**Results all Countries of Self Evaluation for the**

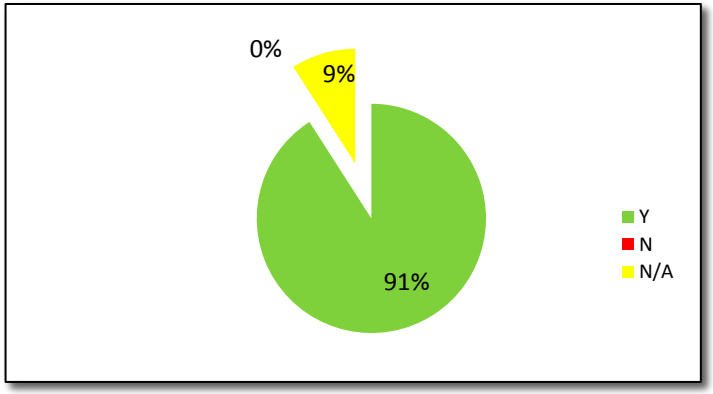
**OECD Best Practice Guidelines for Biological Resource Centres**

Best Practices: General best practice guidelines for all BRCs

## 4. Organisational Requirement

- Does the BRC describe and document the nature of the biological resource it holds?
- Does the BRC define the biological domain and therefore the domain specific criteria that apply?

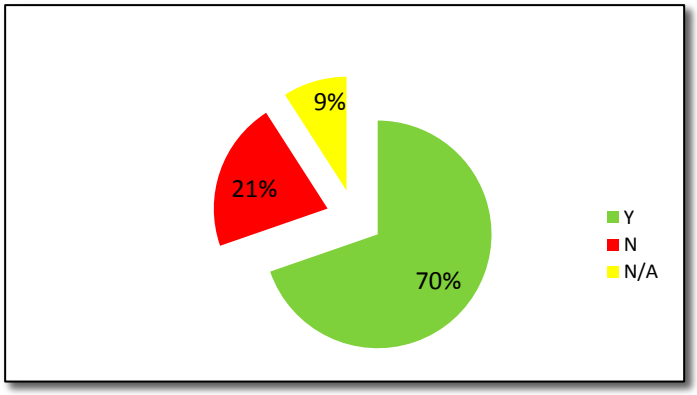
**Result for all Countries**



## 4.1 Long-term sustainability

- Did the BRC develop a strategy für ist long-term sustainability?
- Are adequate and reliable sources of funding available, varying from goverment support, income from services and private support?
- In case that ist future is threatened, does the BRC have a plan to ensure that ist key holdings remain avaiable?

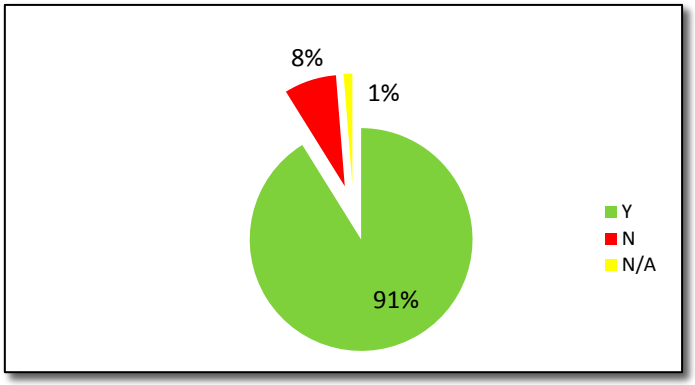
**Result for all Countries**



## 4.2 Responsibilitites of Management

• Does the BRC senior management delegate responsibility for implementation of ist policies to named and suitably qualified membersof staff and provides them with defined responsibilities ans authority?
• Is the list of such staff ant their specific responsibilities avaiable to all ataff of the BRC, particularly to new staff, students ans visitors?
• Does the Senior Management of the BRC ensure that appropriate resources are available for staff members to discharge its responsibility towards this policy?
• Did the BRC appoint a Quality Manager with the following duties:
    1. Administering and monitoring an efficient up-to-date quality management system
    2. Reporting and advising on quality matters
    3. Representing the BRC on quality matters when dealing with users, suppliers and outside bodies
• Can a deputy be appointed to serve in the absence of the Quality Manager?
• Does the Quality Manager have direct access to the Senior Management of the BRC on matters concerning quality?
• Did the BRC designate a biosecurity officer, at operational level within the BRC, whose responsibility is to ensure internal compliance with the "Best Practice Guidelines on Biosecurity for BRC's"?

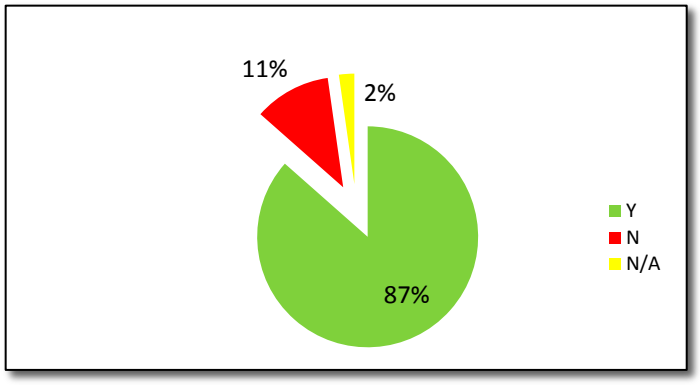
**Result for all Countries** →



## 4.3 Staff - qualifications and training

- Do members of staff receive appropriate tasks according to their training?
- Does each member of staff have documented job descriptions with specific delegated tasks and defined responsibilities?
- Is staff being trained according to documented protocols in skills specific to the job?
- Do members of staff receive training as new technologies or practices are introduced? Is this training being reviewed annually?
- Is the authorisation to use specialist equipment being documented in training records?
- Does staff receive appropriate training before using specialist equipment?
- Is the staff aware that it bears the responsibility to familiarise themselves with documented protocols and comply with the policies and procedures laid down in the BRC Standard Operating Procedures and associated documentation at all times?
- Does the management ensure that staff has access to Quality Manuals and that they are understood and kept informed of any amendments?

