Scientific Institute of Public Health

Section of Biosafety and Biotechnology

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REPORT: "DEMONSTRATING THE QUALITY OF IMPLEMENTING POLIO LABORATORY CONTAINMENT REQUIREMENTS"

From: WHO Containment Coordinator for Belgium

To: WHO Regional Office for Europe, Polio Eradication Programme, at the request of Dr Galina Lipskaya, WHO Containment Coordinator by letter dated the 13th of October, 2003, addressed to all Containment Coordinators

cc: Director of the IPH, Chairman and Secretary of the National Certification Committee, SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement (Relations Internationales)

Purpose of this report

This document aims to help WHO to assess the quality of phase I containment activities in Belgium, thus to document the thoroughness and accuracy of conducting the Laboratory Survey and establishing the National Inventory of laboratories that wish to retain wild poliovirus infectious materials.

Reference technical documents

The present report has been created using the following guidelines:
'WHO Guidelines for Documenting the Quality of Phase I Wild Poliovirus Laboratory Containment Activities
- Laboratory survey
- National inventory'

The WHO document entitled 'Checklist for Reviewing Documentation on Implementing Phase I Wild Poliovirus Laboratory Containment Requirements' has also been used to complete this report.

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INTRODUCTION

The world will be declared free of wild poliovirus transmission when the Global Commission for the Certification of the Eradication of Poliomyelitis is satisfied that all Regions of the World Health Organization (WHO) have documented the absence of wild poliovirus circulation for at least three consecutive years and all wild poliovirus materials in laboratories are adequately contained. The Global Commission has established the requirements for laboratory containment of wild polioviruses, and the 2nd edition of the *Global action plan for laboratory containment of wild polioviruses* (http://whqlibdoc.who.int/hq/2003/WHO_V&B_03.11.pdf) describes those requirements in detail. Guidelines on how to implement the requirements have been issued and adapted by the WHO Regions (for European Region: http://www.who.dk/vaccine/20030724_12).
The Global Certification Commission requirements for containment of wild polioviruses are described in two phases: the Laboratory Survey and Inventory Phase and the Global Certification Phase.

Phase I: Laboratory Survey and Inventory Phase

This phase covers the period when the numbers of polio-free countries and Regions are increasing, but wild polioviruses continue to circulate somewhere in the world. During this phase, countries are required to:

- Survey all biomedical laboratories to identify those with wild poliovirus infectious or potential infectious materials and encourage destruction of all unneeded materials.
- Develop a National Inventory of laboratories that retain such materials and submit this to the Regional Certification Commission.
- Instruct laboratories retaining wild poliovirus infectious or potential infectious materials to institute enhanced biosafety level-2 (BSL-2/polio) measures for safe handling.
- Plan for implementation of the Global Certification Phase.

Phase II: Global Certification Phase

This phase begins when one year has elapsed without isolation of wild poliovirus anywhere in the world. During this phase nations:

- Notify biomedical laboratories that poliovirus transmission has been interrupted.
- Instruct laboratories on the National Inventory to elect one of the following three options:
  - Render materials non-infectious for poliovirus or destroy them under appropriate conditions.
  - Transfer wild poliovirus infectious and potential infectious materials to laboratories capable of meeting the required biosafety standards.
  - Implement biosafety requirements appropriate for the laboratory procedures being carried out (BSL-2/polio or BSL-3/polio).
- Document completion of all containment requirements for global certification.

Components of a high quality laboratory survey and inventory phase of containment activities

The reference technical guidelines mention the following six essential components of a successful program:

1. Strong political endorsement and support for containment
2. A realistic National Plan of Action
3. An effective Containment Coordinator and National Task Force
4. A comprehensive National Laboratory List
5. A high quality Laboratory Survey
6. A complete and active National Laboratory Inventory

The present report gives a description of the process followed in implementing the Phase I laboratory containment activities referring to each of these six components. As requested in the guidelines, it concerns a self-evaluation by the National Containment Coordinator of laboratory survey and inventory activities.

