

**BANKING OF GENETIC MATERIAL AND DATA IN EUROPE:
LEGAL, ETHICAL AND ECONOMICAL ISSUES**

EUROGENBANK
Project BIO4CT98-0570

**SCIENTIFIC AND ECONOMICAL REPORT
FOR
PLANTS, ANIMALS AND MICRO-ORGANISMS
IN SWEDEN**

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Introduction

The object of the study is to make an inventory of the European institutions, which store biological material and data. The inventory will help to analyse the structure of the existing collections and the databases and the way they operate. This study will cover information from Swedish collections of biological material held in institutions, willing to attain in the study.

Methodology for the choice of targets

The companies and organisations, which have been selected to attain in this survey, have been chosen upon following parameters. The organisations should have public or private collections with biological material or data for genetic analysis purposes. The collections should be accessible for the public.

Methodology for the gathering of information

After the target organisations were chosen the questionnaire and a letter in which we described the project were sent to the to the selected organisations. In the first part of the work we sent 29 questionnaires to the chosen target organisations.

We used the French questionnaire as a model with some changes to Swedish conditions. The questionnaire was not translated to Swedish.

Due to long distance to several of the respondents it was not possible to make personal interviews. Therefore the questionnaires were all sent by post.

The respondents who did not answer received a reminder by e-mail or by post, two weeks after the first letter was sent. A second reminder was sent another two weeks later. Some respondents were also contacted by telephone.

After correspondence with other teams participating in the project we decide to increase our target group and to send out another round with questionnaires. The second group consisted of institutions or companies such as medical companies, seed companies, marine research stations, associations for old Swedish landraces as well as zoos. In this second round we sent out 26 new questionnaires.

The compilation of the data was done during the spring 2000.

Results

From the first group of 29 questionnaires we received 11 answers, this result gave us an answering rate on 38 %. The second group with 26 questionnaires sent out, gave poorer result, we received 6 answers, which resulted in an answering rate on 23 %.

The total results from the study gave us 17 questionnaires, which means that 31 % of the addressed actors participated in the study.

In the second group many of the questionnaires were sent to organisations holding biological material or genetic data, but with material not organised in collections.

Some of the institutions were positive to the survey but could not find the time to fill in the questionnaire.

Table 1 shows the different target organisations and companies in the study. Most of the institutions belong to the public sector but we also find private companies in each of the three groups plants, animals, and microorganisms. In total we have eight private companies or organisations in our material.

Table 1. Target institutions in the study.

PLANTS	ANIMALS	MICROBIAL
Research station forest	Co-operative for semen	University
Botanical Garden	Horse -breeding company	Health institute
Genebank	Zoo	Dairy company
University	Embryo company	Veterinary institute
Private seed organisation	Association for conserving old cow varieties	
Potato company	Beekeeper association	
Private seed company		

Constitution of the collections

The creation dates of the collections vary a lot. For the plant and animal groups we have both young and old collections. The plant collections are the oldest ones, with origin back to 1916. Two collections dated back to 1940. In the animal group we find three collections created between 1990 and 1994. Most of the microbiological collections have a gradually organisation or no creation data reported.

The collections in Sweden are centralised into few institutions, which serve the whole country with information and material. In the plant group we have actors from both public and the private sector. In our material we find pure plant collections, pure seed collections as well as collections with combined material. The number of the species and the samples are show in table 2 and 3.

Table 2. Number of species in the plant group.

Crop categories	Number of species
Cereals	26
Fruit and berries	44
Forage crops	38
Vegetables	76
Rot and oil pulses	45
Spices	
Flowers	
Potatoes	1
Landscape forest and ornamental species	16 020

Table 3. Number of samples in the plant group.

Kind of sample	Number of samples	Total number of samples
Plants		113 483
<i>Landscape, forest and ornamental species</i>	110 000	
<i>Potatoes</i>	207	
<i>Fruit and berries</i>	3 320	
Seeds	30 541	30 541
<i>In vitro</i> preservation	173	173

The number of companies and organisations holding samples of genetic material from animals are limited. In our study we have collected data from different organisations such as semen and embryo companies for lifestocks as well as organisations for old Swedish cows and horses, one zoo and one beekeeper organisation. We also tried to collect information from the pig and poultry sector. However they were not interested in the study and we therefor lack information from these groups. In the animal group we find five private organisations and one public. Four of the actors are profit oriented. In table 4 and 5, kind of samples and accessions are presented for the animal group.

Table 4. Kind of samples and number of answers from the animal group

Animals	3
Semen	2
Embryos	1

Table 5. Number and kind of accessions in the animal collections.

	Number of species	Living animals	Embryos	Semen (doses)
Cows	4	260	1387	190 095
Horses	1			4000 doses
Bee communities	1	4000		
Zoo animals		850		

The microbiological collections belong to different kind of actors including one private actor. In the studied group we have collected information from university, one private company and two governmental organisations. Table 6 shows the number of species in the different collections.

Table 6. Content and size of the microbiological collections

Categories	Number of species	Number of collections
Micro-organisms	50	1
Micro-organisms	7100	1
Serum-bank	826 550	
Marine phytoplankton	75	1
Bacteria, fungi, viruses		1

The purpose of the different collections is in most cases research and conservation. As we can see in table 7 the purpose is research in 11 cases. The second most common purpose is conservation.

