Results all COUNTRIES of Self Evaluation for the

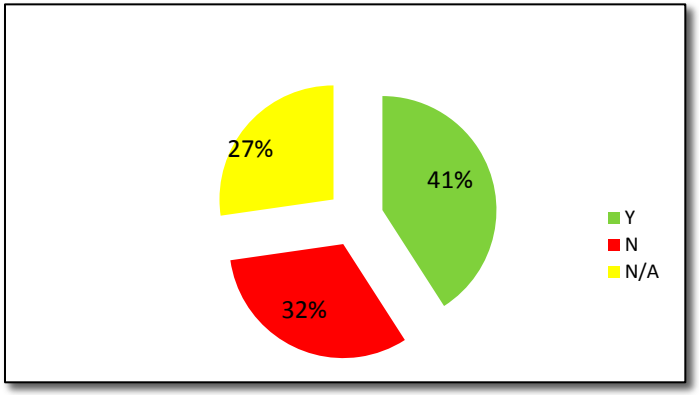
OECD Best Practice Guidelines for Biological Resource Centres

Best Practice Guidelines for the Micro-Organism Domain

4. Specific BRC Best practice guidelines
4.1 Staff- qualifications and training

- Does staff have relevant qualifications, training and competence to carry out their duties?

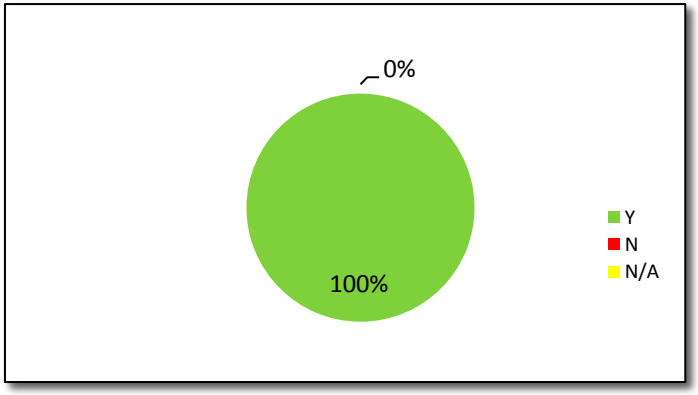
Result for all Countries



4.2 Health and safety

- Does all staff follow the procedures laid down under the appropriate level of containment for the micro-organisms being handled, as defined by the World Health Organisation (WHO, 2004) and as interpreted by national law , regulations and policies, to avoid contaminating samples, risk of infection and environmental dispersion?

Result for all Countries



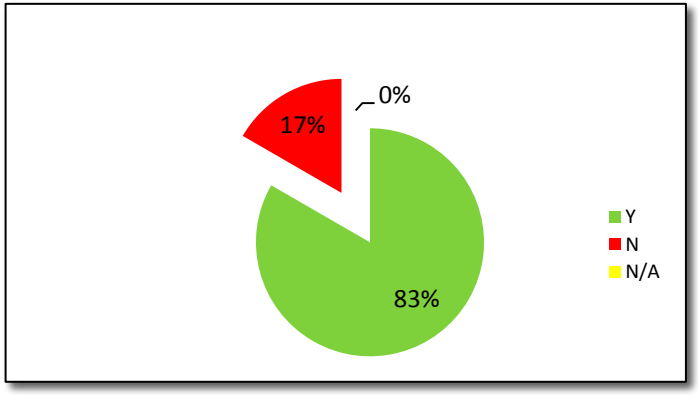
5. Premises

5.1 Construction and operation

•Does the construction respect the containment level appropriate for the risk group of the micro-organisms worked with and does it meet appropriate law, regulations and policies?

•If major building, renovation or repair work, or other work that is likely to compromise containment or clean conditions is necessary in Biological Resource Centres are normal activities being suspended until the building renovation or repair work is completed?