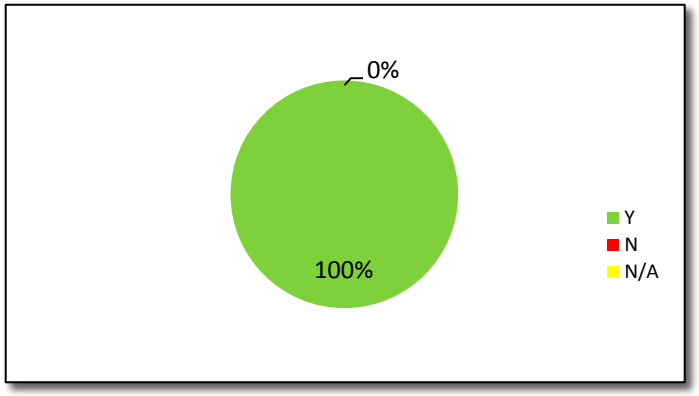
**Result for all Countries**



## 4.4 Health and safety (biosafety)

• Does all staff follow the procedures laid down under the appropriate level of containment for the organisms being handled to avoid contaminating samples and risk infection?

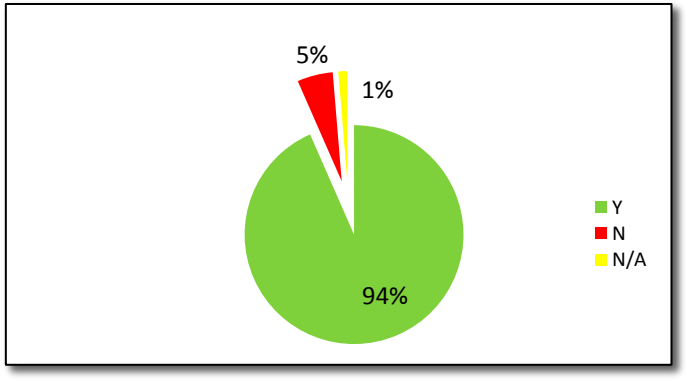
**Result for all Countries**



## 5.1 Biological Resource Centre operations

- Does the BRC dispose of appropriate areas required for the specific operation of a BRC, as required for the domain of the biological materials?
- Are the following activities being accommodated:
  1. Receipt and storage of the initial sample
  2. Preparation, regeneration, handling and processing of samples
  3. Biological material storage area and back-up or safety duplicate collection. Duplicate collection should be preferably in a remote building or alternative site.
  4. Supply, delivery / sales (kept separate from incoming accessions)
  5. Decontamination, cleaning of equipment and processing of wastes
- Are other areas associated with the BRC being kept structurally sound, unobstructed, clean and free from laboratory materials?

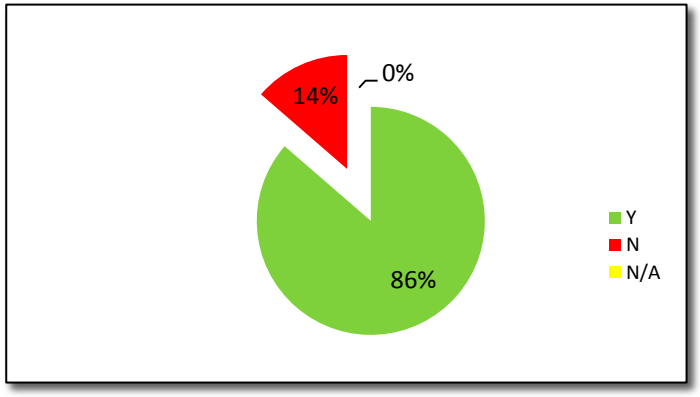
**Result for all Countries**



## 5.2 Construction and operation

- Does the construction meet appropriate national regulations and policies to the containment level appropriate for the risk group of the organisms worked with?
- In case of major building, renovation, repair or dirty work in BRC laboratories, are normal activities being suspended until the building, renovation, repair or dirty work are completed?

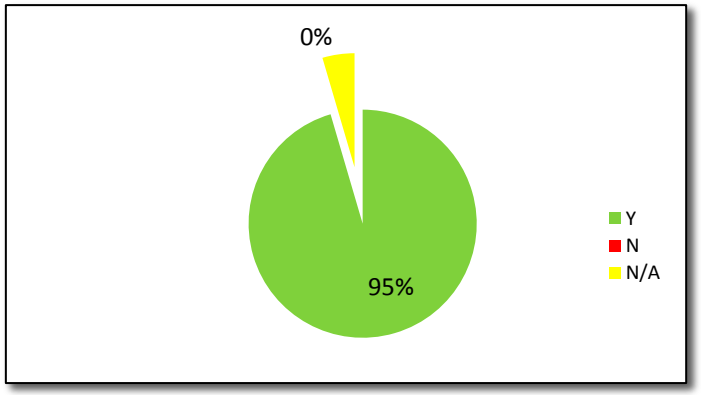
**Result for all Countries**



## 5.3 Access

- Is access to the BRC restricted for authorised staff or those accompanied by them?
- Does the BRC pay particular attention to security and is it fitted with security devices?

