research and clinical trials between rich industrialised and poor developing countries. Only ten percent of the global budget spent on healthcare research is devoted to health problems covering ninety percent of the world's population. As many developing countries have (very) limited funds and a lack of trained staff to conduct their own research and clinical trials, it is vital that the public and private sectors in industrialised countries help to bridge this gap.

For the further development of red biotechnologies to control sexually communicable diseases, like HIV/AIDS, which particularly burden women and children, other poverty-related diseases, such as tuberculosis, malaria, cholera, etc. and neglected tropical diseases, like sleeping sickness, there is now an increasing number of public-private partnerships. The combination of the (international) pharmaceutical industry with its knowledge and expertise and drug discovery and development and the public sector with in-depth expertise on basic biology, clinical medicine, and its public remits constitute the rationale for many of these partnerships. As most public-private partnerships are only at their infancy, practices of good governance and accountability within such partnerships are still evolving.

According to the case study, an interesting example of a recent public-private partnership is Medicines for Malaria Venture (MMV) established in 1999. The background for its establishment was the alarming statistics on malaria. This led many public and private parties to recognise the need to address global health issues in a different way than the traditional public sector approach or the private sector commercially driven drug R&D process that makes access to medicines and vaccines prohibitive in developing countries. The main objective of the MMV is to bring the public and private sector partners together to fund and provide managerial and logistical support for the discovery and development of new medicines to treat and prevent malaria. These medicines should be affordable and appropriate for use by the target population in developing countries.

As in most modern biotechnology applications, 'patent environments', are complex in the area of red biotechnologies and can be a real or perceived obstacle for developing countries. For example, while India has the largest number of diabetics according to the World Health Organisation (WHO), a northern company dominated the Indian market for human insulin. However, as the case study indicated, after its patent expired, an Indian company managed to introduce a generic human insulin on the market and to become the first company from the South to compete with international pharmaceutical companies from the North in the production of this medicine. The result of this innovation has been that the market leaders from the North dropped their prices by thirty to forty percent.

It should be noted that access to medicines in developing countries is a very complex issue governed by many different factors, not only their price or the fact that products might be patent-protected. The range of factors might be totally different depending on the country and the disease in question. From the patient's point of view, the issue is how to access the full treatment she or he needs – including other associated healthcare issues, such as appropriate diagnosis, drug distribution systems, nursing and hospital services, etc. Its not just a question of simply possessing a medicine. However, in certain cases, patent protection on products can be an obstacle to better access to medicines. This issue has been addressed at the level of the World Trade Organization (WTO). In November 2001, the Ministers of Trade from WTO member states adopted a declaration stressing the importance of enforcing intellectual property rights (or patent rights) on medicines in a way that supports public health by promoting both access to existing medicines and the creation of new drugs.

Analogous to a strategy pursuing domestic manufacturing of so-called generic drugs based on off-patent chemically synthesised compounds, biogenerics (or biosimilars) are already enabling Indian companies to supply domestic and export markets in other Asian countries and Latin-America. However, by contrast to 'short-track' approval procedures for generic chemical pharmaceuticals, biogenerics must undergo a full authorisation procedure in the EU. The data requirements for a biogeneric, in order to evaluate their safety, effectiveness and efficacy, are thus the same as for the original biopharmaceutical drug.

The expertise in producing biomedical proteins (biopharmaceuticals) could also be attractive to foreign investors and Northern biotechnology companies seeking to reduce manufacturing costs. Biopharmaceuticals manufacturing operations might therefore be moved to developing countries. Vaccine production might be another opportunity for developing countries. Because the technology is relatively simple and overheads are low, companies and institutions in developing countries might be able to compete against vaccine producers in industrialised countries, which currently suffer from poor profit margins, litigation problems and regulatory changes. So far, most success has been achieved in producing generic versions of existing recombinant-DNA vaccines. Cuba for instance has also developed an innovative vaccine against meningitis B. The potential of cheaper generic vaccines might be extended from home markets to those of other developing countries, and if manufactured under the appropriate standards, innovative or generic vaccines could also be exported to rich countries.

Finally, many industrialised countries have their own comprehensive legislation and mechanisms for ethical scrutiny of clinical trials for testing new medicines on test persons. Notably, a study (*John Hopkins University, USA*) of 2002 found that a quarter of clinical

trials in developing countries did not undergo any kind of ethical review. Advisory groups to the USA government and the EU have therefore called for capacity building of ethical review and monitoring of clinical trials in developing countries. It has also been argued that clinical trials should only be carried out in developing countries where there is a good justification for it, and that the use of placebos in trials should be regulated 'in principle' by the same rules as in industrialised countries.

---

## **2. Potential future of biotechnologies in developing countries**

---

Over the last thirty years many biotechnology tools have been developed by the public and private sectors and further (support to) biotechnology research and development will undoubtedly yield many other biotechnology tools. Some of these tools are specifically applied and further developed within one sector for instance the green sector, but other tools, in particular genomics, bioinformatics and molecular markers, are applied and further developed for use across all sectors. It should be stressed that many molecular biotechnologies are further building on traditional or indigenous biotechnologies, while they often also need to be backed-up by conventional approaches. The use for example, of GM technologies to adapt crops for specific uses in agriculture still requires conventional plant breeding tools to develop an experimental GM plant ('transformation event') into a (commercially) useful GM crop (variety).

None of the molecular biotechnology tools should be considered a panacea for solving the economic, social and environmental challenges faced by industrialised and developing countries. While there are certainly also poor people in industrialised countries, the majority – around four billion – live in developing countries, and these people, particularly women and children, are facing poverty whether in terms of poor access to education and healthcare and poor assets for production of useful goods and services.

Several molecular biotechnology tools hold the promise of reducing poverty in developing countries and at the same time they involve real or perceived risks for human health, the environment and biodiversity. Their responsible usage therefore requires human and material research capabilities, scientific, legal and administrative infrastructures for co-ordinating biotechnology research and development, including intellectual property rights policies, financial support, tax incentives, technology transfer mechanisms, capacity for regulatory oversight on biosafety, public mechanisms for social-ethical scrutiny and logistical infrastructure for transport, storage and distribution. Given these prerequisites and needs for biotechnology development in a (developing) country, the typical assumption that basic research is the first stage in an innovation process to produce useful input for technology is thus a simplification of a much more interactive and dynamic process. Innovation systems are made up of institutions that contribute to the creation, diffusion and use of new, economically useful knowledge, while they are held together by a web of linkages and synergies. Knowledge creation, diffusion and use are at the core of innovation systems, but the process involves non-linear, multidirectional knowledge flows among the various actors. The behaviour of an innovating agent is impacted by a range of influences and institutions that provide constraints and incentives, including laws, regulations, cultural norms, social rules and technical standards.

While addressing the needs of poor people in developing countries through biotechnologies, it is essential that poor people (groups) are engaged in the web of linkages and synergies, which sets the biotechnology R&D priorities and establishes the arrangements for (practical usage and/or market) adoption of biotechnology R&D results. Without their engagement, poor people may only hope that some of the macro-economic benefits of their country's biotechnology development will possibly trickle down to the local economy.

There is thus no simple guarantee that green, blue, white and red biotechnologies will be further researched and developed and eventually applied to serve the needs of poor people in developing countries. As the overarching goal of EU development policy is poverty reduction in developing countries, the issue at stake for developing guidelines for EU support is how these various biotechnologies could be developed and used for addressing the needs of urban and rural poor in developing countries. It therefore calls for the development of appropriate strategies and practices, so that pro-poor biotechnologies will be an important developmental instrument, 'owned' by the beneficiaries and relevant to their needs.