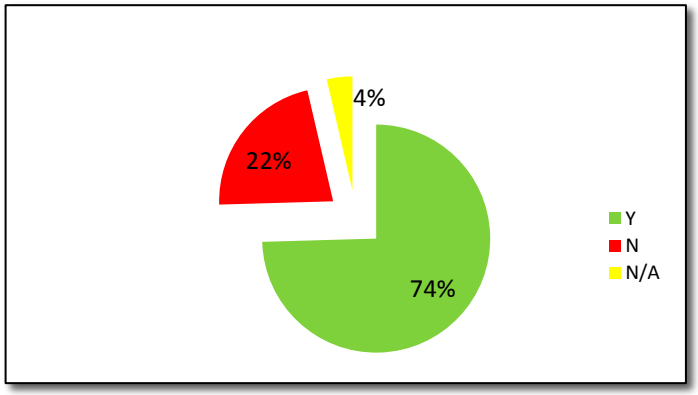
Result for all Countries



5.2 Maintenance and inspection

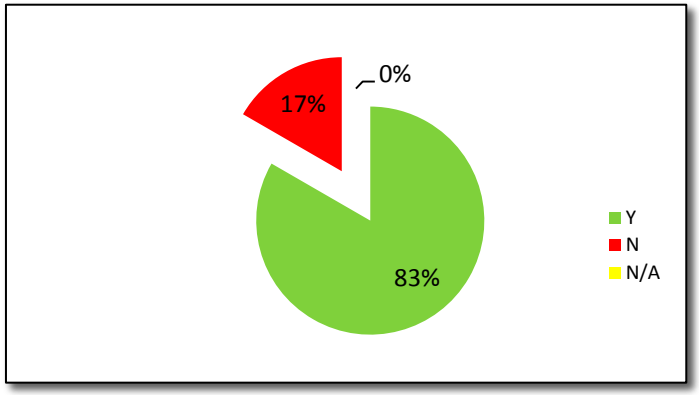
- Is cleaning of laboratory benching and equipment being performed by authorised and trained staff using appropriate personal protection equipment and following documented procedures?
- Is a contamination monitoring programme in place to include environmental monitoring of laboratory air and surfaces?
- If a major contamination problem arises in the BRC, does the BRC manager deal with implementing a cleaning programme and an investigation of the source of contamination?
- Are details of decontamination procedures located in a Procedures Manual or relevant Standard Operating Procedures (SOPs) ?
- Are quality audits and quality reviews being carried out?

Result for all Countries



6. Equipment use, calibration, testing and maintenance records

Result for all Countries

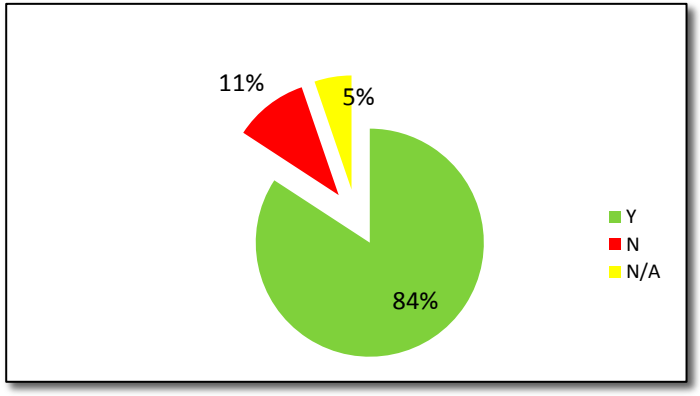


7. Informatics

- Is there a minimum amount of information available for each accession in the collection (Minimum Data Set)?

- Is additional data being included in the Recommended Data Set (RDS) and Full Data Set (FDS)?
- Is the MDS always being recorded and made available, whereas the RDS is only recommended, and the FDS is treated as additional optional information?