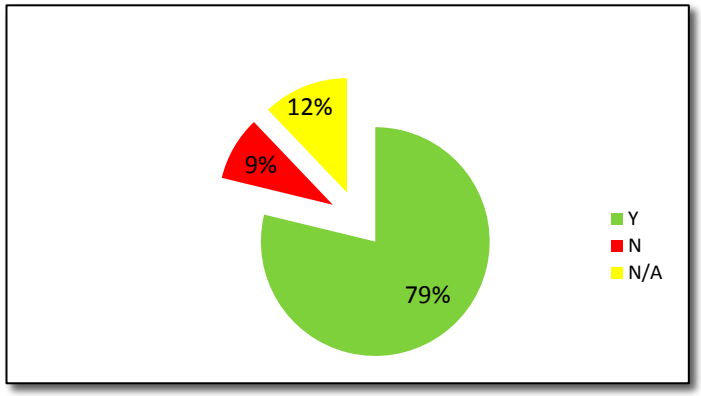
**Result for all Countries**



## 5.4 Maintance and inspection

- Are cleaning and decontamination procedures being documented?
- Is the building being cleaned on a regular basis?
- Is the cleaning of organism containment areas and specialist equipment being performed by authorised and trained staff, using appropriate personal protection equipment following documented procedures?

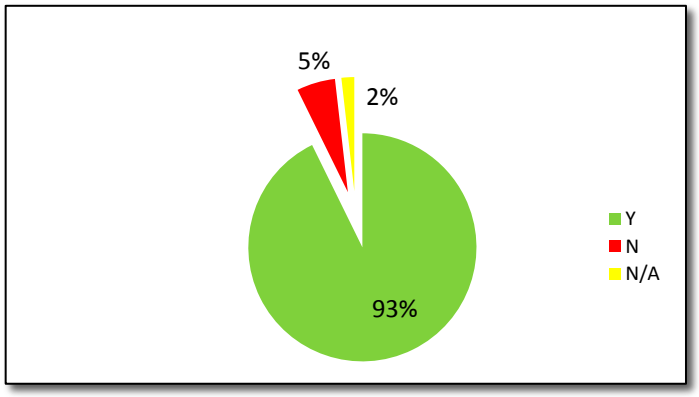
**Result for all Countries**



## 5.5 Outside support services and supplies

- Are support services used by the BRC of adequate quality to sustain confidence in its activities?
- Are supplies being purchased from reputable companies with, if possible, proven quality of products?
- Can the BRC confirm the quality of vital supplies, where no independent assurance of quality of support services is available?
- Are copies of purchase orders being held on file?
- Are records of suppliers, standing orders etc. being maintained for a minimum period of five years?

**Result for all Countries**

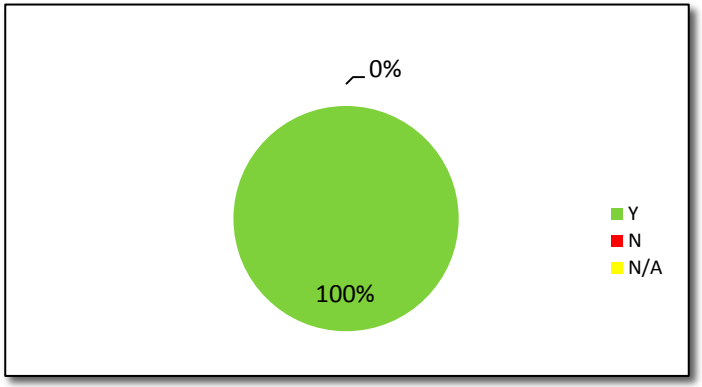


## 6. Equipment use, calibration, testing and maintenance records

Are equipment management procedures including use, control of performance, maintenance and calibration laid down in a predefined schedule?

- Are instructions for these activities laid down in the manufacturer' s handbooks / manuals or in the BRC procedure?
- Are service records and copies of key documents being held in the BRC Equipment Maintenance and Calibration Log books in the care of the Quality Manager?

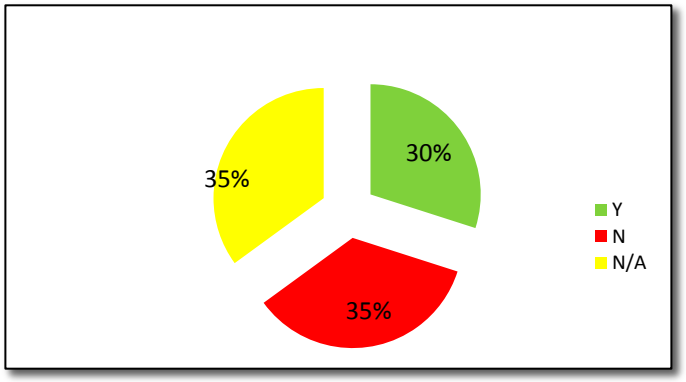
**Result for all Countries**



## 7. Documentation management

- Can the BRC Quality Manager ensure that all documentation is correctly updated?
- Are all alterations to any operating documents being firstly agreed upon by the Quality Manager?
- Are amendment sheets being issued to all holders?
- Are short-term sanctioned alterations being made in ink by scoring through existing wording so that it is still legible?
- Are the alterations signed and dated by the Quality Manager?
- Are copies of the quality manual and, if appropriate, specific procedures made available to enquirers, course participants and staff through the BRC Quality Manager? Are these copies clearly marked as uncontrolled copies and is it clear that such copies should not be updated?