Table 7. Different purposes of the collections

	Number
Research	11
Conservation	9
Identification	1
Storage without defined objective	3
Healthcare	2
Education	2
Production for commercial activities	1
Breeding	1

In the study, 13 of the respondents have classified their collections as samples with unique material. Most of the plant collections consist of material adapted to the Nordic climate. The animal collections consist of animal adapted to the Nordic climate and old native breeds of cattle. We also find many safety duplicates within the collections. In the appendix 1-3 more details concerning the collections are shown.

Scientific work

Organisation

Almost all of the respondents are organised in co-operative agreement projects. Three of the institutions have co-operative agreement projects within the country. The rest also have contacts with institutions both in Sweden and in other countries. Nine of the respondents are organised in networks.

Maintenance of the collection

The level of computerised data is quite high, 11 of the institutions use a database for the management of the collection. Six of the institutions use self-made software while the rest use commercial ones. The sample databases are totally computerised in eight cases, six institutions have only partially computerised data. The year of computerisation varies between 1980 and 2000. Ten of the actors worked with the

computerisation during 1990 and 2000. Non computerised data comprises in most cases of older accessions.

Criteria for inclusion into the collections differ between the individual collections and the purpose of the collections. Some examples of criteria are focus on didactics and protection of threatened species. For the plant collections it is important that the plants shows true type and that they are distinguishable from other cultivars. Most of the collections contain specific varieties from Sweden and countries in the temperate zone. Materials for agriculture and horticulture of Nordic origin with importance for Nordic countries are common criterias for inclusion into the different collections. Other examples are material for breeding work such as botanical varieties, cultivars and genotypes with outstanding value. The microbiological collections operate under different conditions were other criteria such as strains under evolution, identification for research, for production and referee are important for the inclusion. For the animal collection criterias such as healthy Nordic bees and animals with Nordic origin are important for the inclusion.

Concerning inclusion of material, in some case permission is needed from the Swedish Board of Agriculture. Examples to mention are species under restriction and all activities concerning embryo transfer, storage and distribution. Companies and organisations working with semen activities, as collecting, storing and semination as well as distribution of the semen need permission from the Swedish Board of Agriculture. Breeding organisations responsible for the breeding activities in a specific race also have to follow specific guidelines given by the Swedish Board of Agriculture.¹

In the collected material we find one respondent contacting the board concerning inclusion of potato to the collections.

The most common length of time for storage of samples is 11 year or longer. There are no fixed storage times of material within the collections since these often consists of varying materials. The length also depends on the generation length of the material as well as priorities and demand for the material. Seven of the collections are duplicated.

Only one third of the group meant there was an optimum size of the collection. The reasons mentioned were related to the costs and space.

Some institutions have difficulties in handling the acquisition of material as regards to plants. Problems related to seed collecting due to the Biodiversity convention have been mentioned as example. For microorganisms transport safety regulations and survival during transport are other examples.

Concerning the management of collections, most of the institutions have financial difficulties due to lack of economic resources. Other problems could be to find volunteers for the handling of the animals and difficulties to avoid mixture with other raises.

¹ SJV författningar

Standards

Nine of the respondents follow a standard for conservation of the material. Depending on the different character of the material the standards vary between the different institutions. The most common way to conserve the seeds of the plant collections is to store them in a freezer at -20°C.

Plant taxonomists responsible for the identification and naming of samples follow specific standards. The material is monitored at the acquisition and at regular intervals during the storage. As example on standards monitored in the animal sector the international embryo organisations (IETS) manual are followed and as example in the micro-organism group QA system of relevant strains, accreditation according to EN 45001, are followed.

Standards for regeneration are common only in six institutions.

The material is monitored by more or less regular inventories through specific protocols, germination tests, and quantity check. As example mentioned in the animal sector, sometimes the lines have to be checked to secure the origin of the animal. To manage the regeneration of the collection, several activities need to be undertaken depending on the material in the collection. As example of the activities in the plant sector germination tests and quality check could be mentioned. Contract with seed growers needs to be arranged. In one case the members in the organisation take care of the regeneration of the seeds.

One question in the survey concern problems with contamination and how these problems could be avoided. The easiest way is to avoid inclusion of contaminated material by using material controlled by the local plant sanitary authorities. When shipping material a sanitary certificate is used. Other examples of answers are to use good sterile technique and a proper sanitary control. However the methods differ depending on the type of material the institution is working with.

Scientific activities

The activities differ between the different institutions. The most common activities for the institutions are characterisation and diversity study as well as evaluation of quality, evaluation of resistant to diseases and evaluation of agronomic performance. The results are shown in table 8.

Table 8. Different scientific activities in which the banks are engaged on regular or case-by case basis.

ACTIVITY	Number regular	Number case by case
Evaluation; resistance to diseases	3	2
Evaluation; quality	3	3
Evaluation; agronomic performance	3	2
Evaluation; other	2	0
Characterisation (polymorphism assessment, morphological/physiological or molecular)	5	1
Gene mapping	1	2
Functional molecular mechanisms	1	2
Diversity study(popular genetics, evolutionary studies)	3	3
Genetic epidemiology studies	1	1
Identification of useful molecules	1	2
Services, medical use(diagnostic, therapy, disease risk assessment)	1	1
Processes/ biotech	0	3

Different actors and groups within the organisations initiate the research and in the questionnaires we find the following answers; the collection managers or the staff, material curator's partners or working groups project-leader and external partners.