COMPONENT 1. POLITICAL ENDORSEMENT AND SUPPORT

Political support

Containment activities undertaken in the frame of the polio eradication programme in Belgium have been placed under the responsibility of the Federal Government Department of Public Health and more precisely of the Scientific Institute of Public Health (IPH). The Director of this institute has appointed a biosafety expert of the Service of Biosafety and Biotechnology (SBB) of IPH as a focal person for containment (National Coordinator) to assume operational responsibility for the national containment process and particularly to draft the National Plan for Containment and to assume responsibility for the national survey of laboratories.

The National Containment Coordinator has been working in coordination with the National Certification Committee (NCC) on Eradication of Poliomyelitis of which she is a member. The Belgian National Certification Committee is composed of scientific experts, of representatives of IPH, of the Federal Government Department of Public Health and of the Belgian Community authorities. The NCC has endorsed the draft National Plan for Containment and has reviewed the containment activities undertaken under the responsibility of the National Containment Coordinator.

The National Containment Coordinator had also to cooperate with the Belgian Regional authorities.

When the containment activities in the frame of the polio eradication programme begun in Belgium, Belgium already had all legal instruments in place in order to develop adequate laboratory containment procedures.

Legislation

a) Regional 'contained use' regulations

In Belgium, all activities involving the contained use of genetically modified organisms (GMO's) and/or pathogens (for human, animals or plants) must be authorized or notified in accordance with the regional regulations on this matter. These regulations came into force in 1994 in Brussels Region, in 1995 in Flemish Region and in 1996 in Walloon Region. These are part of the Regional Environmental laws for classified installations.

These regulations are:

For the Brussels Region
- "Arrêté du 9 décembre 1993 du Gouvernement de la Région de Bruxelles-Capitale relatif aux installations effectuant des opérations mettant en oeuvre des micro-organismes ou des organismes, pathogènes ou génétiquement modifiés. (MB 25.01.1994, p. 1424) / Besluit van 9 december 1993 van de Brusselse Hoofdstedelijk
Regering betreffende de inrichtingen die activiteiten verrichten waarbij pathogene of genetisch gemodificeerde micro-organismen of organismen worden aangewend. (BS 25.01.1994, p. 1424)"
Now abrogated and replaced by:
- "Arrêté du 8 novembre 2001 du Gouvernement de la Région de Bruxelles-Capitale relatif à l'utilisation confinée d'organismes génétiquement modifiés et/ou pathogènes et au classement des installations concernées. (MB 26.10.2002, p. 7209)/ Besluit van 8 november 2001 van de Brusselse Hoofdstedelijke Regering betreffende het ingeperkt gebruik van genetisch gemodificeerde en/of pathogene organismen en betreffende de indeling van de betrokken installaties. (BS 26.10.2002, p. 7209)"

For the Walloon Region
- "Arrêté du Gouvernement wallon du 13 juin 1996 modifiant le Règlement général pour la protection du travail en ce qui concerne l'utilisation d'organismes génétiquement modifiés et/ou pathogènes. (MB 25.10.1996, p. 27405)"
Now abrogated and replaced by:
- "Arrêté du Gouvernement wallon du 4 juillet 2002 déterminant les conditions sectorielles relatives aux utilisations confinées d'organismes génétiquement modifiés ou pathogènes. (MB 21.09.2002, p. 41711)"

For the Flemish Region
- "Besluit van de Vlaamse regering van 1 juni 1995 houdende algemene en sectorale bepalingen inzake milieuhygiëne (Hoofdstuk 5.51. van VLAREM Titel II - Biotechnologie). (BS 31.07.1995, p. 20526)"
Modified by:
- "Besluit van de Vlaamse regering van 24 maart 1998 tot wijziging van het besluit van de Vlaamse regering van 1 juni 1995 houdende algemene en sectorale bepalingen inzake milieuhygiëne. (BS 30.04.1998, p. 13775)"