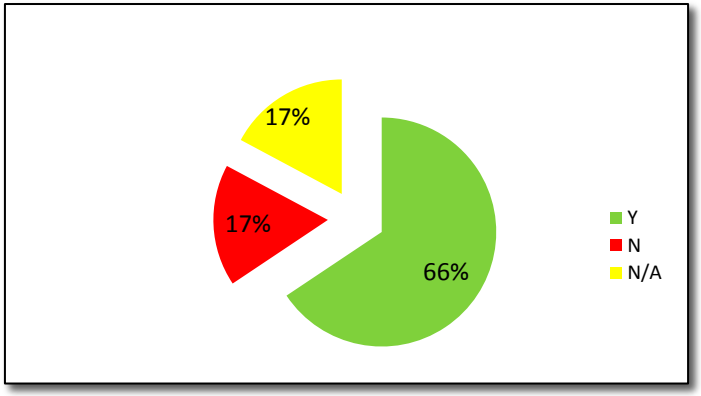
**Result for all Countries**



## 7.1 Compliance with internal dokumentation

- Does all staff adhere to the prescribed policies and procedures?
- Are any departures from documented procedures agreed upon by senior management prior to deviation?
- Are written permission and justification included in the relevant records?
- In the case where a procedure is not followed, is a deviation report being made, outlining the specific error and corrective actions that will be taken?
- If failure has been brought about by a misunderstanding or misdirection, is the error being investigated, rectified and retrained implemented if necessary?

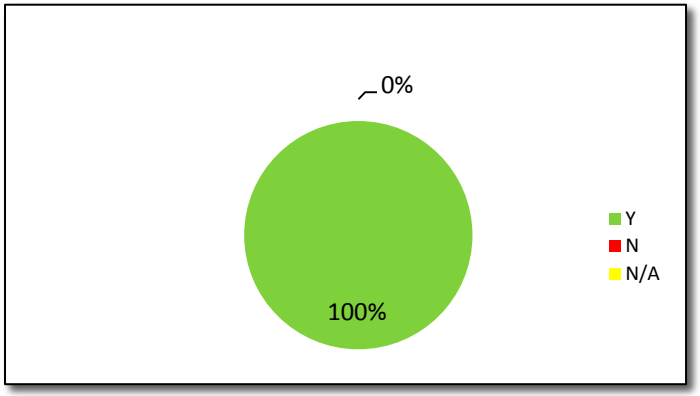
**Result for all Countries**



## 8. Data and informatics

- Does the BRC manage, store data and produce electronic catalogues based on authenticated and validated information?

**Result for all Countries**



## 8.1 Data management

- Can the BRC provide evidence to assure the validity of the data?

  Does the BRC fulfill the following terms connected to authentication of data:

  1. Provide traceability of data through a history of modifications (dates and signatures of inputs, validations, modifications and deletions)

  2. Give signature for data entry, validation, modification or deletion?

  3. Check vocabulary against standard reference lists or thesauri

  4. Keep consistency among BRCs for searching and retrieving of information from catalogues and databases:

- Does the BRC use the following standards of terminology, formats for data management and exchange and standard protocols for data transmission to networks:

- 1. Select data format, data representation and data transportation taking into consideration existing standards for data processing, e.g. DarwinCore/DiGIR and ABCD schema/BioCASE for strain data, CCINFO for the organisational information of BRCs.

- Each biological material record should contain a Minimum Data Set, a Recommended Data Set and/or a Full Data Set in accordance with domain specific criteria

- Spell checking for every field should be a basic requirement

- International English should be chosen as a preferred language of data (in addition to local language if different)

- A standardised approach should be adopted to certain scientific symbols?

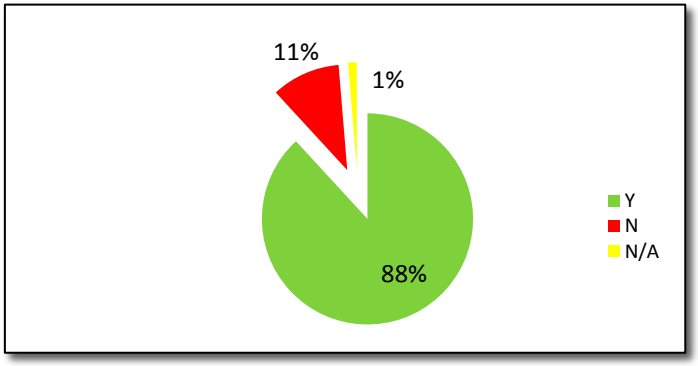
- Does the BRC adopt procedures to detect errors in data in order to improve their quality and consistency?

- Are for the existing data a series of checks being carried out to ascertain their validity and completness?