## Phase II : Current Policy and Strategy Thinking

### 1. Actors, levels and functions

Since the 1980s major actors in the private and public sectors in industrialised countries consider biotechnology development crucial as a means to improve further economic competitiveness as well as to find socially equitable and ecological sustainable solutions in areas like healthcare, agriculture, food production, energy, industrial production and waste management. At the same time, several biotechnology developments, for example GM crops, animal cloning, human embryonic (stem cell) research, etc., have led to public anxiety and fierce controversies between private and public sectors and civil society organisations, both within and in between industrialised and developing countries. Since such controversies are usually also played out in the media, public perceptions and attitudes to new biotechnologies are eventually having a profound influence in shaping the conditions for the further development and adoption of these technologies.

Various actors in the public and private sectors in developing countries, e.g. in China, India, Mexico, Brazil, Argentina, Cuba, Egypt and South Africa have developed and implemented ambitious national biotechnology development plans. As a result, these countries are currently viewed as potential leaders in biotechnology or dynamic adopters, which is for instance certainly true in terms of acreage, on which GM crops are experimentally tested and commercially grown in some of these developing countries, compared to the situation in the EU. Several of these developing countries have also been successful in developing novel GM vaccines and biopharmaceuticals. However, this does not necessarily imply that biotechnology developments in these developing countries are directly benefiting poor people.

Ultimately, strategies and policies of various actors, having specific functions and operating at various geographical levels, shape research and developments in biotechnology. Generally, three kind of actors are involved in developing and shaping biotechnology: 1) The private sector; 2) the public sector, and; 3) the civil society. At each of the geographical levels, i.e. global, regional / sub-regional, and national / local levels, actors support several types of actions relevant to biotechnology research and development and its (commercial) adoption.

---

## 2. The roles of the European Union

---

### 2.1 EU development policy

---

The central objective of the EU development policy of 2002 is poverty eradication, while its aim is to work within existing frameworks of policies, institutions and programmes at national, regional and international levels. It targets six areas for attention: 1) trade and development; 2) regional integration and co-operation; 3) support to macro-economic policies; 4) transport; 5) food security and sustainable development, and; 6) institutional capacity-building, good governance and the rule of law.

At national level the EU still provides development support to developing countries through traditional project-type assistance. However, its current policy stresses the increased development of sector-wide approaches (SWAPs) with investments provided in the form of sector or sub-sector pooled (or 'basket') funds. It is thereby a condition for support that a developing country has developed and adopted a National Poverty Reduction Strategy (NPRS). This approach has the advantage that it is nationally 'owned', as it is based on dialogue with all key stakeholders, like NGOs, producer and trade associations and community-based organisations. Another advantage is that there is potential for donors to invest in one single, prioritised national plan for a sector, such as healthcare, agriculture, food production, energy, industrial production, education, and science and technology.

At regional level the EU provides financial assistance for poverty reduction in the following priority areas: 1) increased economic integration and establishment of free trade areas; 2) harmonisation of food security and agricultural policies; 3) support of (agricultural) research and development of regional centres of excellence, 4) infrastructure; 5) animal health and disease control; 6) management of shared resources and cross border environmental developments, 7) management of international migration, and; 8) capacity building, networking and exchanges.

At the global level the EU particularly provides financial support poverty reduction in the following areas: 1) global agricultural research with an emphasis on genetic resources; 2) collection, conservation, management and improvement and policy research; 3) effective and equitable IPR systems in the context of the TRIPS agreement; 4) actions to combat communicable diseases, like: HIV/AIDS, tuberculosis and malaria; 5) implementation of multilateral agreements by mainstreaming global concerns and objectives into national plans and sectoral strategies and helping developing countries to meet their commitments; 6) promotion of international commodity agreements as a means for dialogues and co-operation among the main market partners (producers/exporters and importers/consumers), and; 7) sharing of knowledge related to poverty reduction and poverty-environment linkages.

---

## **2.2 International co-operation and the life sciences and biotechnology strategy**

---

Since 1983 the EC has been involved in enhancing international scientific and technological (S&T) co-operation. In 1995 all related scientific activities were grouped together in a single international co-operation programme, known as INCO. While the main aim is to create scientific and technological research capacity in developing countries, INCO projects are however not purely technological but they also integrate environmental and social dimensions. This does not necessarily imply that INCO projects should contribute to poverty reduction in developing countries. In 1997 the EC started to mobilise the various existing instruments for science policy, i.e. the Framework Programmes, and development policy, the European Development Fund (EDF), in order to promote research as a development policy instrument.

In 2001 the EC launched the 'European Research Area' (ERA). This also provides a framework for international S&T co-operation, given its four strategic objectives: 1) make the ERA more attractive to the best scientists and make it a world class reference centre; 2) enable European researchers and industrialists to access knowledge and technology available elsewhere in the world; 3) develop scientific and technological activities useful to the implementation of EU foreign and development policy, and 4) enlist the scientific and technological resources of the EU and of third countries in initiatives that provide a response to significant world problems of concerns to the EU.

Furthermore, in 2002 the EU adopted a life sciences and biotechnology strategy, which aims at contributing to the competitiveness objectives established by the Lisbon European Council of 2000, i.e. to become the most dynamic and competitive knowledge-based economy of the world by 2010. This strategy is based on four pillars. One of these pillars is 'responding to global challenges through international collaboration and taking responsibilities towards developing countries', suggesting in a series of support actions in areas, like public health, agriculture, genetic resources conservation and use, and regulatory requirements.

In 2002 the European and Developing Countries Clinical Trials Partnership (EDCTP) was established with funding from the 6<sup>th</sup> Framework Programme and contributions from 14 EU member states and Norway, while also funding will be sought from private sources. The EDCTP provides a platform for bringing together and accelerating the efforts at national level in European states to develop new clinical interventions to fight HIV/AIDS, tuberculosis and malaria in developing countries, particularly sub-Saharan Africa, and to improve the quality of research.

Two years later, in 2004, the EC and public and private stakeholders established two technology platforms in the areas of green and white biotechnologies: 1) the European Technology Platform Plants for the Future co-ordinated by the European Plants Science Organisation (EPSO) and the European biotechnology industries association EuropaBio, and; 2) the European Technology Platform for Sustainable Chemistry co-ordinated by the European chemical industries association CEFIC and EuropaBio. Both platforms are intended to function as multi-stakeholders forums. None of these two platforms has as yet identified opportunities for development of (pro-poor) biotechnologies in developing countries.

### 3. Other public and private stakeholders

---

Other actors from the public sector, the private sector and the civil society also have strategies and are implementing programmes and actions, which shape the three biotechnology development functions. However, the resources dedicated and the political-economic bargaining power available to shape the conditions for biotechnology development vary considerably between large international (biotechnology-based) corporations versus the public sector and end-users (groups), like small and medium-sized Enterprises (SMEs), local entrepreneurs, (resource-poor) farmers organisations and consumers and patients (organisations), especially in developing countries.

At present, the investments by the private sector in material and human research capabilities for biotechnology research and development substantially outrank those provided by the public sector. Particularly in the area of healthcare, red biotechnologies are therefore mostly directed at needs and markets in industrialised countries. By contrast, in the area of green, blue and white biotechnologies, the public sector is the main investor in Agricultural Research for Development (ARD) and biotechnology research directed at the needs of small-scale farmers growing local 'economically orphan' crops, like millet, sorghum, cassava, and fish species, like tilapia. Though, for export products, like oil palm, coffee, cotton and shrimps, the public and private sectors nowadays have complementary roles. Similarly, for control of major (communicable) diseases as HIV/AIDS, tuberculosis and malaria, it seems that today the public and private sectors have also complementary roles. This is probably also true for 'economically orphan' or 'neglected' diseases, for instance sleeping sickness, although the public sector seems so far to be the main investor.