The text of these regulations is available on the Belgian Biosafety Server (BBS) held by the SBB at the following Internet address:
http://www.biosafety.be/GB/LegGB.html#P2

This set of regulations includes provisions for an assessment of the contained uses as regards the risks to human health and the environment that these contained uses may incur and for the

application of an appropriate containment and other protective measures corresponding to the risk level of the contained use, so as to keep workplace and environmental exposure to any GMO and/or pathogen to the lowest reasonably practicable level, and so that a high level of safety is ensured.
All operations in which wild polioviruses, pathogens for human of biological class of risk 2, are cultured, stored, used, destroyed or disposed are thus regulated in this context and must be previously authorized by the competent authority.

These biosafety regulations have been set up within the spirit of the Cooperation Agreement between the Federal State and the Regions on the administrative and scientific co-ordination concerning biosafety (1997) which is juridically situated between the Constitution and the law levels.

The text of the Law of 3 March 1998 approving the Cooperation Agreement between the Federal State and the Regions on the administrative and scientific co-ordination concerning Biosafety, as well as the text of the decrees of the Flemish Government, of the Wallonian Government and of the Government of the Brussels-Capital Region approving the Cooperation agreement are available in French and in Dutch on the BBS at the following Internet address: http://www.biosafety.be/GB/LegGB.html

This co-operation agreement provides the essential legal tools necessary to apply any biosafety regulation in Belgium.

These are mainly:

- A definition of biosafety: "the safety for human health and the environment, including biodiversity protection, of the uses of genetically-modified organisms or micro-organisms and of the contained use of human pathogenic organisms".

- A common science-based biosafety advisory system composed of the "Biosafety Advisory Council" and its executive body the Service of Biosafety and Biotechnology (SBB).
SBB was noteworthy defined by the regions as the “advisory authority” for the review of contained installations and operations.

This co-operation agreement has as objective among others to implement and to harmonize the application in Belgium of regulations on contained use of GMO's and pathogens. The Regions have committed themselves to harmonize the biosafety technical criteria as well as the classification of GMO'S and pathogens and their classes of risk.

The decisions of authorization by different administrative bodies representing different institutional levels are thus mainly based on a single common science-based biosafety advisory system. In such a system, all regulatory-related aspects of the uses of GMO's and pathogens

are assessed altogether in a coordinated way, independently of the implicated specific regulation(s). The advice on the biological safety is given on a case-by-case basis taking the precautionary and the familiarity principles as 1st and 2nd priorities.

In particular, regarding contained use regulation, the SBB defines the specific containment criteria to be applied in a given installation on a case-by-case basis and advises the Regional competent authority about the licensing conditions of installation and the authorizations for contained uses, according to their risk level.

The SBB is in charge of archiving all biosafety dossiers. The SBB has also built up databases for "contained use" data. The SBB holds thus information on all laboratories that have notified activities in which GMO's and/or pathogens are involved. These data are the property of the Regional competent authorities.

With regard to the process of laboratory containment of wild poliovirus, this regulatory context provided:
- Advanced databases for contained use data from which it was possible to extract a provisional national laboratory list for the polio survey.
- The persuasion strength to lead institutions and laboratories to comply with the survey.
- A compulsory authorization for any installation or laboratory culturing, storing, using, destroying or disposing wild polioviruses. The legally binding requirements concerning the containment measures are clearly listed in the authorization and adapted to the contained use. Specific requirements for poliovirus laboratories can be included in such an authorization, directly referring to the WHO requirements. These specific requirements have already been mentioned since 1998 in the conditions bound to the authorization (cf for example the authorization delivered to the company GlaxoSmithKline for all their activities with wild polioviruses, including vaccine production activities).

b) Register of medical diagnostic laboratories

All laboratories of clinical biology must be registered. The national list of these laboratories is hosted in the Section of Clinical Biology of IPH. This list has been used to establish the national laboratory list for the survey.