About ten of the actors in the survey have research partners. The number of partners differs between the different actors, most of them have given a number below ten partners. The partners are to find in institutions, universities as well as in private companies. The structure of the co-operation could be both as case-by-case projects to more permanent networks.

Table 9. Framework constitution of the research.

Autonomous research	9
EU programs	8
Public-private programs	8
Networks	4
Research through institutional links such as between subsidiaries	5

Information linked with the material

The modality of sharing research is solved in different ways. Some of the institutions distribute the material free of charge. The material and the results are shared in accordance with individual agreements between the different actors.

Flows of material and information

In most cases the exchange of material and information is made between collections and scientific institutions. The results in table 10 shows that the exchange of material is common with national as well as international partners. The results are shown in table 11.

Regarding exchanges of material and information with other teams, in most cases no difficulties are mentioned. Examples from the plant sector indicate some problems due to the Convention of Biodiversity. One respondent means that it reduces the availability of propagative material from some countries, strictly applying the norms in the convention.

Table 10. Main partners in the exchange of material.

Other collections	8
Scientific institutions	8
Agricultural users	4
Industrial users	1
National users	6
International users	7
Other	1

Table 11. Flows of material with different kind of users of the collections (regular: R or case by case: C)

Partners	Acquisition	Distribution
Other collections	R4 C1	R3 C1
Scientific institutions	R2 C2	R2 C2
Agricultural users	R2	R1 C1
Industrial users	R1	R1 C1
National users	R1 C2	R2 C2
International users	R1 C2	R2 C2

From the question whether there is different kind of diffusion according to different kind of research partners or material, we received very few answers. The lack of answers probably depends on problems for the respondents to fill in the table in a proper way. The results are presented in table 12, which shows that the most common diffusion is made through journal publications and databases. In one case in the plant sector we found the conditions of diffusion are different from one kind of material to another.

Table 12. Different kinds of diffusion according to different kinds of research, partners or material.

Kind of diffusion	Research	Partners	Material
Journal publications	7	3	2
Catalogue	2	2	2
Databases	4	2	2
Web site	3	1	1
Training	2	2	2
IPR; patents	1	1	
IPR; licensing Secrecy			
Participation in networks	2	2	2

Links to other databases or information sources are not common. There are some examples on networks in the plant sector such as Plant Genetic Resources networks in the Baltic and SADC countries as well as the European Co-operative Programme for Plant Genetic Resources (ECP/GR).

Results from research are published in different journals. Five of the actors publish in international journals and another two in national journals. The number of publications is on average two to four per year.

Economical aspects of the genbanks

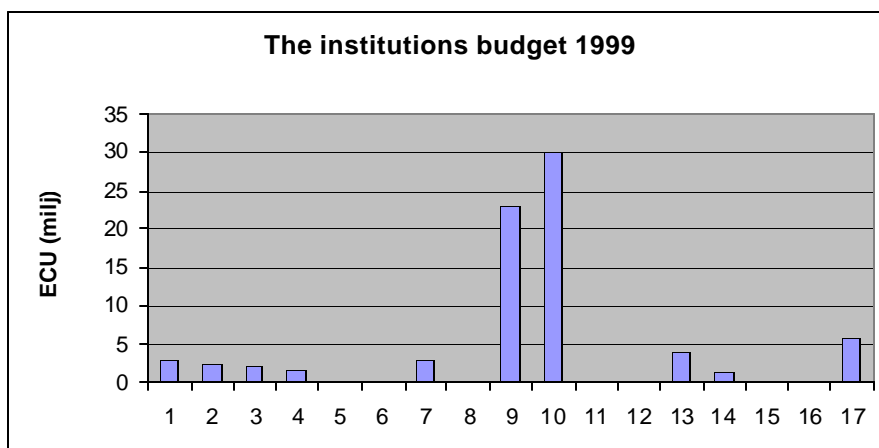
Some of the questions regarding economical issues received few answers. The reason could be lack of information or in some case non-official information.

In the previous part of the report we have presented the different target institutions and as mentioned before the institutions are active in different fields and work under different conditions.

Economical conditions for the genbanks

One of the big differences between the institutions is the financial situation. The total budget of the institutions is shown in figure 1. The result shows that there are both small and large institutions and companies in our survey. In some cases the banking activity is the major activity of the institution, in others it is only a minor part of the activity. Five of the institutions and private companies did not give any information concerning their budget. The figure also shows two very small actors with a minor budget. In comparison to the large actors their budget is not visual in the figure. The institution with the lowest budget had a budget of 16 000 ECU while the largest had 280 millions ECU during 1999.

Figure 1.



Different alternatives for number of employees were given in the questionnaire. These were: less than 10, between 10 and 49, between 50 and 249, 250-499 500-1999 and 2000 or more. The result in table 13 shows the size of the different institutions. Our target companies cover both small and larger companies with up to 500 employees.