The role of end-users and the civil society in setting policy and research priorities and implementing solutions is thereby increasingly acknowledged, particularly in the context of development co-operation policy. In the context of biotechnology development, the civil society, i.e. environmental, consumer and development non-governmental organisations (NGOs), also play an important role in shaping the conditions for the development and adoption of biotechnologies. Many of these NGOs in the North and the South have adopted a critical stance on further biotechnology development. From their perspective, the agenda for biotechnology development is largely determined by the private sector, often supported by governmental policies. Particularly, the application of GM technologies to agriculture and food production is rejected for environmental as well as socio-economic reasons. These organisations mostly advocate to further develop organic and (low-input) agro-ecological agricultural systems in the North and in the South. Moreover, developments of healthcare biotechnology, e.g. cloning of human embryo's and animals, testing on humans and animals of experimental medicines, stemcell research, gene therapy, etc., are also scrutinised by

various NGOs, like patients and human rights groups and animal rights and animal welfare organisations, whose views and interests do not necessarily coincide.

Finally, other actors from the public sector at the national level in EU member states and non-EU countries and at regional and global levels also contribute to the shaping of the conditions for biotechnology development. It should thereby be noted that both the EU and its member states have delegations in many of the international bodies. Three different types of international organisations with different public sector actors can be distinguished:

- Science-based organisations or institutions, including the World Health Organisation (WHO), the United Nations Food and Agriculture Organisation (FAO), Codex Alimentarius, the Consultative Group on International Agricultural Research (CGIAR), etc.
- Trade based organisations, like the World Trade Organisation (WTO), and intellectual property rights organisations, like the World Intellectual Property Organisation (WIPO), the Union for the Protection Of Varieties of Plants (UPOV), and the European Patent Convention, etc.
- Institutions with social-political and environment protection goals, including the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety, various United Nations (UN) organisations, the Organisation of Economic Co-operation and Development (OECD), regional initiatives like the European Union (EU), etc.

Again, all these other public sector actors may have views, interests and strategies for biotechnology development, which sometimes converge and sometimes diverge or even conflict with each other. Moreover, communication strategies and information campaigns by various actors of the public and private sector and civil society aim at impacting public opinion as formed in the media, and thereby also attempt to shape conditions for developments in biotechnology.

---

#### 4. Clustering developing countries

---

Similar to the term ‘biotechnology’, many definitions and classifications have been proposed by various institutions and organisations for ‘developing countries’. Three different clusters of developing countries can be distinguished on the basis of the institutional development of biotechnology R&D, coherence of implementation of national policies, involvement in International Conventions and trade agreements, and socio-economic opportunities and constraints in (market) adoption of biotechnology R&D:

- Potential leaders in biotechnology: China, India, Brazil and Argentina.
- Dynamic adopters of biotechnology: Egypt, Kenya, South Africa, Thailand, Malaysia, Cuba, Mexico, Chile, Honduras and Costa Rica
- Marginalised countries: majority of African, Caribbean and Pacific countries.

Moreover, also many different criteria and classifications have been suggested for ‘poor’ or ‘resource-poor’ countries, like for instance ‘living on less than one US dollar per day’. While there are currently about 75 to 100 million people having a purchasing power parity of 20,000 dollars per year or more, 1.5 to 1.75 billion people have a purchasing power parity of 1,500 to 20,000 US dollars per years. Of the remaining four billion people with substantially lower purchasing power, the overwhelming majority lives in a ‘developing country’, irrespective of the country’s stage of advancement in research and application of biotechnologies. Most of these people are somehow confronted with poverty in at least one of the six EC poverty reduction policy dimensions.

At present, not all biotechnology developments in a developing country are necessarily ‘pro-poor’. Yet, a pro-poor biotechnology may also directly or indirectly be beneficial to middle-income and high-income people in developing and industrialised countries. For example, new vaccines for the prevention of animal diseases will affect all income-groups similarly, as national or regional sources of the diseases are eradicated. This could also be important to control zoonotic animal pathogens turning into dangerous human pathogens, like SARS, which can rapidly spread over the globe. The same goes for a water sanitation installation using white (pro-poor) biotechnologies, which helps prevent the spread of diseases like cholera.

## **Phase III : Key Elements of an EU Pro-Poor Biotechnology Strategy**

### **1. Purpose of Phase III**

The purpose of Phase III is to design practical operational guidelines to assist decision-makers considering EU support for pro-poor biotechnologies in developing countries. The guidelines presented in Phase III build on a review of the present and future situation of (pro-poor) biotechnology development in developing countries (Phase I) and of current biotechnology policies/strategies of the EU and various other actors from the public and private sector and civil society (Phase II).

### **2. Necessity of pro-poor biotechnology development in developing countries**

The analysis in Phase I pointed at the potential of biotechnologies to address problems related to poverty reduction and sustainable development in developing countries. Yet, it is not simply the case of needing to indicate in general when and why pro-poor biotechnology is necessary in a developing country. Biotechnologies may provide the most efficient technical means to address a problem, but that problem first requires to be carefully analysed by all stakeholders involved in order to establish the different perspectives and solutions available to the developing country.

It can be argued in general that public sector actors in developing countries have an incentive to seek (further) development of biotechnology. Otherwise it will be difficult to integrate their countries into a global economy of products and services, which are increasingly based on the application of life sciences and biotechnologies.

### **3. Essential features of a pro-poor biotechnology**

A biotechnology can be defined as ‘pro-poor’, if it contributes to an economically, socially and environmentally sustainable solution to one of the different types of poverty existing in a developing country. Given the prevailing livelihoods of most ‘resource-poor’ people in developing countries, essential features of a pro-poor biotechnology programme should include that:

- It takes into account that in developing countries particularly women and children carry the burden of poverty.
- It is affordable and accessible for urban and/or rural poor.
- It is applicable under marginal conditions.
- It enhances the efficiency and sustainability of production systems and assets of poor in both urban or rural areas while fostering local entrepreneurship.
- It improves the livelihoods of poor both in urban and rural areas.

- It complies with international safety and quality standards.
- It is based on a sound risk assessment and risk management framework adapted to local environmental and socio-economic circumstances.

Furthermore, a pro-poor biotechnology requires appropriate back-up services of legal and regulatory advice, education, training, maintenance, (micro-) credit-systems, storage facilities and distribution channels or markets.

#### **4. Prerequisites and needs for pro-poor biotechnology development**

---

Biotechnology development requires long-term commitment from developing country governments. It is not a quick fix for growing economies, enhancing the health and food security of their populations. It requires funding for many years and it takes time to build all the elements needed for adoption of biotechnology products and services.

Essential building blocks are an advanced education system, a high level of scientific excellence, a business-friendly set of intellectual property rights laws, an adequate regulatory infrastructure, and adequate systems for healthcare, seed distribution, agricultural extension services, financing (small and medium-sized) enterprises, facilities for transport, storage and distribution facilities, etc. Even if all these elements are in place, there are still no guarantees that a national biotechnology programme will be successful. For investors in industrialised countries biotechnology is a *'leap of faith'* with high financial risks at stake. For developing countries where research & development expenditures are only a fraction of the gross national product, educated labour is rather limited, economic difficulties are frequent, venture capital is an unknown phenomenon, intellectual protection is uncertain and political turmoil regularly upsets good governance, it is much harder to advance successfully a national biotechnology programme.