Multi-sector involvement

Laboratories from different sectors may retain poliovirus infectious materials.
As previously mentioned, any installation or laboratory from any sector where wild polioviruses are cultured, stored, used, destroyed or disposed must fulfill the requirements of regional regulations on contained uses of pathogens. These regulations are in force since 1994. Different sectors or stakeholders such as private industries, universities, governmental

scientific institutes have been consulted during the legislative process of adoption of these regulations and are aware of their existence.

Effects of decentralization

The Scientific Institute of Public Health and more precisely the SBB where the National Containment Coordinator works has been entrusted with the laboratory survey to identify laboratories in Belgium retaining wild poliovirus infectious and/or potentially infectious materials.

The contained use of wild poliovirus falls under the scope of the regional regulations on contained use of pathogens. Although the survey is under the responsibility of the Federal Government Department of Public Health, the Regions have to assume the responsibility to control that each laboratory of the national inventory has got an appropriate authorization to use or retain wild poliovirus and also to inspect the premises and verify that the required containment measures are respected.

The SBB has informed the Regional Ministers for the Environment about the containment activities in the frame of the polio eradication programme undertaken at the Federal level and the implications for the Regional authorities. Copies of these letters can be found in annex 1.

COMPONENT 2. THE NATIONAL PLAN OF ACTION

Responsibility for the Plan

The National Containment Coordinator has drafted the National Plan of Action. To help her in her task, she received the Austrian National Plan of Action, from the WHO Coordinator of Polio Eradication Programme. This plan was used as an example for the development of the national plan in Belgium.
The members of the NCC have agreed the National Plan of Action in December 2001.

Realistic timeframe for activities

The National Plan of Action can be found in annex 2.
Timelines and milestones clearly appear in the plan. It was initially foreseen that the plan would be brought into operation from February until September 2002. At the end of May 2002, the implementation process of the plan has been monitored. The timelines have to be revised and the starting date of the survey has been postponed from 15 April to 1 June 2002 and the completion of the National Inventory from September to October 2002 (the updated Plan can be found in Annex 3).
Finally, the first mailing for the survey has been sent on 10 June 2002. A first reminder has been sent afterwards, on 19 Augustus 2002, and a second one on 2 October 2002. As foreseen, the completion of the Inventory has been achieved at the end of October 2002. Finally no delay occurs referring to the date of completion of the updated plan.

Personnel and funding resource allocation

The Service of Biosafety and Biotechnology has at its disposal a general budget that allowed funding the cost of the survey. The Coordinator has also the scientific support of the team of biosafety experts of the SBB as well as a significant administrative and logistic help. The implementation of the Plan has been taken in charge by the SBB as any other important biosafety issue or task.

Multi-sector involvement

For the process of establishing the National Laboratory List, the plan mentions the use of the above-mentioned databases of contained use data hosted by the SBB.
In accordance with the regional regulations on contained use of pathogens and GMO's, nearly 400 institutions/laboratories had at the moment of the survey notified more than 1100 'contained use' activities. The corresponding databases give an overview of institutions and laboratories handling pathogenic and genetically modified organisms in Belgium. Different types of installations are involved: federal, regional or provincial scientific institutes,

universities and associated institutes or centers, high schools, diagnostic clinical laboratories including hospitals and clinics, private laboratories, small companies and big industries.
The plan foresees that other registers should be used to complete or to control the completeness of these 'contained use' databases and are mentioned in the plan.

Effects of decentralization

As already mentioned, the survey was under the operational responsibility of the National Containment Coordinator.
The Regional authorities were also involved for the last steps of the phase I containment activities. As foreseen in the plan, the Belgian Regional authorities should receive the list of institutions/laboratories that didn't answer to the survey even after two reminders to take the appropriate measures.
Notification under the regional biosafety regulations of all poliovirus "activities" of identified institutions/laboratories should also be promoted by the Regional authorities as well as inspections of their facilities to control the implementation of the right containment measures.

COMPONENT 3. THE NATIONAL CONTAINMENT COORDINATOR

Sufficient Political or Administrative Stature

The National Coordinator for containment has been appointed in November 2001 by the Director of the Scientific Institute of Public Health (IPH) to assume operational responsibility for the national containment process and particularly to draft the National Plan for Containment and to assume responsibility for the national survey of laboratories (see annex 4).