Table 13. Numbers employed at the institutions

Less than 10	4
10-49	3
50-249	6
250-499	4
500-1999	0
2000 or more	0

The funding of the activities related to the collections comes in most cases from global funding and by co-operative agreements. In several cases the respondents have given more than one alternative which means that the activities are funded by different sources. The results are shown in table 14. Under the alternative other the following explanations were presented; funding from short-term projects, membership fee, research and development budget, jointly funded by the forestry sector and by the government.

Table 14. Funding of the activities related to the collections

Global budget of the organisation	4
Funding by co-operative agreements	4
Sales, cession of samples	3
Subventions	3
Other	5

The percentages of the budget allocated to conservation and to regeneration were difficult to sort out. Not many respondents were able to answer this question. In total we received three answers. These indicated that between 70 and 85 % of the budget of the collection were allocated to conservation while 15-30 % was allocated to regeneration.

The cost per sample for conservation does not differ very much between the three different groups plants, animal and micro-organisms, even if the target group consist of a very big range of samples. Only 50 % of the respondents gave an answer to the question concerning costs per sample. The answers differ between 0,4 ECU and 200 ECU for the conservation. The regeneration cost differs between 30 ECU and 830 ECU. The costs include consumable product costs, staff and equipment costs.

Most of the institutions only charge shipping expenses in connection to withdrawal of the samples. The distribution cost per sample is only presented in seven cases. The cost per sample varies between 1 ECU and 60 ECU for all different kind of materials except living animals, where we have no presented costs.

Concerning the price for selling genetic material, only one respondent from the animal group gave an answer to the question. The price for living animals differs very much and is estimated to between 6 ECU and 1200 ECU.

Samples free of charge are provided by some institutions, especially for scientific projects, horticultural research or co-operative projects.

No specific routines or standards for distribution of the material are specified in the answers. The plant material is distributed as dormant buds. Semen are distributed directly to the farms or companies. Only a small part, one to two percent of the budget is allocated to distribution.

For the acquisition of samples see table 15. The most important ways of acquisition of samples are in connection to research collection of material, gift, and exchange.

Table 15. Organisation of the acquisition of samples.

Research	10
Own collections	10
Gift or exchange	10
Purchase	7
Legal deposit	3

We received very few answers regarding the costs for acquisition of samples. The costs vary between 24 ECU and 1190 ECU.

Most of the institutions are involved in research, and thereby have contact with different research partners. The research partners are in most case universities or institutions with similar activities both in Sweden and in other countries. The structure for the co-operation are regulated by co-operative projects or working groups. Only three of the institutions have presented the amount of the annual budget allocated for research activities. The budget allocated for research differs between 4-12 percent of the annual budget in these institutions.

The sector's organisation

In the questionnaires a positive increasing trend for most of the studied collections can be obtained, this is also the case for the past five years. For the next five years the collections will remain the same or in some cases increase.

All of the organisations in the survey are of the opinion that they need more support to carry on with their work, especially financial support. There is also an increasing need for resources for work on preservation and taxonomy.

The collaboration between the public and the private sector is good as well as the co-operation between institutions at national and international level. Some of the smaller organisations wish to improve their co-operation with other partners in order to increase their networks.

Centralisation

In the last part of the questionnaire the respondents were asked to give some general comments concerning the future and the centralisation of the sector. The questions concerning the economical and scientifically part are presented in this report. Questions concerning the legal and ethical part are presented in the Legal ethical empirical report.

The respondents were asked to present their opinion concerning the centralisation of the collections in one single bank and at which level this centralisation should be organised. The most common opinion regarding a centralisation of the collections to one single bank are that the collections should be organised due to the purpose of the collections and type of samples, at regional or in some cases country level.

The respondents were also asked if they would store their samples in these central banks and under which conditions. We received few answers to this question one example of the answers are, only for in vitro and cryopreservation material.

Another opinion was that the central bank has to give free access to the material and information and to offer storage under optimal conditions. Another demand from the respondents is that the bank will be taken care of by a sustainable organisation in order to secure the storage for a long period. Four organisations in our survey are willing to play the role of a central bank.

Conclusions

The aim of the study is to give an overview of a selected number of collections held at different institutions and companies.

The target institutions were selected upon the following parameters, private or public institutions with collections of biological material or genetic data, accessible to the public. In total 55 questionnaires was sent to different institutions during the spring 2000. We received 17 answers from actors willing to fill in the questionnaires, which gave us an answering rate of 31 %.

The collections consist of material of different type, the institutions also work under varying conditions. The collections have different purposes and size, not just between the three groups plants animals and micro-organisms but also within these groups.

Even if there are big differences between the collections, we also find many similarities. In the material we have both public and private institutions and companies within the groups plants, animal and microbiological material.

The plant collections are the most decentralised ones with collections in different kind of organisations as Botanical gardens, private seed companies and genebanks. In the animal group the structure is centralised on regional basis, for lifestocks and pigs. For other animal collections as horses, bees and old Swedish landraces we find institutions with national collections which serve the whole country.

Microbiological collections are to found in larger companies or institutions.

The creation dates of the collections vary a lot. For the plant and animal groups we have both young and old collections. The plant collections are the oldest ones, with origin back to 1916. Most of the microbiological collections have a gradually organisation or no creation date reported.