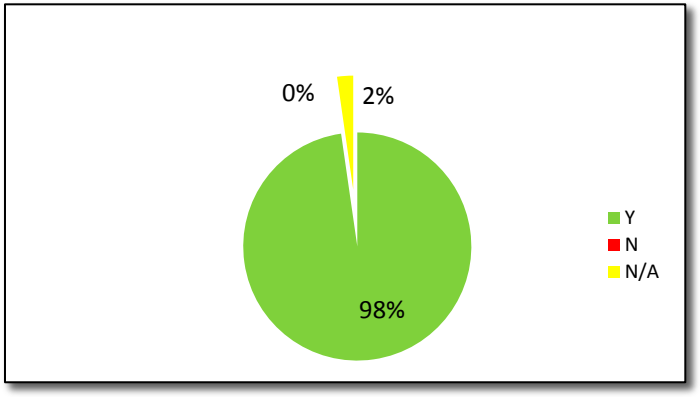
Result for all Countries



8. Preparation of media and reagents

- Is special attention given to accurate preparation and storage conditions of culture media (one of the fundamental steps in the growth and maintenance of biological materials)?
- Has the BRC defined standards for all preparations?
- Is media formulae being documented and procedures put in place to make changes to procedures and to ensure their approval and adoption?
- Are media batches clearly labelled and are expiry dates defined and clearly indicated?

Result for all Countries



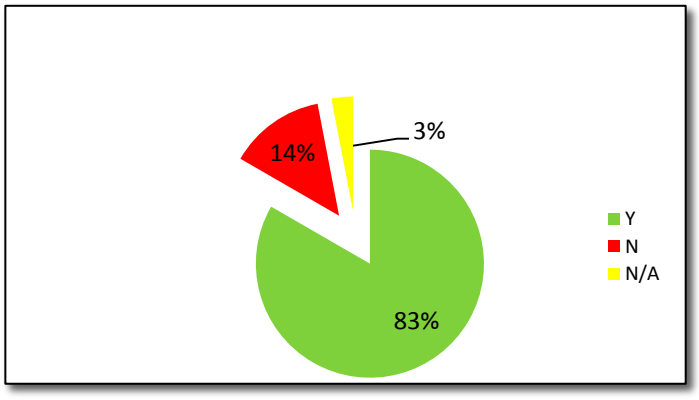
9. Accession of deposits to the BRC

9.1 Receipt and handling of biological materials

- Does the BRC document and implement safe procedures for a receipt and storage appropriate to the type of biological materials handled?

- Are all incoming parcels that contain known or unknown micro-organisms opened in a suitable containment laboratory or appropriate microbiological safety cabinet with local facilities for the safe handling and disposal of biological materials?
- Does the depositor provide assurance that biological materials were obtained legitimately?
- Are conditions of deposit determined, agreed and laid down in a material transfer agreement (MTA)?
- Are quality control procedures being carried out upon receipt of biological material to confirm its purity, identity and viability?
- Before accepting a deposit, does the BRC check against risk group lists and other lists to make sure that the biological material does not exceed the laboratory's biological safety containment level?

Result for all Countries



10. Preservation

10.1 Long-term preservation

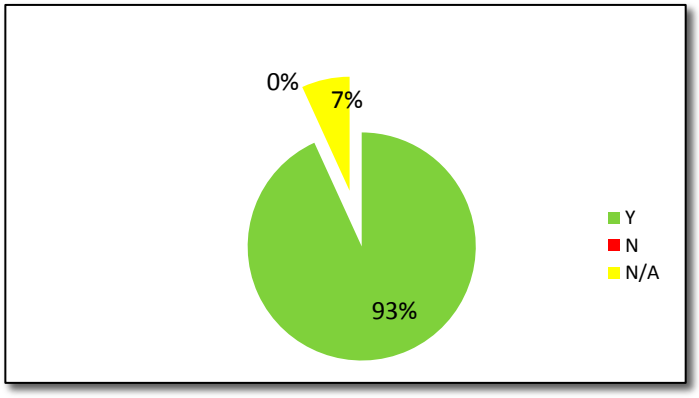
- Has the BRC chosen an appropriate preservation method for each micro-organism culture, based on its own experience or on the recommendations of the depositor?
- Do the methods used ensure the following:

1. High viability/recovery of the preserved culture

2. No contaminant in the preserved culture (this does not include any recognised co-culture e.g. symbiotic micro-organisms) which are not regarded as contaminants so long as the constituents are correctly specified and checked by microbiological and molecular analysis, as applicable)

3. Authenticity of the preserved culture and genome integrity (molecular, phenotypic analysis) where applicable

Result for all Countries



10.2 Validation of methods and procedures

•Is a validation of methods and procedures used for preservation being carried out to ensure their reproductibility and reliability as well as general compliance during the quality control of biological material?