- Is for new data, wherever possible, inputting being checked against authorised lists of not only scientific names, but also thesaurus/ontology to prevent errors such as mistyping?

- Can the BRC present evidence that they have applied a recognised protocol appropriate for each data element?

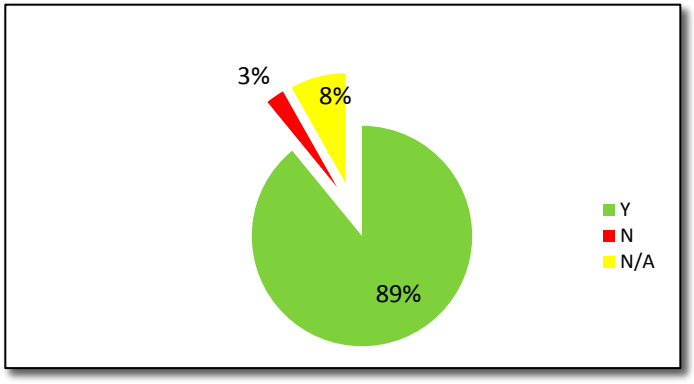
## Result for all Countries



## 8.2 Data processing

- Does the BRC provide appropriate facilities for information management, linkage and exchange of the BRC?
- Do databases contain information related to strains held by a BRC or other relevant data items or composite data needed by the BRC?
- On the loss of a strain, is either a database record being printed out and stored on file or copied to a digital archive before the entry is removed from the working database, placed in reserve or annotated to indicate that it is no longer available as living material?
- Has the BRC chosen standard data schema and protocols to make the databases distributed and interoperable?
- Is confidential data clearly identified in relation with user authentication capability, encryption techniques and other related information security tools?
- Does the informatics system ensure regular data back-up?
- Are data archives maintained in accordance with the maintenance of the biological resource storage policy?
- Is the support of these archives being regularly updated according to its physical characteristics (obsolence) and to software compatibility?
- Can the BRC assure reasonable security of information by introducing appropriate measures in their own informatics system?
- Are the backup-files being stored in secure cabinets?

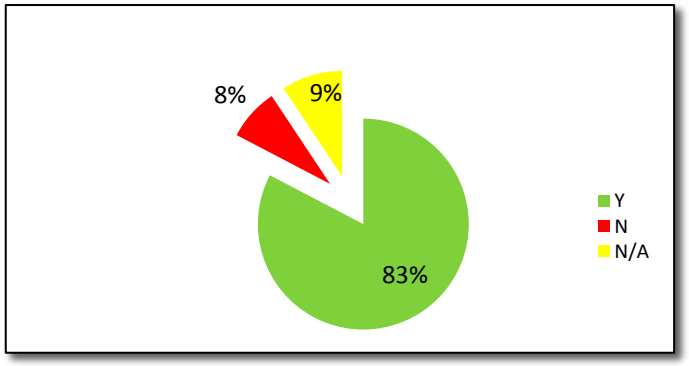
**Result for all Countries**



## 8.3 Access to data and publication

- Has the BRC made available the data describing the biological material and its origins and does it provide electronic catalogues to users through their own facilities or through focused, national, regional or global networks?
- Does the BRC respect a defined update frequency for data publication, in accordance with the flow of available biological resources?
- Can the BRC ensure the quality and consistency of data sets and provide data to users while ensuring information security, bio-security, protection of IPRs, client information and human dignity?
- Does the BRC adhere to national data protection regulations?
- Is the exchange of information in line with the OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal data?
- Does the BRC restrict access to the electronic catalogues where appropriate?
- Are specific identities and passwords being provided by the BRC to users in order to access different categories of information and services?

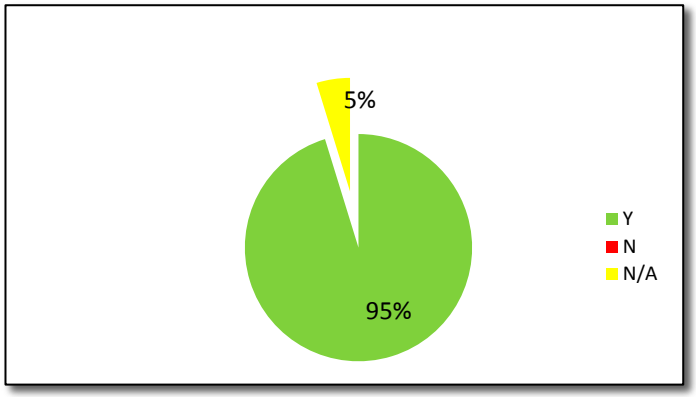
**Result for all Countries**



## 9. Preparation of media and reagents

- Did the BRC define standards for all preparations used in the growth and/or maintenance of the living biological materials held? Are these standards documented with the appropriate mechanisms in place to allow changes in procedures?
- Are supplies of materials for use of high standard and not at all contaminated?