The purposes of the collections are research and conservation. In the plant and the animal groups we find unique samples of material adapted to the Nordic climate and Nordic nature. In the microbiological group we find collections which are used in the food and medical sectors as well as in the healthcare sector.

Most of the respondents have good contacts with other institutions and companies both in Sweden and in other countries. The contacts are maintained through co-operation agreements and EU-projects.

The institutions work under different economical conditions. The institutions with plant and animal collections are more equal considering budget size and the number of employed, in comparison to the microbiological collections. The microbiological group consists of larger institutions with a budget four or five times as high as in the plant and animal groups.

During the next five years the collections size will probably remain the same or in some cases increase, although the budget in several cases have decreased. To secure the activity in the future many institutions needs more financial support. Despite of the problems most of the institutions show confidence to the future.

Concerning inclusion of material, in some case permission is needed from the Swedish Board of Agriculture. Examples to mention are species under restriction and all activities concerning embryo transfer, storage and distribution.

The access to the collections varies between the different collections. Six of the institutions allow free access to their collections. The microbiological collections are closed except for the university collection. In the animal group the collections are the most opened with free access to three of the collections. Collections not open for the public is open for the staff working at the institution. Some of the institutions with limited access to the collections are open to healthcare institutions, owners, the Nordic Gene Bank and other Non Governmental Organisations.

Only a one third of the institutions do protect the collections with patents or confidential treatment of the results.

In the study we found both positive and negative opinions considering a centralisation of the collections. Most of the respondents are positive to a centralisation of the information but not considering the material.

Appendix 1

PLANT COLLECTIONS SWEDEN

	Kind and number of samples		Purpose of the collections	Originality of the collection	Creation date of the collection	Staff
1	A selection of the words flora	80 000	Research, identification, conservation, education.	Unique samples, safety duplicates	1916	50-249
2	Solanum tuberosum	100	Conservation, base for seed potato production	Safety duplicates, tested meristem potato plants for seed production	1979 1988	Less than 10
5	Apples, pears, plums, cherries, strawberries, raspberries, blackberries, blackcurrant redcurrants gooseberries	Plants 3320 In vitro preservation 173	Research , conservation, plant breeding	Unique samples, safety duplicates, genotypes with outstanding value in breeding	1942-2000	10-49
6	Cereals fruit and berries , potatoes, forage crops, vegetables, root oil and pulses, landscape and ornaments spices	Plants 63, Seeds 29 964	Conservation	Unique samples, safety duplicates, genotypes with outstanding value in breeding	1979	10-49
8	Vegetables, potatoes, cereals, medical plants, flowers	377	To conserve old Swedish vegetable species	Unique samples, collection of great variation	1982	250-499
15	Beta vulgaris	200	Research, conservation	Unique samples	1960	250-499
17	Pinus sylvestris Picea abies, Betula pendula, Fagus sylvatica, Quercus robur, Fraxinus exelsior, Acer platanoides, Tilia cordata, Prunus avium.	33 000	Research, conservation	Unique samples	1940	50-249

Appendix 2

ANIMAL COLLECTIONS SWEDEN

	Kind and number of material		Purpose of the collections	Originality of the collection	Creation date of the collection	Staff
7	Nordic bees	Comunities 500-800	Research, conservation, production and breeding	Unique samples	1990	10 (active)
10	Horses	Sperm doses 4000	To sell sperm from the stallions	Unique samples	ND	50-249
11	Nordic animals	850 animals	Research, conservation, education	Nordic animals	1952	10-49
12	Cows	Vänecow Ringamålacow , Bohus polled 11	Research, identification, conservation	Unique samples Living gene banks of old native breeds of cattle	1993	Less than 10
13	Cows	Cows 330 Embryos 1387	Breeding	Embryos of special breeding combinations	ND	Less than 10
14	SLB Cows	Cows 25 Semen 190 095 doses	Storage without defined objective	Unique samples	1994	50-249

Appendix 3

MICRO-ORGANISM COLLECTIONS SWEDEN

	Kind of material	Type	Purpose of the collections	Originality of the collection	Creation date of the collection	Staff
3	Micro-organisms		Storage without defined objective 50	Safety duplicates	ND	50-249
4	Microorganisms Serumbank	7100 550	826 Research, healthcare	Unique samples, quality assurance. Epidemiology and outbreaks of infection Diseases	Gradual organisation	250-499
9	Bacteria, virus fungi	ND	Research, identification	A broad collection of veterinary pathogen with a large number of strains	No official collection	250-499
16	Marine phytoplankton		75 Research	Safety duplicates marine phytoplankton	ND	50-249

QUESTIONNAIRE REGARDING GENETIC MATERIAL OF PLANTS, ANIMALS AND MICRO-ORGANISMS

1. GENERAL INFORMATION

1.1 Category: plants
animals
micro-organisms

1.2 Institution in charge of the collection(s):

1.3 Name and title of manager in charge of the collection(s):

1.4 Name of the respondent:

1.5 Function of the respondent:

1.6 Address and telephone number of the respondent:

1.7 Status of the institution:

- | | |
|---|--|
| <input type="checkbox"/> private | <input type="checkbox"/> public |
| <input type="checkbox"/> for profit | <input type="checkbox"/> non-for-profit |
| <input type="checkbox"/> research | <input type="checkbox"/> NGO's ¹ |
| <input type="checkbox"/> healthcare | <input type="checkbox"/> education, teaching |
| <input type="checkbox"/> administration | <input type="checkbox"/> industry |
| <input type="checkbox"/> other: _____ | |