•Is the validation of quality check, characterisation and preservation methods being carried out by using at least one of the following approaches:

1.Performing blind tests

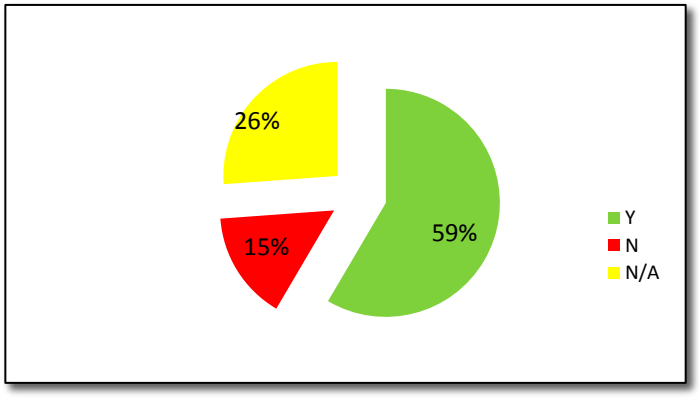
2.Comparing the results of the same method performed at different times (reproductibility)

3.Comparing results obtained with different methods (reliability)

4. Comparing the results obtained for the same method performed by different persons.

5. Are the results of quality checks and the procedure used being recorded?

Result for all Countries

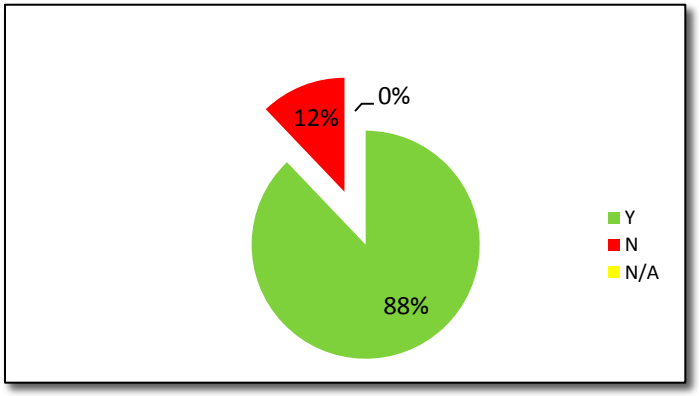


11. Supply of material

11.1 Order placement

To the extent that can be determined, does the BRC supply micro-organisms only to laboratories and only to those individuals who are trained in microbiology and have access to properly equipped laboratories, unless otherwise justified and documented?

Result for all Countries



11.2 User validation

• To ensure that only authorised users may access biological material that is pathogenic or toxic to humans, animals and plants, does the BRC implement any national and international requirements, and as applicable, the following measures for the respective hazardous material:

1.Comply with the measures set out in Best Practice Guidelines on Biosecurity for BRCs

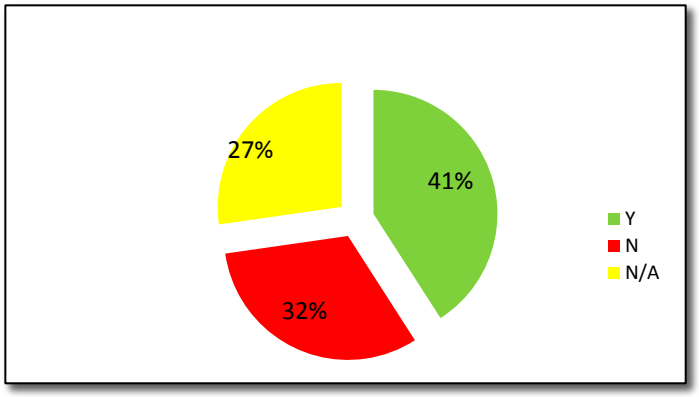
2. Check that the name and signature of the head of department/division match against those registered in the BRCs list of authorised institutions

3. Check that the name and signature of the user match against those registered in the BRC's list of authorised users

4. Have written and signed documentation proving that the user has the appropriate containment facilities and the authorisation to import and handle such biological material?