The Institute where the Coordinator works belongs to the Federal Government Department of Public Health.

The coordinator has been chosen as a biosafety expert of the Service of Biosafety and Biotechnology (SBB), one of the 15 sections of the Institute. She has been working in this section since 9 years as a senior scientist and has been nominated as a permanent senior government employee since September 2001.

The Service of Biosafety and Biotechnology (SBB) has been instituted by the aforementioned cooperation agreement between the Federal State and the Regions "on the administrative and scientific co-ordination concerning Biosafety", with the Biosafety Council, as the single scientific advisory system common to the Federal and Regional authorities. Such a system is competent for advising about all biosafety-related matters whatever the specific concerned regulation(s) could be.

The SBB is composed of an administrative secretariat, a multidisciplinary group of biosafety scientists and a laboratory for biosafety research and expertise. Approximately twenty persons work in this service. More than a half are senior scientists and have a PhD level in science.

Chiefly, the SBB is carrying out the following practical tasks in the biosafety field:
i) Support the petitioners when preparing their petitions.
ii) The risk assessment of contained installations and contained R&D activities: the SBB defines the specific normative criteria to be applied in a given installation on a case-by-case basis and advises the Regional authority about the licensing conditions from the biosafety viewpoint.
iii) Check whether the petitions for deliberate releases of GMO in the environment or for the placing on the market of GMO's, GMO's-based or GMO-derived products fulfill the provisions of the law.
iv) The risk assessment of those deliberate releases, placing on the market or product for which the SBB has got a mandate of the Council on basis of the familiarity principle.

v) Manage -and report on- the meetings of expert groups and members of the Council.
vi) Participate to scientific normative programs or meetings and draft measures for the protection of the human health and the environment for the Council or the authorities.
vii) Archive the dossiers and safeguard confidential information.
viii) Communicate all necessary information to the European Commission.
ix) Sustain the Belgian delegations at the international level.

The National Containment Coordinator is currently the group leader of the SBB team working on all matters concerning the contained use of GMO's and pathogens.

The Coordinator has access to the Director of IPH and to the Minister through the official hierarchical channel. However, according to the cooperation agreement, the SBB can propose measures for the protection of public health directly to the higher level of Federal authorities and to Regional Ministers.

As the Coordinator had to assume responsibility for the national survey of laboratories, she has taken the operational decisions in relation with the realization of the survey.
In the letter that have been sent to the institutions for the survey, the Coordinator has demanded compliance on responding to the survey, even though there were no strict legal support. The regional regulations on contained use of pathogens have been remembered in the mailing. Mentioning that this survey was performed following the request of WHO was also persuasive.

The coordinator has worked in coordination with the National Certification Committee (NCC) on Eradication of Poliomyelitis of which she is a member. The NCC has endorsed the draft National Plan for Containment and has reviewed the containment activities undertaken under the responsibility of the National Containment Coordinator. The coordinator has maintained frequent contacts with the secretary of the NCC, which is hosted in the same Institute.

High level of Competence

The Coordinator, born in 1962, obtained her graduate of bio-engineer and her teaching diploma for higher secondary education at the University of Gembloux in 1985. She worked as research scientist in different areas: she studied rotaviruses and pestiviruses at the University of Liège (1985-1988) and then the molecular endocrinology of bovine development at the University of Gembloux (1988-1994) where she received her PhD. She also gained experience in the pharmaceutical industry (Glaxo SmithKline Biologicals) where she worked as research scientist on SIV and HIV (1988) and as quality control supervisor of vaccines, among others polio vaccine (1994-1995). She expanded her formation by following MBA courses at the University of Louvain-La-Neuve (1992-1994). Since 1995, she is biosafety expert for the Service of Biosafety and Biotechnology at the Scientific Institute of Public Health. She is

working within the framework of regulations on the contained use of GMO's and pathogens and deliberate release and placing on the market of GMO's. Her specific biosafety domains of expertise are high containment levels, animal facilities, gene therapy, vaccines, growth factors, clinical trials, human and veterinary medicinal products. She is group leader of the SBB team of biosafety experts on contained use of GMO's and pathogens.