1.8 The activity of the institution is:

- national
international
other: _____

1.9 Does your institution/society belong to a group? If so, which one?

- subsidiary (please precise): _____
joint-venture
start-up company
"technopole" - Which other institutions are parts of this pole?

other: _____

1.10 How many people in total work at the institution?

- | | |
|---|--|
| <input type="checkbox"/> less than 10 | <input type="checkbox"/> from 10 to 49 |
| <input type="checkbox"/> from 50 to 249 | <input type="checkbox"/> from 250 to 499 |
| <input type="checkbox"/> from 500 to 1999 | <input type="checkbox"/> 2000 and more |

¹ NGO = private non-for-profit institution

1.11 Please specify the institution's budget or turnover in;

1998? _____ 1999? _____ 2000? _____

1.12 Is there any collection(s) with non-identified owners?

yes no

1.13 Is the institution that is in charge of the collection(s), also the owner of the collection(s)?

yes, for all collections

yes, for a part of them

no

other: _____

If **no**, please specify how many owners of the collection(s) there are and who they are.

1.14 What is the status of the institution that owns the collection(s), in case it is **not** the institution that is in charge of the collection:

private

public

for profit

non-for-profit

research

NGO's

care

education, teaching

administration

industry

other:.....

1.15 Its activity is:

national

international

other:

1.16 Other activities of the institution besides management of the collection(s):

1.17 Are the owners organised in a network?

yes

no

other.....

1.18 Do you have any co-operative agreement or do you work with other institutions?

yes

no

If **yes**, which ones: pharmaceuticals companies

biotech firms

hospitals

public laboratories

associations

other: _____

Please provide an example of a contract form.

1.19 Where are these institutions?

in the same country as your institution

in another country

1.20 Do you know if there exists a relevant and **specific** national and international regulatory framework for your activity?

yes

no

other: _____

If **yes**, who is responsible for the regulatory framework?

- administrative office
- legal office
- ethic committee
- hospital commission
- other: _____

2. CONSTITUTION OF COLLECTION

2.1 Creation date of the collection(s): _____

2.2 For which purposes is the collection(s) constituted?

- research
- healthcare
- storage without defined objective
- identification
- conservation
- other purpose: _____

2.3 Originality of collection(s):

- unique samples
- non replicable samples
- safety duplicates
- other, please specify if possible: _____

2.4 According to you, what are the characteristics that make your collection(s) original?

2.5 What kind and which number of species does the collection(s) constitute of? Could you please describe the past & future evolution? Is this number or percentage increasing (+), reducing (-) or stable (s)?

Preferably, please add a list.

KIND OF SPECIES	SPECIES IN 1999		TRENDS/EVOLUTION FOR THE PAST 5 YEARS, OR NUMBER IN 1994	TRENDS FOR THE NEXT 5 YEARS
	NUMBER	PERCENTAGE		
Total				

2.6 What is the number or percentage of samples in the collection(s) and could you please describe the past & future evolution? Is this number or percentage increasing (+), reducing (-) or stable (s)?

KIND OF SAMPLE	SAMPLES IN 1999		TRENDS/EVOLUTION FOR THE PAST 5 YEARS, OR NUMBER IN 1994	TRENDS FOR THE NEXT 5 YEARS
	NUMBER			
plants				
seeds				
organs				
embryos				
semen				
DNA, nucleic acids				
cells				
cell lines				
body fluids				
tissue sections				
strains				
type culture				
serotypes				
animals				
other				
Total				

2.7 Other genetic material than plant, animal or micro-organism?

2.8 How is the activity related to the collection(s) funded? Please indicate the part in the global funding.

- global budget of the organisation
 - funding by co-operative agreements
 - sales, cession of samples
 - subventions
 - other: _____
-

3. MAINTENANCE OF THE COLLECTION

3.1 Do you use a database for collection management?

- yes no

If **yes**, do you use a: self-made software commercial software, which one?

3.2 Is the samples' database computerised?

- totally partially not at all

3.3 Since when is your service computerised? (Specify the year)

3.4 Which kinds of data are not computerised? Why?

3.5 Which criteria do you have for inclusion into your collection(s)? Please indicate the total number of stored samples for each criterion, if possible.

3.6 For the inclusion of samples, do you have to request an administrative authorisation? Which administrative body do you consult?

3.7 For how long do you store biological samples?

- less than 1 year from 1 year to 5 years
 from 5 years to 10 years more than 11 years

3.8 Your length of storage is:

- fixed variable

If **variable**, why can the length vary?

3.9 Is a part of your collection(s) duplicated and stored in another bank?

- yes no

If **yes**, in which institution?

3.10 How is the acquisition of samples organised?

- purchase research
 gift or exchange with other services own collection(s)
 legal deposit
 other: _____

3.11 What are the costs for acquisition of samples (*please list*)?

3.12 What kind of difficulties do you meet (including ethical, legal ,etc.);

For the acquisition of your collection(s)?