Is an order only then processed when the required accompanying documentation is completed, signed and returned?

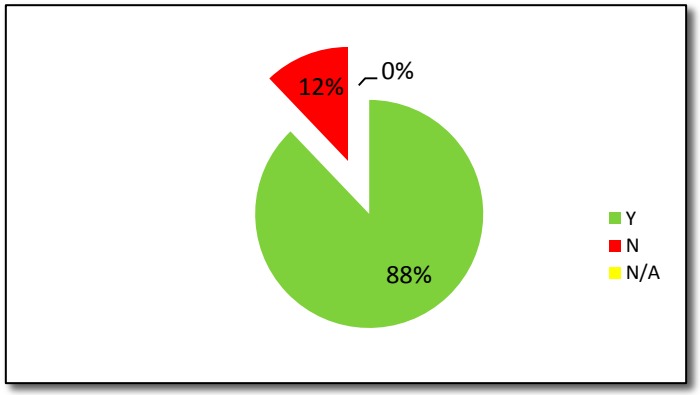
Result for all Countries



11.3 Availability of the biological material ordered

- Is freeze-dried or cryo-preserved (when supplied frozen) material being dispatched as soon as possible once necessary licenses and/or documentation are provided?
- Does the dispatch for such material occur according to laid down procedures and conditions?
- Where materials cannot be delivered within 3 working days, does the BRC inform the client of the delay within 3 working days?

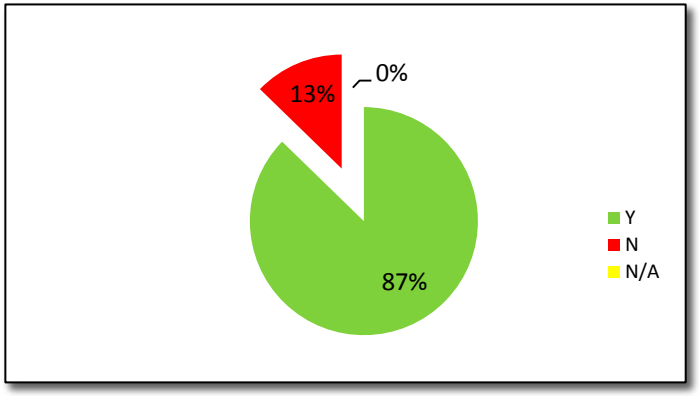
Result for all Countries



11.4 Packaging and Transport

- To ensure safe and secure packaging and transportation of biological material, does the BRC follow the WHO Guidelines on International Regulations for the Packaging and Transport of Infectious Substances?
- Are materials exempt from the WHO guidelines (non-infectious micro-organisms allocated to Risk Group 1) sent by (air) mail or other means of transport according to the Universal Postal Union requirements?
- Does the BRC follow the IATA DGR and other respective regulations, to ensure that all applicable requirements for packaging and shipping dangerous goods on ground and air are met?
- Does the BRC ensure that staff responsible for the distribution of biological material have the necessary knowledge and training?
- Do staff responsible for the distribution of dangerous goods (including infectious substances) via air have the shipper's training certificate as required by IATA?