The table below sets out the various prerequisites and needs of a pro-poor biotechnology development programme in a developing country and the possible strategic actions to address them.

<b>PREREQUISITES &amp; NEEDS FOR BIOTECHNOLOGY AND STRATEGIC ACTIONS</b>
--------------------------------------------------------------------------

<b>BIOTECHNOLOGY RESEARCH &amp; DEVELOPMENT (R&amp;D) CAPABILITIES</b>	
Human research capabilities	<ul style="list-style-type: none"> <li>• Strengthen education and training, nationally and internationally.</li> <li>• Support integration into the international scientific community.</li> <li>• Support exchange of scientists and engineers.</li> <li>• Prevent brain-drain.</li> <li>• Strengthen R&amp;D management expertise.</li> </ul>
Material research capabilities	<ul style="list-style-type: none"> <li>• Improve IT infrastructure and computing power.</li> <li>• Ensure access to the Internet, scientific literature, patent databases and databases with biological data central to bio-informatics.</li> <li>• Support building and upgrading of laboratories, greenhouses, clinics, etc., incl. Facilities for so-called 'contained use' of GMOs.</li> <li>• Ensure availability of equipment, chemicals, tests, facilities, etc.</li> </ul>
Public-private partnerships & technology platforms	<ul style="list-style-type: none"> <li>• Gain knowledge and better understanding of 'successful' models for public-private partnerships (PPP).</li> <li>• Test and implement models for PPP.</li> <li>• Extend European technology platforms to include collaboration with parties in developing countries.</li> </ul>
<b>FACILITATION AND CO-ORDINATION OF PRO-POOR BIOTECHNOLOGY R&amp;D</b>	
Aligning biotechnology R&D priorities with National Poverty Reduction Strategy and Sector-Wide Approaches	<ul style="list-style-type: none"> <li>• Strengthen social sciences research and policy evaluation.</li> <li>• Provide aid to policy analysis, formulation and implementation.</li> <li>• Support access to findings of international research on social, economic and environmental impacts.</li> <li>• Support awareness rising and involvement of poor people, civil society organisations and small and medium-sized enterprises in the policy processes.</li> <li>• Create an attractive financial environment for public-private partnerships and innovative (start-up) firms.</li> <li>• Monitor regional and international developments in biotechnology R&amp;D and policies and strategies of various actors from the public and private sectors and civil society.</li> </ul>
Establishing benefit-sharing mechanisms for technology transfer and intellectual property rights	<ul style="list-style-type: none"> <li>• Train public sector actors to deal with legal and material issues surrounding proprietary technologies and genetic resources.</li> <li>• Support public sector patenting and license-free usage of pro-poor biotechnologies.</li> <li>• Stimulate initiatives for open source biotechnology tools.</li> </ul>
Establishing regulatory oversight on biotechnology R&D activities	<ul style="list-style-type: none"> <li>• Support building of administrative capacity for regulatory oversight on experimental testing and commercial use of GMOs.</li> <li>• Enhance scientific capacity for risk assessment and management of GMOs.</li> </ul>

	<ul style="list-style-type: none"> <li>• Strengthen capacity for enforcement of biosafety regulations.</li> <li>• Ensure transparency of regulatory systems and public understanding of regulatory oversight practices.</li> <li>• Address liability issues.</li> <li>• Ensure freedom of choice for consumers, farmers and other operators in the agro-food chain between GM and non-GM products.</li> <li>• Ensure that international regulatory requirements remain manageable in developing countries.</li> </ul>
Implementing and influencing international conventions and trade agreements	<ul style="list-style-type: none"> <li>• Provide support to building implementation expertise.</li> <li>• Support participation of developing country delegates in negotiation of international conventions and trade agreements.</li> <li>• Support legitimate interests of DCs in international fora for pro-poor biotechnology.</li> <li>• Improve capacity for economic and policy research.</li> <li>• Promote <i>sui generis</i> systems for intellectual protection of indigenous knowledge.</li> </ul>
<b>FACILITATION OF ADOPTION OF PRO-POOR BIOTECHNOLOGY R&amp;D RESULTS</b>	
Establishing arrangements for adoption of biotechnology R&D results	<ul style="list-style-type: none"> <li>• Support engagement of poor people (groups), civil society organisations, small and medium-sized enterprises and public-private partnerships in determining adoption arrangements.</li> <li>• Create financial instruments to facilitate adoption.</li> </ul>
Strengthening public mechanisms for social-ethical scrutiny of biotechnology	<ul style="list-style-type: none"> <li>• Improve capacity for social sciences, philosophy and (bio)ethics.</li> <li>• Foster public communication and public mechanisms for social-ethical scrutiny, like ethical committees, stakeholder dialogues, citizens' juries, public debates, etc.</li> <li>• Provide information to media and journalists.</li> </ul>
Disseminating biotechnology R&D results	<ul style="list-style-type: none"> <li>• Support building and upgrading of infrastructures for storage, transport and distribution/marketing of seeds, planting materials, harvest, etc.</li> <li>• Support building and upgrading healthcare infrastructures.</li> </ul>

**5. Present EU policies and strategies relevant to developing countries**

**CURRENT EU POLICIES AND STRATEGIES RELEVANT TO PRO-POOR BIOTECHNOLOGY**

Trade policy	Development policy: Reduce poverty in DCs	European life sciences and biotechnology strategy: Respond to global challenges	
	Development policy concentration areas*	International Science & Technology (S&T) co-operation: Objectives	Life sciences and biotechnology strategy (“Response to global challenges”): Actions
EU Regulation for tiered pricing pharmaceuticals for DCs	Trade and development	<p>Three of the four objectives of the ‘European Research Area’ are:</p> <ol style="list-style-type: none"> <li>1) Attract the best scientists and make the ERA a world class reference centre.</li> <li>2) Enable Europe to access knowledge and technologies available elsewhere in the world.</li> <li>3) Enlist S&amp;T resources of the EU and third countries to tackle global problems of concern to the EU.</li> </ol>	<ol style="list-style-type: none"> <li>1) Ensure that international regulatory requirements remain manageable in DCs.</li> <li>2) Support participation of DC delegates in negotiation of international conventions.</li> <li>3) Disseminate findings of international research on social, economic and environmental impacts.</li> </ol>
Zero tariffs import pharmaceuticals from WTO members	Regional integration and co-operation	<ol style="list-style-type: none"> <li>1) INCO programmes for creating S&amp;T research capacity in DCs.</li> <li>2) One of the four objectives of the European Research Area is to develop S&amp;T useful to the implementation of EU foreign and development policy.</li> </ol>	Promote greater regional co-ordination in legislation.
Support to Doha declaration TRIPs & public health	Support to macro-economic policies		<ol style="list-style-type: none"> <li>1) Support research to combat HIV/AIDS, tuberculosis, malaria and other poverty-related diseases.</li> <li>2) Support DCs in establishing a healthcare infrastructure.</li> </ol>

	Food security and sustainable (rural) development		1) Support agricultural research. 2) Establish public private partnerships. 3) Support conservation, sustainable use and benefit sharing of genetic resources.
	Institutional capacity-building, good governance, rule of law		Support biosafety capacity building in DCs for implementation of the Cartagena Protocol on Biosafety

\* Transport is the sixth development policy area of concentration and also of relevance to pro-poor biotechnology

The main objective of EU development policy is poverty reduction in developing countries (DCs) in alignment with the United Nations (UN) Millennium Development Goals (MDGs). It thereby aims at increased civil society participation and private sector involvement and synergy between national, regional and global levels, ensuring regional integration. Moreover, within the European life sciences and biotechnology strategy a series of actions is explicitly aimed at addressing various prerequisites and needs of developing countries for (further) development of (pro-poor) biotechnology. EU trade policy importantly seeks to improve access for developing countries to medicines in various ways. As the analysis in Phase II indicated, at all geographical levels the EU is currently intervening and supporting actions that are relevant to each category of prerequisites and needs for pro-poor biotechnology development in developing countries. It is therefore suggested that for an effective implementation of an EU strategy for pro-poor biotechnologies in developing countries coherence [synergy of biotechnology actions] across various EU policy areas is a primary condition. The table above summarises the main intervention areas of current EU policies and strategies in so far as they are relevant to (pro-poor) biotechnology development in developing countries.