The Coordinator gets of course a great technical support from all the members of her team who has a great diversity of specializations. She counted in particular on a research scientist who gained a solid experience with polioviruses.
The Coordinator had also fruitful discussions with the medical virology experts of the NCC.
Moreover the experts of the SBB have daily contacts with their homologous in the field of biosafety everywhere in the world where they get technical and scientific advices.

Availability of Sufficient Time and Support

The National Coordinator has not been appointed full time to the containment activities in the frame of the polio eradication programme. However she works full time on biosafety matters and especially in the field of contained use of GMO's and pathogens. She gets an important technical, scientific and administrative support from the team she is coordinating. She carries out all the work in relation with containment activities with the help of this team.
She experienced a little delay of one month for the achievement of the plan if referred to the initial plan of action. This delay was due to internal promotion of three members of the team 'contained use' of the SBB inside the IPH and to the necessity to engage three new experts.

COMPONENT 4. THE NATIONAL LABORATORY LIST

Process of establishing the list

The list of institutions has been essentially established by consulting the aforementioned existing databases outlined for regulations on contained use of pathogens and GMO's. Other recent lists of institutions/laboratories, such as the last official list of registered medical diagnostic laboratories managed by the Section of Clinical Biology of the IPH, and the current database of companies and laboratory departments available on Internet site of the Belgian Bioindustries Association, have also been taken into consideration. The different lists have been merged and redundant information eliminated.
It must be noted that the SBB team has already experienced the establishment of such lists to help inspection Regional authorities to control installations where contained uses of GMO's and/or pathogens could occur.

During the process of generating the final list, it was not attempted to identify all the laboratories of each institution that it could be relevant to include in the list. It was rather focused on the inclusion of all the institutions where wild poliovirus infectious or potentially infectious materials could be retained. Indeed, from the legal point of view, the exploitant of the institution is juridically responsible for the contained uses of pathogens in all the laboratories of his institution. The survey letters and forms have thus been addressed to this person and he was responsible to lead the survey inside his own institution.

The final list of institutions/laboratories is maintained at the SBB.

Completeness of the List

As already mentioned, different types of installations have been involved in the survey: federal, regional or provincial scientific institutes, universities and associated institutes or centers, high schools, diagnostic clinical laboratories including hospitals and clinics, private laboratories, small companies and big industries. Representative institutions of all these sectors have been included in the survey. A total of 411 institutions have been included in the list for the survey (see annex 5).

The aforementioned 'contained use' databases are permanently reviewed and updated by all new information the SBB registers.

Management of the List

A specific database for poliovirus laboratories linked with the aforementioned 'contained use' databases has been created and is hosted at the SBB.

It includes both:
- The name, type and address of the institutions and laboratories to which the letters and forms for national survey have been sent.
- And for each institution/laboratory, the results of the survey for wild poliovirus infectious and/or potentially infectious materials.

All modifications or additions of information that occurred during the survey process have been registered in the database by the Coordinator or by her substitute for polio containment activities. The Coordinator has clearly instructed her substitute.

The maintenance of this database is under the responsibility of the Coordinator. Backup copies of all databases and files hosted at the SBB are regularly made.

COMPONENT 5. THE LABORATORY SURVEY

Thoroughness of the Survey

Survey questionnaires have been sent to all institutions/laboratories included in the National list.

Completeness of responses

The National Laboratory Containment Survey has been conducted during period from June 2002 to November 2002 and has been performed following the National Action Plan for laboratory containment of wild poliovirus in Belgium.