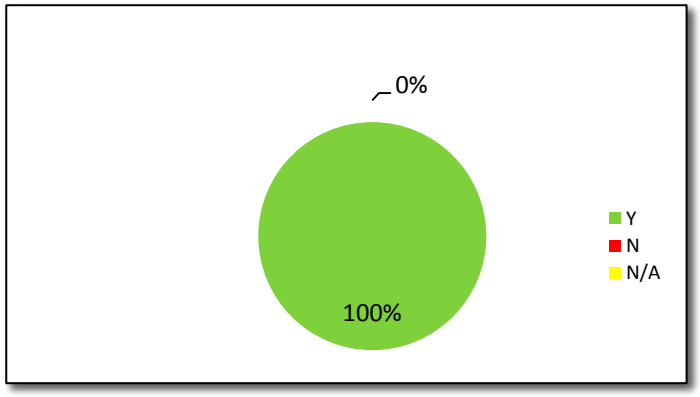
Result for all Countries



11.5 Traceability of hazardous biological material

Does the BRC maintain individual records of all requests for hazardous biological materials, including those requests refused for any reason, showing the biological material, method and date of shipment, and name and address of the person to whom it is sent?

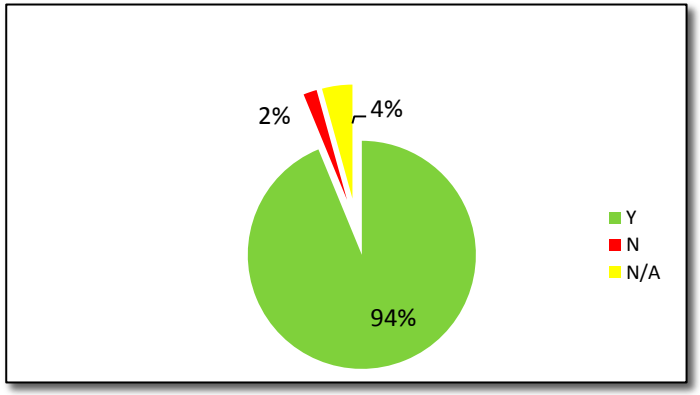
Result for all Countries



12. Micro-organism Biological Resource Centres' compliance with national and international law

- Does the BRC carry out all actions regarding to micro-organisms in compliance with the various legislation and regulations that control these matters?
- Does the BRC ensure that any changes to applicable legislation and regulations are implemented in their procedures?
- Are safety and shipping regulations followed in order to ensure safe transit?
- Does the BRC adhere to regulations relevant to the distribution of micro-organisms?
- Does the BRC comply with the following regulations:
- 1. Applicable health and safety requirements
- 2. Classification of micro-organisms on the basis of risk
- 3. Applicable quarantine regulations
- 4. Intellectual property rights (IPR)
- 5. Requirement that safety information is provided to the recipient of micro-organisms
- 6. Applicable regulations governing shipping of cultures
- 7. Control of distribution of biological material
- 8. Provision of appropriate safety information to the recipient of micro-organisms
- Does the BRC comply with the following essential components for a safe workplace:

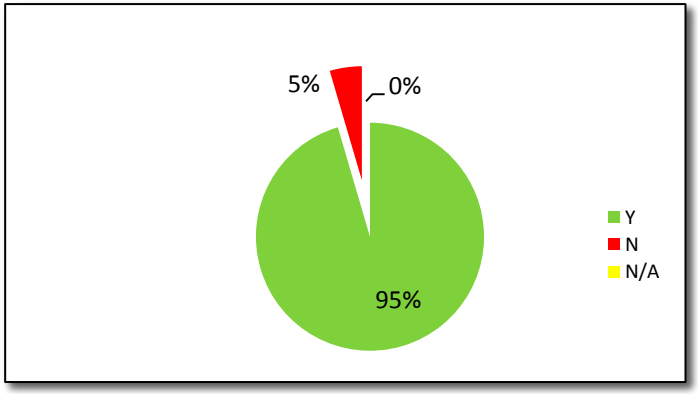
Result for all Countries



12.1 Classification of micro-organisms according to risk-groups

- Does the BRC ensure that all biological materials are assigned to appropriate risk groups?
- Is risk group information recorded and made available to recipients of biological materials?