For the collection(s) management?

3.13 Is there an optimum size or composition of your collection(s)?

3.14 Do you use any standards for conservation?

yes no

If **yes**, please fill in the following table.

CONSERVATION STANDARDS:	
length	
storage conditions	
safety duplicates packaging	
quantity stored	
sanitary measures	
identification germinative quality	
other	

3.15 How are these standards monitored?

3.16 What is the average length of conservation of one sample? _____ years

3.17 Do you use any standards for regeneration?

yes no

If **yes**, please fill in the following table.

REGENERATION STANDARDS:	
frequency	
samples used for regeneration	
identity	
sanitary measures	
other	

3.18 How are these standards monitored?

3.19 What are, practically, the activities undertaken to manage the collection and how? Please describe the situation for conservation and regeneration.

Conservation: _____

Regeneration: _____

3.20 What is the amount or percentage of the collection's budget allocated to conservation and regeneration? If financing comes from different sources, please identify the origin of financing.

Conservation: _____

Regeneration: _____

3.21 What are the costs per sample for conservation and regeneration?

SAMPLES	CONSERVATION	REGENERATION
plants		
seeds		
organs embryos		
semen		
DNA, nucleic acid		
cells cell lines		
body fluids		
tissue sections		
strains type culture		
serotypes		
animals		
other		
Total		

3.22 What do these costs include?

consumable product costs

staff

equipment costs

other: _____

3.23 What are your conditions or criteria of withdrawal? *Please join a procedure form.*

For example:

Do you use an agreement document? yes no

Do you impose restrictions for using your samples? yes no

If your institution is the owner of samples, do you transfer
 This property in the case of the cession of samples? yes no other:

3.24 What do you charge for withdrawal of samples? *Please, join a price catalogue if possible.*

shipping expenses

manipulations on the samples. Please, specify: (extraction, viral transformation...)

other:

3.25 Do you perform quality control for your activity?

yes

no

other: _____

If **yes**, which test do you apply?

3.26 What kind of security measures do you take?

3.27 How do you solve your problems of contamination?

3.28 How do you protect your results?

secret/confidentiality

IPRs² (patent...)

other:

4. SCIENTIFIC ACTIVITIES CARRIED OUT ON THE COLLECTION

4.1 Please indicate, for each of the different scientific activities in which your bank is engaged, if it is a regular (R) activity or only on a case-by-case basis (C) and the percentage of the collection annually concerned by these activities.

ACTIVITY	REGULAR OR CASE-BY-CASE	PERCENTAGE ANNUALLY
evaluation; resistance to diseases		
evaluation; quality		
evaluation; agronomic performance		
evaluation; other		
characterisation (polymorphism assessment, morphological/physiological or molecular)		
gene mapping		
functional molecular mechanisms		
diversity study (popular genetics, evolutionary studies)		
genetic epidemiology studies		
identification of useful molecules		
services, medical use (diagnostic, therapy, disease risk assessment)		
processes/biotech		
other		

² IPR = Intellectual Property Rights

4.2 Who has initiated the research that is done on the collection(s)? (Collection managers, others in the same institution or out of the institution)

4.3 How is the framework of your research constituted?

- | | | |
|---|------------------------------|-----------------------------|
| autonomous research | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| EU programs | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| public-private programs | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| networks | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| research through institutional links such as between subsidiaries | <input type="checkbox"/> yes | <input type="checkbox"/> no |

4.4 Do you have any research partners?

yes no

If **yes**, could you please specify:

number of partners _____

kind of structures _____

nationality of the partners _____

4.5 If you co-operate with several research partners, how are the modalities of sharing of research?

4.6 If several partners are involved, how are the modalities of the sharing of results (IPRs etc.)?

4.7 Please specify, if possible, the budget that is allocated annually to the research activities and its origin.

5. FLOW OF GENETIC MATERIAL AND INFORMATION

5.1 Who are the main partners in the exchange of genetic material?

- other collections
- scientific institutions
- agricultural users
- industrial users
- national users
- international users
- other: _____

5.2 What kind of difficulties do you meet regarding exchanges with other teams? (including ethical, legal etc.)

5.3 Please indicate, in the following table, the different kinds of diffusion according to the different kinds of research, partners or material.

KIND OF DIFFUSION	RESEARCH	PARTNERS	MATERIAL
journal publications			
catalogue			
databases			
web site			
training			
IPR; patents			
IPR; licensing			
secrecy			
participation in networks			
other			

5.4 Are the conditions of diffusion different from one kind of genetic material to another?

yes no

If **yes**, please specify.

5.5 Do you have any links with other databases or information sources?

5.6 In what kind of journals have your research results been published ?

5.7 Approximately, how many publications per year have been published?

5.8 Please describe briefly your routines for distribution.

5.9 What are, practically, the activities for distribution?

5.10 Do you use any standards for distribution?

yes no

If **yes**, what is the standard distribution procedure of the collection material?

5.11 Are there any specific conditions for distribution?

yes no

If **yes**, please fill in the following table.

DISTRIBUTION STANDARDS (ACCESS):	
quantity	
delay	
charge packaging	
associated information	
responsibility	
other	

5.12 How are these standards monitored?

5.13 What is the amount or percentage of the collection's budget allocated to distribution? If financing comes from different sources, please identify the origin of financing.