A total of 411 institutions have been contacted (see annex 5). The questionnaire that has been sent to these institutions has been built up following the recommendations laid down in 'the Guidelines for Implementation of Laboratory Containment of Wild Poliovirus' (http://www.who.dk/vaccine/20030724_12) and adapted to the Belgian linguistic and regulatory situation.
A questionnaire has been prepared in French and has also been translated in Dutch.
The mailing included an Introduction letter, an Inventory form for person in charge of the institution, and an Inventory form with its accompanying letter for person in charge of the laboratory (see annex 6).
A note about the plan for laboratory containment of wild polioviruses has also been provided on the SBB website in a chapter entitled 'Polio Eradication and Laboratory Containment' (http://biosafety.ihe.be/Polio/PolioContain.html), essentially in order to help notifiers and also to promote the implementation of the WHO programme on containment in Belgium (see annex 7).

The mailing has been sent on 10 June 2002. A first reminder has been sent afterwards, on 19 Augustus 2002, to the 153 non-responding institutions and a second one on 2 October 2002 to the last 33 non-responding institutions.

Finally, the SBB has obtained a response for all the contacted institutions except for 17 of them. At this stage a 95,9% response rate has been obtained.

Coordination between the Federal level and the Regional competent authorities for regulations on contained use of pathogens and GMO's has been organized.
The list of institutions/laboratories that have been contacted but have not answered to the survey has been sent to the Belgian Regional Ministers for the Environment to let the inspection Regional authorities control these institutions/laboratories (see annex 8 for the letters sent by the SBB to the Regional Ministers for the Environment). The SBB has however written that the 17 laboratories have a very low probability of retaining wild

poliovirus infectious materials referring to the nature of their activities and by extrapolation of the survey results obtained for the same type of institutions.

The SBB obtained a feedback from the Brussels Region. The inspectors of this Region have compelled the 6 non-responding institutions located on their territory to finally send completed forms. None of them retained wild polioviruses (see annex 9). No feedback has been received yet from the two other Regions about the 11 non-responding institutions located on their territory.

Taking into account this last information, a 97,3% response rate has been achieved.

The 11 non-responding institutions have been submitted to a thorough risk assessment. On the basis of knowledge of the activities performed in these institutions and of the results of the survey obtained for similar institutions, it has been concluded that these non-responders can be considered to have a very low probability of retaining wild poliovirus infectious materials. They have thus been afterwards excluded from the survey.

Taking into account the risk assessment performed on the non-responders and their exclusion from the survey, it has finally been considered that a 100% response rate has been achieved.

Quality of the Survey

The fact that the institutions surveyed have responded or not has been daily followed during the survey process and registered.
The analysis of the survey responses has been performed afterwards after all responses have been obtained (except for the aforementioned non-responding 17 institutions). The Coordinator and one other expert of the SBB have analyzed the responses and institutions/laboratories have been classified in three categories: institutions and laboratories that did not retain wild poliovirus infectious materials, institutions and laboratories that clearly retain wild poliovirus infectious materials and doubtful responses. These last cases have been resolved by direct phone contact with the responsible of the laboratory (<1%). The type of activities (control, diagnostic, research, production, teaching) of institutions/laboratories retaining wild poliovirus infectious materials has been encoded as well as the nature of retained materials (wild poliovirus strains, infectious, potentially infectious materials only).
All the institutions/laboratories known to work with poliovirus on the basis of local previous knowledge have responded and gave expected results.

Management of Survey data

As previously mentioned, a specific database for poliovirus hosted by the SBB has been created. This database is linked to existing databases for contained use of GMO's and pathogens in Belgium. The database includes the name, type and address of the institutions and laboratories to which the letters and forms for national survey have been sent as well as the results of the survey for wild poliovirus and/or potentially infectious materials.
All modifications or additions of information that occurred during the survey process have been registered in the database by the Coordinator or by her substitute for polio containment activities. The Coordinator has clearly instructed her substitute.
The maintenance of this database is under the responsibility of the Coordinator. Backup copies of all databases and files hosted at the SBB are regularly made.
All technical documentation related to the National Laboratory Containment Survey is kept at the SBB, IPH.