**Result for all Countries**

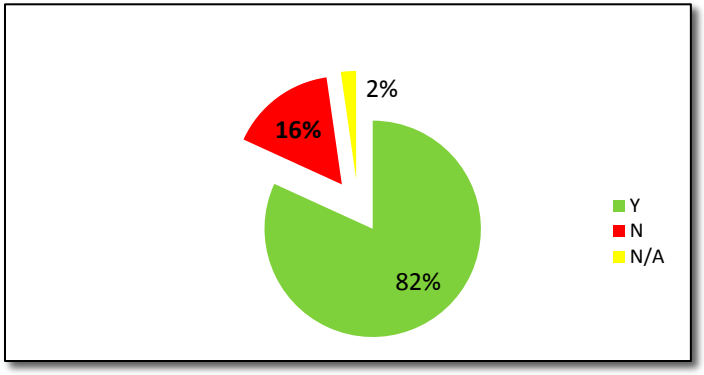


## 10. Accession of desposits to the BRC

### 10.1 Receipt and handling of biological materials

- Does the BRC document and implement procedures for the receipt and storage appropriate to the type of biological materials handled?
- Is a risk assessment being carried out on the biological material?
- Is the risk assessment being regularly reviewed and updated?
- Is a unique collection number being allocated to the biological material?

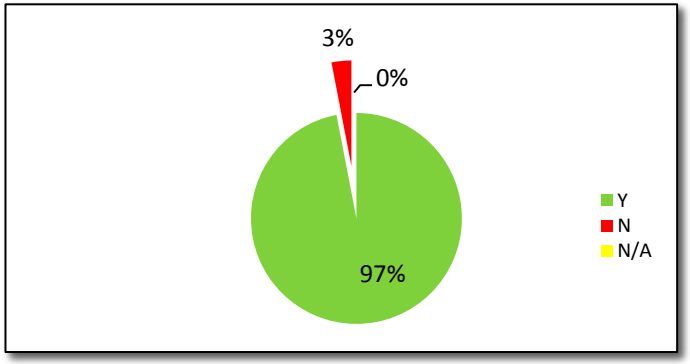
**Result for all Countries**



## 10.2 Accession

- Does the BRC document its acquisition policy by defining the biological material to be maintained and the criteria on which the acceptance of new biological material offered to the collection is based?
- Does the BRC only accept desposits of biological material that meet its acquisition criteria and fall into the groups of its specialist expertise?
- Does the biological material received hold the following information:
  1. Name (where one can be applied), other identifier or cell culture description.
  2. Depositor's name and address
  3. Source, substrate or host from which the biological material was isolated or derived (where identified) and date of isolation
  4. Geographical origin of material (the minimum requirement is the country of origin or the furnisher of the source, substrate or host)
  5. Depositor's biological material number or other collection number(s), if deposited elsewhere
  6. Growth media and conditions, cell preservations or storage sonditions where known
  7. Hazard information e.g. in the form of a safety data sheet

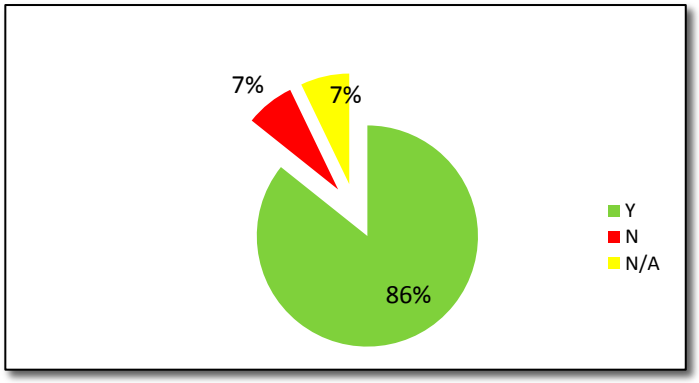
**Result for all Countries**



## 10.3 Quality checks on the biological material

- Does the BRC perform authentication tests as well as determine the stability of some key features, growth requirements and methods of maintenance and/or preservation as appropriate to the biological material maintained, using appropriate technology?
- Does the BRC retain these records and are these used when in-storage maintenance checks are performed or for validation after preservation restocking?
- Is the identity of the biological material being confirmed after receipt by a competent person?
- Is the biological material being checked again by the competent persons before and after preservation? (This step may include identity, purity or property check of the biological material performed by the depositor)
- Is a "maintenance plan" in place for each item stored?
- Is the maintenance check appropriate for the biological material and is it laid down in the domain specific criteria?

**Result for all Countries**

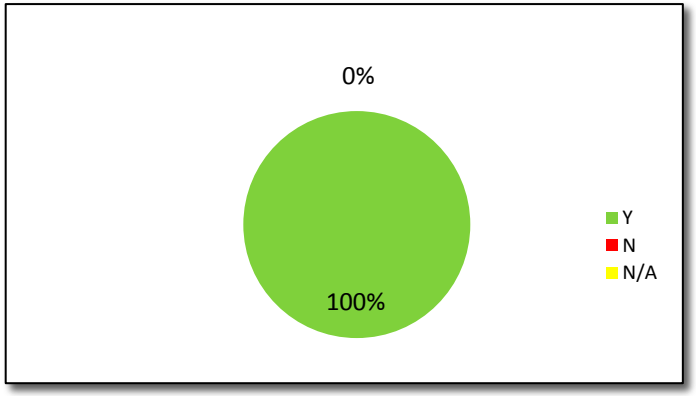


## 11. Preservation and maintance

- Did the BRC select preservation and maintenance methods according to recommendations from the depositor and/or previous experience?

- Does the BRC document the preservation procedures to ensure that they are reproductible and that key parameters of the process are recorded and monitored?