5.14 What are the distribution costs per sample?

SAMPLES	DISTRIBUTION COSTS
plants	
seeds	
organs embryos	
semen	
DNA, nucleic acid	
cells cell lines	
body fluids	
tissue sections	
strains type culture	
serotypes	
animals	
other	
Total	

5.15 What are the prices for selling genetic material?

Please join a price list if possible.

5.16 In which cases do you provide samples free of charge?

5.17 How are the flows of material with different kinds of users of the collection(s)? Regular (r) or case by case (c)
Please fill in the following table.

PARTNERS	ACQUISITION	DISTRIBUTION
other collections		
scientific institutions		
agricultural users		
industrial users		
national users		
international users		
other		

5.18 Please indicate the number of samples per year that are acquired or distributed.

KIND OF SAMPLE	N° ACQUIRED	N° DISTRIBUTED
plants		
seeds		
organs embryos		
semen		
DNA, nucleic acids		
cells cell lines		
body fluids		
tissue sections		
strains type culture		
serotypes		
animals		
other		
Total		

5.19 Are the conditions of acquisition different from one kind of genetic material to another?

yes no

If **yes**, please specify.

5.20 Please list the information that is associated with the material exchanged (passport data etc.).

5.21 Do you depose or retire your own samples?

yes no

Please, indicate the most frequent cases:

From what kind of organisations?

What kind of samples?

5.22 What are the conditions of temporary disposal of genetic material

within a research program: _____

for sanitary reasons: _____

for regeneration reasons: _____

5.23 Are there other exchanges, based on reciprocity?

yes no

If **yes**, please specify.

5.24 Does your service use a recommendation? (good practises guidelines)

yes no other: _____

If **yes**, could you please provide us with a copy of it?

5.25 Are there any other regulations, regarding secrecy of information, material and results?

yes no

If **yes**, please specify.

6. ACCESS OF INFORMATION

6.1 Who have access to information about the collection(s)?

everybody staff working for your institution
public research teams private organisations and private research teams
healthcare institutions legally authorised staff
other: _____

6.2 Are your conditions of access to information varying according to the kind of collection(s)?

yes no other: _____

If **yes**, why?

6.3 Are your conditions of access to information varying with;

the status of the institution (for ex. public or private sector): yes no
the purposes of its project (for ex. research, industrial): yes no
other: _____

6.4 Is the access only national?

yes no other: _____

If **no**, which are the countries that are authorised to access?

6.5 Are there any rules of access, either general or specific, to information about the collection or to some kinds of materials:

yes no

If **yes**, please specify:

7. LEGAL ASPECTS

7.1 Does there exist a general international agreement for;
acquisition of material to the collection(s): yes no
distribution of material from the collection(s): yes no

7.2 Does there exist a national legislation (such as on sanitary issues or on animal breeding) for;
acquisition of material to the collection(s): yes no
distribution of material from the collection(s): yes no

7.3 Is there a contractual (such as a material transfer agreement) of;
acquisition of material to the collection(s): yes no
distribution of material from the collection(s): yes no

7.4 For the distribution of samples, do you have to request an authorisation?
yes no

If **yes**, which administrative body did you consult?

7.5 Are there any specific legal provisions?
yes no

If **yes**, please specify.

- ownership
- intellectual property rights
- transfer of the material to third parties
- sharing of information obtained on the material exchanged
- sharing of results obtained on the material exchanged
- other: _____

7.6 How many intellectual property rights do you currently hold? Please specify for each.

patents: _____

licensing: _____

other: _____

7.7 How long do these intellectual property rights maintain?

patents: _____

licensing: _____

other: _____

7.8 What geographical coverage do these intellectual property rights have?

patents: _____

licensing: _____

other: _____

8. GENERAL COMMENTS

8.1 What do you think about your sector's organisation?

Of its legal framework?

Of its economical context at national and European level?

Of its partition between public sector and private sector?

Of the co-operation between institutions at the national and the international level (collaboration networks etc.)?

8.2 Are there any recent changes or evolution in your sector? (concentration, merging company setting up, creation of institutions, federate institutions, new formalised partnerships, etc.).

Describe you opinion about the recent changes.

8.3 How do you see the sector in the near future?

8.4 Would you agree with the constitution of agreements, concerning biobanks, at the European level?

yes no

8.5 Would you agree with a harmonisation of the legal framework, concerning biobanks, at European level?

yes no

8.6 Would you agree with a European harmonisation, concerning biobanks, of the ethical framework?

yes no

Please explain your answers:

8.7 What do you think about the centralisation of collections in one single bank? Do you think that this centralisation should be organised by/at:

- | | |
|---|--|
| <input type="checkbox"/> kind of collection | <input type="checkbox"/> region |
| <input type="checkbox"/> purpose of collection | <input type="checkbox"/> country |
| <input type="checkbox"/> kind of samples | <input type="checkbox"/> an European level |
| <input type="checkbox"/> an international level | |

Please explain your answer:

8.8 Under what conditions, would you store your samples in this central bank?

8.9 Do you think that your institution or service is able to play the role of centralising organisation?