**6. Specific features of clusters of developing countries**

In developing countries most poor people are confronted with poverty in one or more of its dimensions. At the same time a few developing countries are well advanced in biotechnology development and are closely followed by a series of other developing countries, whereas most developing countries are marginalised.

It should thereby be noted that from a perspective of the EC domestic policies on competitiveness and science and technology, support for international collaboration in biotechnology in whatever developing country, and not necessarily pro-poor, is considered to be in the interest of the EU’s own domestic strategic objectives. International science and

technology collaboration would enable the EU to access knowledge and biotechnologies available elsewhere in world, in particular in the case of potential leaders and dynamic adopters of biotechnology in developing countries. Moreover, the EU has also an interest to gain access to biodiversity and genetic resources, which are mostly present in DCs, whatever the cluster it belongs to.

The table below shows specific features of each of the three different clusters of DCs in relation to biotechnology development prerequisites and needs.

#### CLUSTERS OF DEVELOPING COUNTRIES & BIOTECHNOLOGY PREREQUISITES / NEEDS

Prerequisites / needs	Potential leaders	Dynamic adopters	Marginalised countries
R&D capability	Superior	Substantial	Limited
Biosafety capacity	Substantial	Limited	Very limited
Involvement ICs & TAs	Adequate	Limited	Very limited
Adoption by markets	Yes	Not easily	If any, not easily
Examples	China, India, Brazil, Argentina	Egypt, Kenya, South Africa, Thailand, Malaysia, Cuba, Mexico, Chile, Honduras, Costa Rica	Majority of African, Caribbean and Pacific (ACP) countries

R&D = research & development; ICs = international conventions; TAs = trade agreements

**Potential leaders** have superior biotechnology R&D capabilities themselves and also have considerable capacity to evaluate and to adopt biotechnology innovations developed in industrialised countries. Yet, these developing countries might lack some biosafety capacity, while mechanisms for ensuring public participation in decision-making are often rather weak. As this constrains the safe use of biotechnologies as well as equitable benefit sharing between innovators and poor people, the EU's main contribution should be to **support further capacity building for biosafety** and to **support the introduction of the goal of poverty reduction into national biotechnology development programmes**.

Most **dynamic adopters** often lack capacity to evaluate whether to accept or reject biotechnology innovations from industrialised countries. Moreover, they regular lack biosafety capacity and often do not have sufficient human and material research capabilities and a skilled public administration capable of analysing, formulating and implementing the various policies for co-ordination of biotechnology R&D activities and the (market) adoption of biotechnology R&D findings. The EU's main contribution should be to assist these developing countries in **building and sustaining capacity for biosafety and for policy analysis, formulation and implementation**, including mechanisms for a reasonable

evaluation of biotechnology innovations. The EU should also provide **support to the introduction of the goal of poverty reduction into national biotechnology development programmes.**

Many of the **marginalised countries** are however beyond this kind of assistance, as they even do not have the most basic features to develop, evaluate and/or adopt biotechnology innovations from industrialised countries. They may be willing to accept any biotechnology offered, provided it has a reasonable potential to contribute to further (macro-) economic development. The EU should **provide support to these developing countries in addressing the various prerequisites and needs for biotechnology development.** In this case the EU should also work at the global level to prompt the global community to **support the positions of these developing countries in negotiations in international conventions and trade agreements.**

At present a wide range of other actors from the public and private sectors and civil society are also supporting a variety of actions for addressing the prerequisites and needs of biotechnology development in developing countries at national, regional and global levels. It should thereby be noted that the EU and its member states are at the same time also represented in many international institutions and organisations, including WTO, WHO, Codex Alimentarius, FAO, CGIAR, UNIDO, UNESCO, UNICEF, UNEP, OECD, WIPO, UPOV, CBD, etc. In addition, several EU member states are also supporting programmes for biotechnology development in various developing countries.

In this intricate international policy context, the **EU should essentially seek to strengthen support actions by other actors and contribute to their co-ordination, in order to avoid duplication of efforts.** If necessary, the EU should support complementary actions. For example, some EU member states but also the USA, Canada and Switzerland have supported programmes and projects for biosafety capacity building in a series of developing countries over the last decade. Moreover, several UN organisations have also provided support and have recently stepped up their efforts, in particular for enabling developing countries to meet the requirements of the Cartagena Biosafety Protocol. So, if the EU chooses to support an action for biosafety capacity building in developing countries, the appropriate geographical level (national/regional) for intervention and the added value thereof should be clarified beforehand. On the other hand, as the EU and its Member States are also members of international organisations, which negotiate technical standards and regulatory requirements, they should aim to ensure that international biosafety requirements remain manageable for developing countries.

Another example is support for actions improving human research capabilities and policy analysis in developing countries. Several international organisations, such as UNIDO and

UNESCO, as well as the EU, some Member States and countries like the USA and Canada are now supporting a series of programmes to increase human research capabilities in developing countries. In order to enhance the effectiveness of all these efforts, the EU should not only choose to extend its own programmes and actions but also seek to create synergies with the support provided by other public sector actors through better co-ordination.

It should further noted that the EU and/or Member States are also involved in several multi-stakeholder forums, technology platforms and public-private partnerships, which are already addressing or could be addressing the prerequisites and needs of biotechnology development in developing countries at national, regional and global levels. Since public-private partnerships are increasingly viewed as being indispensable for further biotechnology development, not only in developing countries but also in developed countries, it is urgent to identify the conditions for success and best governance practices for public-private partnerships. While the number of public-private partnerships in agricultural biotechnology has been rather modest compared to their number in healthcare biotechnology, many of them could not be sustained, often due to cultural mistrust between public and private sector actors and intellectual property issues. Yet, there are also promising examples of successful public-private partnerships, which yielded access for public research institutes to proprietary technologies of private sector actors from industrialised countries, while the latter gained access to local genetic resources.

There are various regional initiatives for co-operation in legislation and other policy matters, as well as research networks, which are also relevant for addressing one or more of the prerequisites for pro-poor biotechnology development in developing countries and regions thereof. The EU should also target such regional initiatives and networks for support actions, in so far as it would yield added value.