COMPONENT 6. THE NATIONAL LABORATORY INVENTORY

Thoroughness of the inventory process

The laboratory survey has identified 8 laboratories holding wild poliovirus materials. They were all included in the inventory (see annex 10).
As the inventory questionnaire was included in the survey questionnaire, it was not necessary to send a second questionnaire to the laboratories identified on the survey.

Quality of responses

The type and extent of information requested from laboratories for the inventory process can be found in the inventory form (see annex 6) that has been sent at the time of the survey process. The inventory form followed the recommendations laid down in 'the Guidelines for Implementation of Laboratory Containment of Wild Poliovirus'.

As previously mentioned, coordination between the Federal level and the Regional competent authorities for regulations on contained use of pathogens and GMO's has been organized. The list of institutions/laboratories retaining wild poliovirus and/or (potentially) infectious materials has been sent to the Belgian Regional authorities (see annex 8 for the letters sent by the SBB to the Regional Ministers for the Environment).
It is within the competence of these authorities to verify if each laboratory of the inventory list has an appropriate environmental permit and an authorization for contained use of wild polioviruses. Notification under the regional biosafety regulation of 'contained use' of poliovirus by these institutions/laboratories has also to be urged, if it has not yet been carried out. These authorities must also organize inspections of the facilities to control the implementation of the required containment measures.

As the technical expert of these Regional authorities, the SBB is informed that these laboratories have already notified their contained use activities and that they have mentioned to meet BSL-2 requirements. Experts of the SBB have also taken part in inspection visits to some of these laboratories, as technical support.
However, the SBB has not yet gathered all the information to make a complete report now on this matter. This will be done at the beginning of 2004.

Since March 2003, the inventory list and the information thereon have not been reviewed. It will be done as early as the SBB will have gathered the aforementioned information.

Management of the Inventory data

A current list of such laboratories will be maintained and regularly updated in the SBB database.
As previously mentioned, a specific database for poliovirus hosted by the SBB has been created. The database includes the list of laboratories, which are on the inventory list. The type of these laboratories as well as the type of retained wild poliovirus infectious materials is recorded in this database and in the extracted tables.
The maintenance of this database and of the extracted tables is under the responsibility of the Coordinator.
Backup copies of all databases and files hosted at the SBB are regularly made.
All technical documentation related to the National Laboratory Containment Inventory is kept at the SBB, IPH.

Maintenance of the Inventory

The inventory list has been established for the first time at the beginning of 2003.
The Coordinator is responsible to gather the information from the concerned laboratories as well as from the Regional authorities or from the SBB acting as technical expert for the Regional authorities to review the current inventory list. It has been foreseen that the list will be updated at the beginning of 2004 with all the information that have been gathered. A plan for future actions could then be established.

LIST OF ANNEXES

1. Letters of the SBB to the Regional Ministers for the Environment about the containment activities in the frame of the polio eradication programme undertaken at the Federal level and the implications for the Regional authorities

2. National Plan of Action as it can be found in the following document: 'National documentation for certification of the eradication of poliomyelitis. Country report and update. Belgium. The Belgian Certification Committee. December 2001'

3. Updated National Plan of Action, 22/05/2002

4. Letter of the Director of the Scientific Institute of Public Health (IPH) for the appointment of the National Coordinator for containment

5. National Laboratory List used for the survey

6. Survey mailing: Introduction letter, and Inventory form for person in charge of the institution, and an Inventory form with its accompanying letter for person in charge of the laboratory

7. Page menu of the SBB website on 'Polio Eradication and Laboratory Containment' (http://biosafety.ihe.be/Polio/PolioContain.html)

8. Letters of the SBB to the Regional Ministers for the Environment about the results of the survey

9. Response of the Brussels Regional authorities concerning the 6 non-responding institutes to the survey located on their territory

10. National Inventory of laboratories possessing wild poliovirus strain and infectious materials as it has been reported in the following document: 'Annual update on the status of poliomyelitis Eradication in Belgium. The Belgian Certification Committee. March 2003'