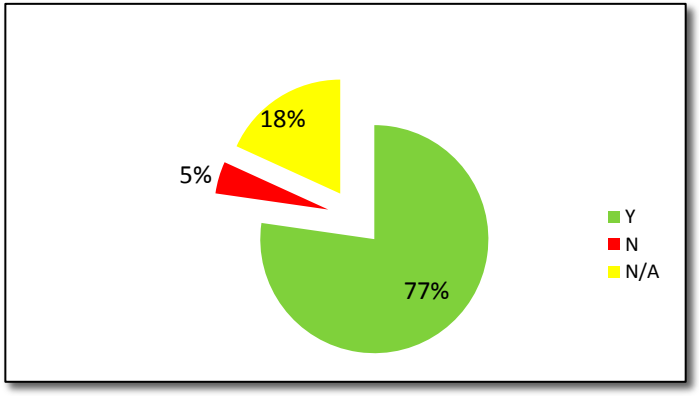
Result for all Countries



12.2 Quarantine regulations

- Are plant pathogens handled by BRCs that are subject to quarantine regulations being registered by an appropriate governmental officer?
- Is import and transfer of such pathogens within the country carried out according to relevant law?

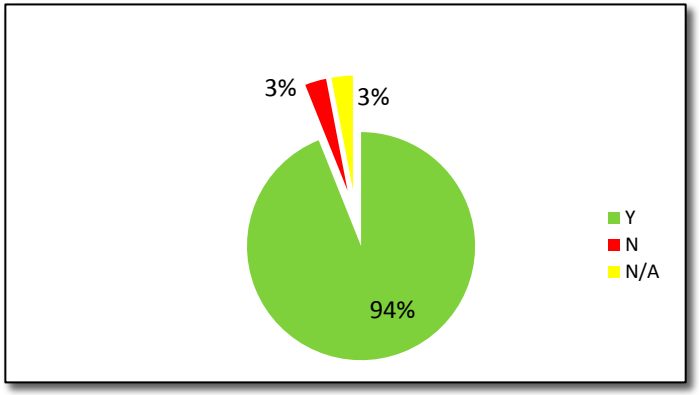
Result for all Countries



12.3 Intellectual Property Rights (IPRs):

- On deposit of a micro-organism, does the BRC record terms and conditions for its further distribution?
- Does the BRC comply with the practice of transparency, retaining the link between the source and all recipients of biological materials?
- Where appropriate, are material transfer agreements being put in place?

Result for all Countries



12.4 Safety information provided to the recipient of micro-organisms

- Is safety information being dispatched with a micro-organism indicating which risk group it belongs to and what containment and disposal procedures are necessary?
- Does a safety data sheet for a micro-organism include the following:

  1.The risk group of the organism being dispatched

  2. A definition of the risks and assessment of the risks involved in handling the organism

  3. Requirements for the safe handling and disposal of the micro-organism

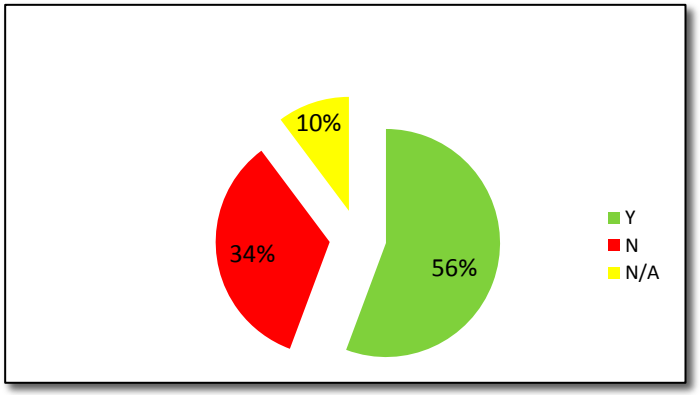
  4. Containment level

  5. Opening procedure for cultures and ampoules

  6. Appropriate transportation of the micro-organism

  7. Procedures in case of spillage

Result for all Countries



12.5 Control of Distribution of Hazardous Micro-organisms

- Does the BRC have procedures in place which meet national requirements to check the validity of customers that wish to receive hazardous organisms?

Result for all Countries