Finally, it should be acknowledged that there may often be an over-lap in decisions between EU and developing countries. Whatever policy and strategy the EU elaborates within life science and biotechnology, they will undoubtedly have major impacts for developing countries, while the potential benefits for the EU are knowledge and experience from developing countries of agricultural (and industrial) systems operating under marginal conditions. As the EU has its own domestic strategy for life sciences and biotechnology, the internal EU deliberation mechanisms for the facilitation and co-ordination of its implementation could also be helpful for a coherent implementation of an EU strategy for pro-poor biotechnology development in developing countries. For that purpose, the monitoring and foresight functions of the EU and its member states should be extended, so that the prerequisites and needs of pro-poor biotechnology development in (regions of) developing countries can be precisely identified. The aim should be to **create coherence in**

**EU policies, added value from EU support actions and synergies with support actions by other actors from the public and private sectors and civil society.**

Support of pro-poor biotechnology research & development activities of transboundary interest, its facilitation and co-ordination and the facilitation of adoption of pro-poor biotechnology R&D results at the regional level could be the primary strategic choice for the EU, as:

- It takes into account EU advantages, like its regional co-operation focus, political and economic weight, grant aid, etc., and limitations, such as limited staff, financial and procurement procedures, etc.
- It bridges and complements other sources of support to (pro-poor) biotechnology development in developing countries at national, regional and/or global levels, either multilateral, e.g. United Nations (UN) agencies, World Bank and Regional Development Banks, etc.), or bilateral, in particular from EU Member States.

**7. Specific features of green, blue, white and red biotechnologies**

---

As the analysis in Phase II showed, most of the green, white and blue biotechnologies could in principle be further developed to address themes identified by Agricultural Research for Development (ARD) and priorities identified by the CGIAR. The EU support guidelines and the evaluation mechanisms developed within the European Initiative on Agricultural Research for Development (EIARD) should therefore be used for advice to EU decision-making on proposals to address one or more of the prerequisites and needs of development of green, blue and white biotechnologies.

Green biotechnologies in developing countries should thereby focus on the development of those crops that are better suited to fight against poverty. The GM crops that have been developed so far are largely ill suited to contribute to that objective.

Though, it should be noted that EU (policy) initiatives for blue and white biotechnologies has so far been rather limited, in future initiatives in these areas could not only address problems in developing countries but also to find solutions for its own problems in fisheries, aquaculture, industrial production and environmental management.

Recent initiatives, like the European Technology Platform for Sustainable Chemistry should be extended with a view to address several of the prerequisites and needs of development of white biotechnologies in developing countries. The European Technology Platform Plants for the Future should also be extended, in order to contribute to poverty reduction and

sustainable development in developing countries. And a European Technology Platform Fish for the Future should be launched, in order to address problems with fisheries and aquaculture in the EU, as well as developing countries.

In a similar vein, consideration should be given to use the European Developing Countries Clinical Trials Partnership for advice to EU decision-making on proposals to address one or more of the prerequisites and needs of development of red biotechnologies.

While biotechnologies encompass a wide range of tools and methods to adapt the genetic make-up of organisms used in agriculture and food production, genetic modification of crops and animals, including fish, are areas where green and blue biotechnologies most directly affect agriculture and aquaculture in developing countries. In these areas public concerns and debates have emerged in the industrialised world, as well as in developing countries. The use of genetic modification for the development of red biotechnologies may be less controversial to the public, but even so it is imperative in order to gain public trust to **ensure transparent regulatory oversight on biosafety of testing and using genetically modified organisms**. In the EU public concerns have led to a stringent regulatory framework for the use of genetically modified organisms, i.e. GM crops, from farm to fork. These public concerns also contributed to decisions by major retail firms and food manufacturers to avoid the use of ingredients of GM crops. Consequently, several biotechnology companies and seed industries decided to stop GM plant breeding in the EU. At present, the number of field experiments is still limited in the EU, while commercial cultivation of GM crops is negligible. By contrast, in several developing countries GM crops have been commercially grown on millions of hectares over the last couple years and many public research institutes have a large variety of different GM crops in the pipeline. At the same time, many of these developing countries lack sufficient capacity for regulatory oversight of (field) testing and growing GM crops. **Capacity building on biosafety is therefore essential in developing countries**.

A public research institute in Egypt has developed a GM insect-resistant consumption potato, which is more or less ready for commercial use. However, this GM consumption potato cannot be exported to one of its usual markets, Europe, since it first needs regulatory clearance. Moreover, exports of conventional non-GM consumption potatoes to Europe will be jeopardised, if Egypt does not take appropriate measures for co-existence and segregation to avoid admixture of GM and non-GM potatoes.

Additionally, for developing countries wishing to export GM crops and GM foods and feeds to the EU, it is imperative they meet the EU regulatory requirements for risk assessment but also for **labelling and traceability of GM agro-food products**. The EU regulatory

requirements have a two-fold aim, ensuring a high level of safety and freedom of choice for consumers and operators in the agro-food chain between GM and non-GM products. The labelling-threshold for the adventitious presence of GM material in non-GM food and feed (ingredients) has thereby been set at 0.9 %, while the labelling-thresholds in case of non-GM seeds and planting materials have not yet been determined. It should also be noted that all ingredients of GM crops, like soybean oil or maize starch, also must be labelled, irrespective of the presence of ‘modified’ DNA or protein. Traceability of such ingredients can only be assured through documentation. The three main sources of ‘GM contamination’ are seed multiplication and crop cultivation, due to ‘outcrossing’ of GM material, and admixture during harvesting, storage, transport and processing. Ensuring choice between GM and non-GM products thus requires ‘co-existence’ measures for growing GM, conventional and organic crops, as well as segregation measures for harvesting, storage, transport and processing. Support to adequate capacity building in developing countries for implementing and enforcing biosafety regulations and for **enabling freedom of choice** for consumers and operators in the agro-food chain **between GM and non-GM products** is of utmost importance.

For red biotechnology products, like biomedical proteins (biopharmaceuticals), and gene and cell therapy products, the EU has recently revised its pharmaceuticals legislation. By contrast to the short-track authorisation procedures for chemically synthesised generic pharmaceuticals, so-called ‘biogenerics’ (generic biomedical proteins) need to undergo a full authorisation procedure. For developing countries with R&D and production capacity for biomedical proteins, this might be an obstacle to exporting biogenerics to the EU.

The implementation of both EU regulatory frameworks for healthcare biotechnology products and for agro-food biotechnology products requires an efficient and effective functioning of the interfaces between ‘vertical’ product legislation and ‘horizontal’ GMO legislation. Notably, at these interfaces the Commission, the European Medicines Evaluation Agency (EMA), the European Food Safety Authority (EFSA) and Member States sometimes experience difficulties in co-ordinating and fine-tuning data or protocol requirements in the context of centralised assessment and authorisation procedures, given specific national or regional circumstances. Developing countries pursuing regional strategies for regulatory oversight of biosafety might be confronted with similar challenges.

There is a worrying trend that threatens to hinder the progress of science and technology at a fundamental level in developing countries. **Access to key data and research tools used in the development of new biotechnologies has become increasingly limited.**

In the case of so-called Golden Rice, a GM rice variety with enhanced vitamin A content to combat vitamin A deficiency in developing countries, patent rights on research tools had initially been side-stepped by the researchers. But the effect of the existing 'patent thicket' presented severe difficulties after the Golden Rice had been created. Six different alternative strategies were discussed, ranging from inventing around the current patents (a time-consuming and possibly futile endeavour), to risking litigation by ignoring all intellectual property rights. Nonetheless, in order to release the rice free of proprietary restrictions to resource-poor farmers in all developing countries in Asia, the International Rice Research Institute (IRRI) needed a freedom-to-operate (FTO), which required to obtain about 30 to 40 patent licenses from a dozen private and public entities. According to the CGIAR, the negotiations to obtain a licence for the central patents required an enormous effort.