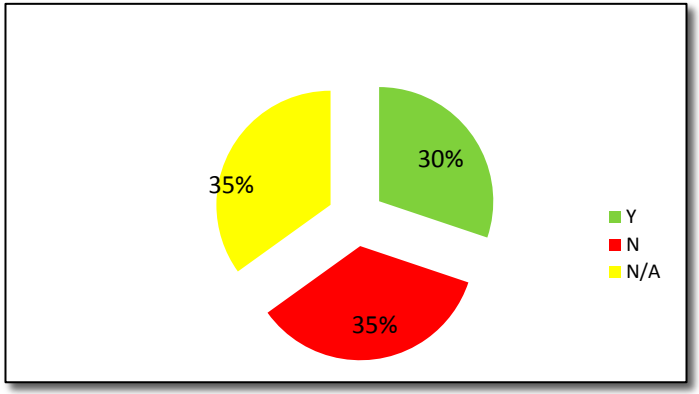
**Result for all Countries**



## 11.1 Methodology

- Is the biological material being preserved by at least two methods?
- Do labels include at least the batch date or number and the BRC accession number?

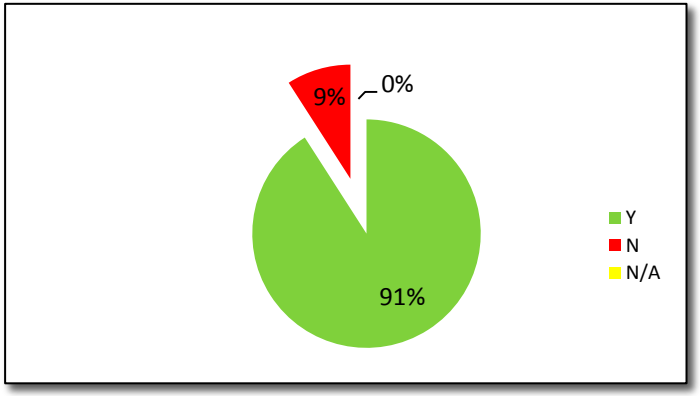
**Result for all Countries**



## 11.2 Stock control of the preserved biological materials

- Does the BRC use master (or seed) and distribution stocks?
- Does the BRC produce the master stock from the original biological material?
- Is this master stock being used to generate the distribution stock?
- Does the BRC adapt the size of these masters and distribution stocks to the anticipated distribution rate?

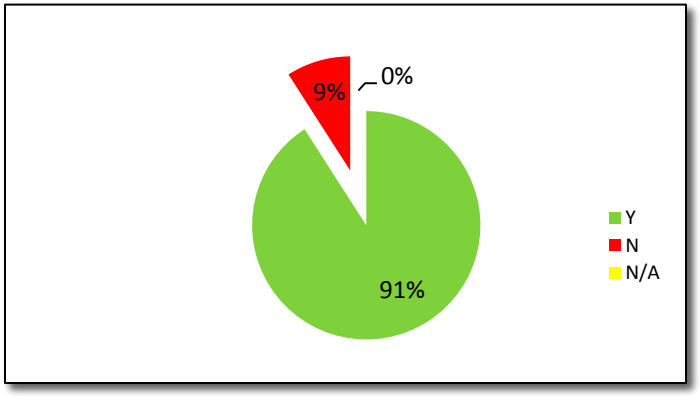
**Result for all Countries**



## 11.3 Storage of preserved biological materials

- Is the biological material stored under environmental parameters that assure the stability of its properties?
- Are details of the inventory control, lead times and re-stocking practices documented?
- Is a duplicate collection being maintained ?

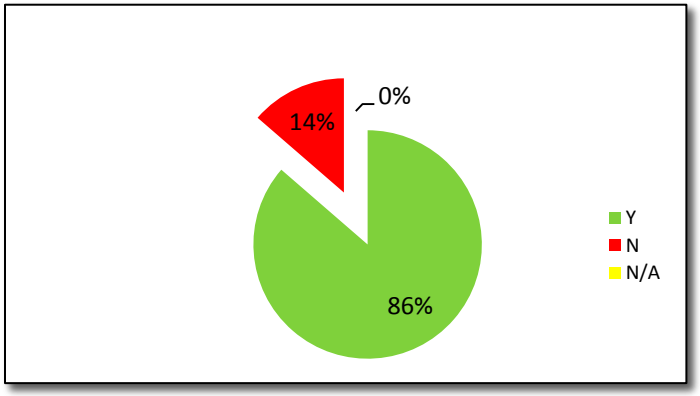
**Result for all Countries**



## 11.4 Validation of methods and procesdures

- Does the BRC document all methods and procedures used in validation?
- Are the results of method and procedure validation recorded?

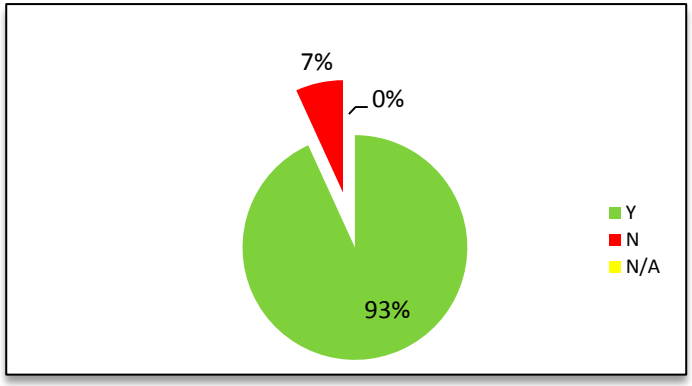
**Result for all Countries**



## 12. Supply
## 12.1 Order Placement

- Does BRC only supply to users who have the appropriate facilities and meet the specific requirements for receipt as required by relevant national and international regulations and policies?
- Are the materials distributed according to the policy of each depository?
- Does this policy take into account the nature of the biological materials and meet all relevant national and international regulations and policies?
- Is an order only then accepted when the required accompanying documentation is completed, signed and returned?