A broadening of intellectual property rights and increased pressures for commercialisation in both the private and public sectors mainly in industrialised countries seems to constrain the public domain for basic research, as well as to magnify the difficulty of obtaining the variety of research tools. In particular the proliferation of patent rights can impede or effectively preclude use of the tools altogether. Not surprisingly, some studies indicate that researchers have circumvented the patent system, in order to carry out their work.

As the CGIAR operates under a policy of free dissemination of information and biological materials, its germplasm collection is available to anyone wishing to make use of its resources. For example, one of the rice varieties bred by the IRRI, which contained the so-called Xa21 gene from a genetic sample/resource from Mali and which forms the basis for a particular resistance to rice viruses and other environmental factors, was obtained by a university in the USA. There the Xa21 gene was mapped, sequenced and cloned. Since the researchers were able to express its general utility, a patent was granted, which essentially covered the Xa21 gene sequence. Given its importance for developing pest-resistant crops, the CGIAR wished to secure the right to use the gene and was therefore forced to enter into protracted and difficult negotiations, in order to gain access. It took several years of negotiations because the patent holder had already granted an exclusive license on the gene sequence to a private company. Eventually, the CGIAR was granted free access to the gene for research use in a non-commercial capacity. This type of third party patenting of genes derived from materials held in gene banks of public international agricultural research centres, has led the CGIAR to suggest that the IRRI reconsiders its limited proprietary protection over its own biological materials.

In relation to red biotechnologies development and products, it has been recognised by the EU and various other public sector actors that the intellectual property rights standards within the WTO agreement might be an obstacle to better access to medicines in developing countries. The compliance date for lesser-developed countries has therefore recently been

extended until 2016 by the Doha Ministerial Agreement. On the other hand, the US government is using bilateral and regional free trade agreements to impose intellectual property standards that go beyond WTO requirements, favouring the short-term commercial interest of US pharmaceutical companies at the expense of public health in developing countries.

Over the last couple of years, several international and regional public sector actors, like the World Bank, WIPO, FAO, EPO, etc. have provided technical training and support to developing countries. In addition, several public-private partnerships, such as ISAAA and the Medicines for Malaria Venture, have gained experience in brokering deals between private sector actors and public sector actors in developing countries. Nonetheless, actors from the public sector in developing countries often still lack the capacity and skills required for negotiating deals for access to proprietary biotechnologies from industrialised countries and giving public and private sector actors from these countries access to their country's biological and genetic resources. The EU should therefore seek to **support training programmes in intellectual property rights management for public sector actors in developing countries**. In accordance with the CBD the EU should thereby also seek to **strengthen good governance of public-private partnerships** aiming at technology transfer and equitable benefit sharing of the use of genetic resources in developing countries.

In order to formalise the protection of indigenous knowledge and local genetic resources, developing countries have advocated creating so-called *sui generis* protection systems, which would ensure equitable benefit sharing and technology transfer in the spirit of Convention on Biological Diversity (CBD). **Support to a *sui generis* approach** offers the possibility of moving beyond traditional forms of intellectual property rights and examining other mechanisms for regulating access to genetic resources and equitable benefit sharing between the users and custodians of the resources. Finally, in parallel to open source software developments in information technology, initiatives for open source biotechnology tools have been started recently, in particular to enable developing countries accessing knowledge and skills for developing biotechnologies. The EU should therefore start exploring whether to **support the development of open source biotechnology tools**.

The EU life sciences and biotechnology strategy indicates that **Europe attaches high value to social-ethical scrutiny of developments in life sciences and biotechnology**. On the other hand, practical experience shows that public debates and people's concerns and hopes are elementary forces shaping biotechnology R&D agendas and adoption arrangements for biotechnology products. While for example in some regions of the world GM foods seem to be adopted smoothly by consumer markets, public debate in Europe led to adoption arrangements ensuring choice between GM and non-GM foods. The cloning of animals, the development of GM laboratory animals and their patenting, gene therapy trials,

xenotransplantation and research on human stemcells are other examples of modern biotechnology, which led to different forms of social-ethical scrutiny in various parts of the world. For example, in some regions of the world governments kept funding human stemcell research, whereas in other parts of the world political debates led to restrictions. During the last decade the EU and many of its member states have gained considerable experience with a variety of public mechanisms for social-ethical scrutiny of biotechnology developments. Examples include public debates organised by national governments, citizens' juries, national and European stakeholder consultations and ethical committees at national level, the EU-level and the level of research institutions.

Another form of social-ethical scrutiny is public opinion as formed in the media by journalists and influenced by communication activities and information campaigns of actors from the public and private sectors and civil society. In the context of public opinion forming, the European Commission services and National Governments of EU Member States have also learned lessons in public communication, which are relevant to (regions of) developing countries.

Public mechanisms for social-ethical scrutiny are thus essential elements of governance of pro-poor biotechnology development in developing countries. Biotechnologies might provide the most efficient technical means to address a problem, but that problem first requires being carefully analysed by the stakeholders affected, in order to establish the different perspectives and solutions available to the developing country so as to agree upon the most appropriate actions for pro-poor biotechnology development. The EU should therefore **support initiatives at regional level, enabling the development and implementation of national public mechanisms for social-ethical scrutiny** of pro-poor biotechnology development in developing countries.

## 8. Key elements of an EU pro-poor biotechnology strategy

### CHOICES FOR EU SUPPORT TO DIFFERENT CLUSTERS OF DEVELOPING COUNTRIES

- **Potential leaders:** Support biosafety capacity building and support the introduction of the objective goal of poverty reduction in national biotechnology development programmes.
- **Dynamic adopters:** Support capacity building for biosafety and for policy analysis, formulation and implementation and support the introduction of the objective goal of poverty reduction in national biotechnology development programmes.
- **Marginalised countries:** Support actions for addressing the various prerequisites and needs of biotechnology development and support their positions in negotiations in international conventions and trade agreements.
- Seek to **avoid duplication of efforts** through contributing to **better co-ordination both EU and international level**. Identify the conditions of success and **good governance practices for public-private partnerships**.
- Support co-ordination of **North-South collaboration between EU member states and potential leaders, dynamic adopters and marginalised countries** for sharing of knowledge and best practices on pro-poor biotechnology R&D, facilitation and co-ordination of pro-poor biotechnology R&D and facilitation of adoption of pro-poor biotechnology R&D results by poor populations.
- Support co-ordination of **South-South collaboration between potential leaders, dynamic adopters and marginalised countries** on pro-poor biotechnology R&D, facilitation and co-ordination of pro-poor biotechnology R&D and facilitation of adoption of pro-poor biotechnology R&D results by poor populations.
- Extend the **monitoring and foresight functions of the EU** established for its own domestic life sciences and biotechnology strategy, in order to identify precisely the prerequisites and needs of biotechnology development in (regions of) developing countries. The aim should be **to create coherence between EU policies, added value from EU support actions and synergies with support actions by other actors** from the public and private sectors and civil society.

## MECHANISMS FOR CHANNELING EU DECISION-MAKING AND SUPPORT ACTIONS

### **Green, blue and white biotechnologies:**

- Use the (guidelines of) the European Initiative on Agricultural Research for Development (EIARD) for advice on EU decision-making on support actions.
- Extend the European Technology Platform Plants for the Future and the European Technology Platform for Sustainable Chemistry, in order to address also problems in developing countries. Launch a European Technology Platform Fish for the Future, in order to address problems with fisheries and aquaculture in the EU, as well as developing countries.

### **Red biotechnologies:**

- Use the (guidelines of) the European Developing Countries Clinical Trials Partnerships for advice on EU decision-making on support actions.

## CRUCIAL AREAS FOR EU INTERVENTIONS

### **Biosafety**

- Support administrative, legal and scientific capacity building in developing countries for implementing and enforcing biosafety regulations.
- Support administrative and technical capacity building in developing countries (exporting to Europe) in meeting EU traceability and labelling requirements of GM seeds, GM crops and GM food and feed (ingredients).
- Support capacity building for management of co-existence of cultivation of GM and non-GM crops and for segregation of harvesting, transport, storage and harvesting of GM and non-GM products.

### **Intellectual Property Rights**

- Support training programmes in intellectual property rights management for public sector actors in developing countries.
- Strengthen good governance of public-private partnerships, aiming at technology transfer and equitable benefit sharing of the use of genetic resources in developing countries.
- Support to a *sui generis* approach for regulating access to genetic resources and equitable benefit sharing between the users and custodians of the resources.
- Support the development of open source biotechnology tools.

### **Social-ethical scrutiny**

- Support initiatives at regional level for the development and implementation of national public mechanisms for social-ethical scrutiny of pro-poor biotechnology development in developing countries.

## **Phase IV : Implementation Modalities**

### **1. Introduction**

In Phase IV the principles are set out, which could be used to deal with the presentation of pro-poor biotechnology proposals submitted to the EU. These principles will thus be of interest to EU partners in developing countries, EC services and delegations themselves, and legal entities in the EU together with a partner in a developing country, wishing support for collaboration.

Furthermore, it is useful for EU partners in developing countries, delegations and legal entities in the EU and their partner(s) from the developing world to have a common view on how pro-poor biotechnology proposals for funding are analysed and assessed. Basically, a two-step procedure will be followed. Depending on the source of funds targeted, the EC delegations can provide developing country's institutions with the appropriate format to submit a pro-poor biotechnology proposal proposal. Legal entities in the EU and their partner(s) from the developing world can be provided by the EC services with appropriate formats.

### **2. Step 1: Screening a pro-poor biotechnology proposal against EU guidelines**

The first evaluation of a pro-poor biotechnology proposal will assess whether the considered developing country is a potential leader in biotechnology, a dynamic adopter or a marginalised country. It will also be assessed whether it will contribute to one or more of the prerequisites and needs for biotechnology development in a DC, and whether it addresses one or more of the different classes of poverty reduction identified by the EU's development policy.

The main aim of this first screening step is to identify the appropriate EU financial instruments and the appropriate bodies for advice on EC decision-making.

### **3. Step 2: Detailed assessment of the proposal**

After it has been established that a proposal fulfils most of the general eligibility criteria for EU support, the next step is to ensure that its approach is adequate to achieve the expected results.

The EC delegation in charge and/or the EC services involved should therefore request external experts and/or appropriate bodies (EIARD, EDCTP, technology platforms, etc.)

for a detailed assessment of its 'pro-poor' relevance, the proposed methodology, and the adequacy between objectives and means.

Given the various prerequisites and needs for (pro-poor) biotechnology development in a developing country, depending on the cluster it belongs to, there are a number of general and specific perspectives for the assessment of a proposal. It should be noted that the prerequisites and needs for facilitation and co-ordination of (pro-poor) biotechnology research and development and facilitation of adoption of biotechnology research results largely overlap, though, they might in the end differ considerably in their practical elaboration.

#### **ASSESSMENT OF PRO-POOR BIOTECHNOLOGY PROPOSALS FOR FACILITATION AND CO-ORDINATION**

- Is the proposal designed with the participation of intended beneficiaries and in response to their specific and defined needs?
- Is it likely that the proposal will contribute to the reduction of the various classes of poverty as highlighted in the EU's development policy?
- Will the proposal contribute to improved scientific, legal and administrative knowledge for better management and co-ordination of one or more of the three prerequisites and needs for (pro-poor) biotechnology development?
- Does the proposal carefully consider issues such as national macro-economic and sectoral policies, local producers, SMEs and public-private partnerships strategies in healthcare, agriculture, food security, industrial production, energy and environmental management?
- Could the proposal be dealt with better at another level, e.g. local, national, regional or global?
- Do the references cited in the proposal show that the request is relevant to the current state of the art of (pro-poor) biotechnology development, and that no replicate work will be done?
- Is the team presenting the offer best placed to execute the programme on the proposed issues?
- Are adequate scientific, technical, legal, administrative, commercial and social partnerships foreseen?
- Do individual experts, scientists, managers and assistants or teams and partners involved, like local producers and distributors, SMEs, public-private partnerships, poor people (groups) and NGOs have the necessary capabilities (or can acquire them) to carry out the programme?
- Are the work programme and methods, human resources and planning, and management procedures adequate to achieve the expected results?
- Are proper monitoring and evaluation systems incorporated, including perspectives of poor people (groups)?

## ASSESSMENT OF PROPOSALS FOR RESEARCH & DEVELOPMENT

### Pro-poor relevance

- The proposal states the major social, cultural, political, economic or technical issues to be addressed.
- It indicates explicitly how the needs of the beneficiaries have been identified and it includes an socio-economic analysis of the target group.
- The expected impact of the project in alleviating poverty is assessed.
- The expected impact on women is assessed.
- The expected impact on the environment is assessed.
- The project will contribute to building local research capacity and mechanisms for transferring knowledge are described.
- The proposal describes the risks associated with the research and its results; biosafety issues are addressed.
- The proposal is in line with the country's biotechnology and development policies.
- The proposal indicates the institutional and physical infrastructure required for the dissemination and adoption of new technologies.
- The project has the support of researchers, policy makers, beneficiaries and other stakeholders.

### Scientific relevance

- The research problem and objectives are clearly stated in the proposal.
- The proposed methodology is sound and takes into consideration the current state-of-the-art.
- The proposal indicates the scientific qualification of the individuals and organisations involved.
- The opportunities for national and international co-operation are identified.
- The scientific importance of the work and its originality are discussed.

### Operational and management aspects

- The proposal describes how the project will be managed.
- It describes how continuity will be ensured and it includes a realistic schedule for project implementation.
- It indicates how progress will be monitored and evaluated.
- It lists resource requirements: funds, scientific and support staff, buildings and equipment.

---

#### 4. Concluding remarks

---

Currently, the EU supports a series of actions that are relevant to various prerequisites and needs for (pro-poor) biotechnology development at all geographical levels, following from its policies in various areas, like trade, development and science & technology. For an effective implementation of a pro-poor biotechnology strategy, coherence across various EU policy areas and policy actors is a primary condition. This also applies to the implementation of the EU's own domestic life sciences and biotechnology strategy.

Experience so far shows that its implementation puts high demands on co-ordination and harmonisation of the various policies and actions at the national level of EU Member States and the regional EU-level on strengthening science and technology infrastructures, raising capital, improving human research capabilities, regulatory oversight, and societal-ethical scrutiny. The EU's internal deliberation mechanisms for the facilitation and co-ordination of the implementation of its own domestic strategy for biotechnology development could therefore also be helpful for an effective implementation of an EU pro-poor biotechnology strategy in developing countries, as well as to monitor the impact of such a policy in the developing world.

For all strategic choices identified in Phase III a series of financial instruments can be mobilised from various EU development co-operation and international science and technology co-operation policies, to support pro-poor biotechnology development at various geographical levels:

- Geographical budget lines: Asia, Latin America, Mediterranean, etc.
- Thematic budget lines: environment, food security, civil society participation, etc.
- European Development Fund: national, regional and intra-ACP funds.
- Framework Programme: INCO, European Research Area, Technology Platforms, etc.