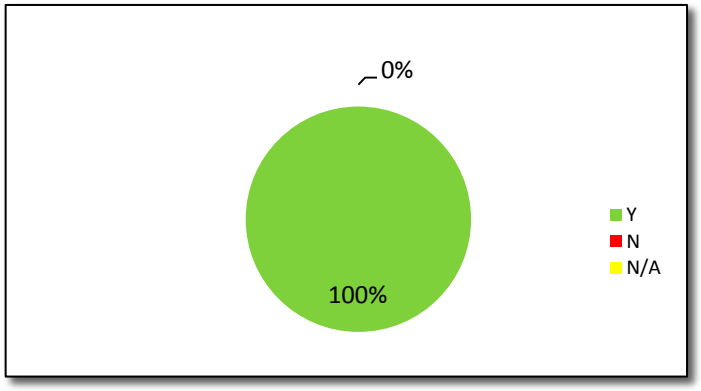
**Result for all Countries**



## 12.2 Availability of the biological material ordered

- If a biological material cannot be delivered within the specified delivery time, does the BRC contact the user with an estimated supply date?

**Result for all Countries**

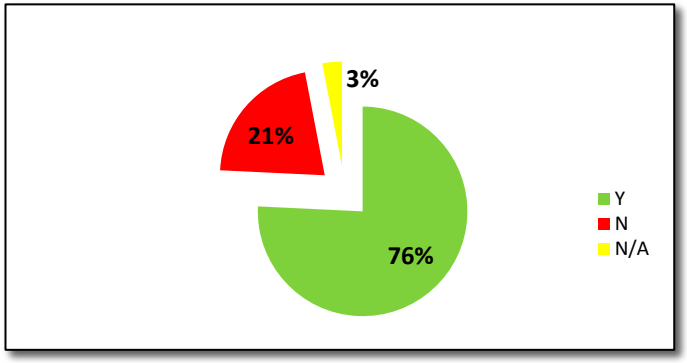


## 12.3 Information provided with the biological material supplied

- Does the BRC provide at least the following information to the user:

1. Biological material identifier, accession number and batch number
2. An estimate of shelf-life, storage conditions, storage instructions and if appropriate, conditions of growth
3. Instructions for opening ampoules or vials (when appropriate and in all cases where materials are being provided to new users)
4. A safety data sheet including the containment level required for handling the biological material, disposal measures and measures to take in case of spillage.
5. A Material Transfer Agreement: an essential requirement to protect IPR and mandatory where they are required by national law. They are used to relay the depositor's and/or country of origin requirements on use of the biological material
6. Fax-back sheet to acknowledge receipt of materials may be desirable

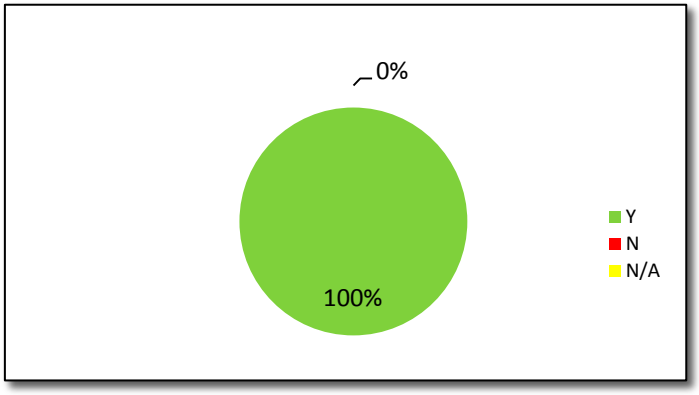
**Result for all Countries**



## 12.4 Packaging

- Does the BRC pack and send its biological material according to current postal, IATA and ADR regulations?
- Does the BRC also meet additional requirements imposed by other regulations such as quarantine, biosafety and/or biosecurity regulations?

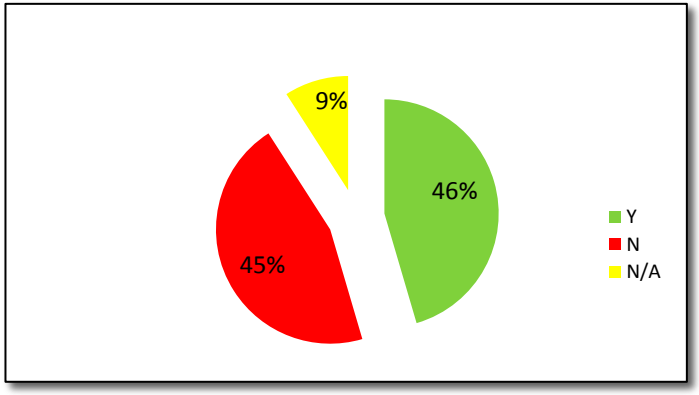
**Result for all Countries**



## 12.5 Invoicing for supply charges

- Are invoices normally being dispatched at the same time as the material unless otherwise instructed or where pro forma invoices have been paid in advance?

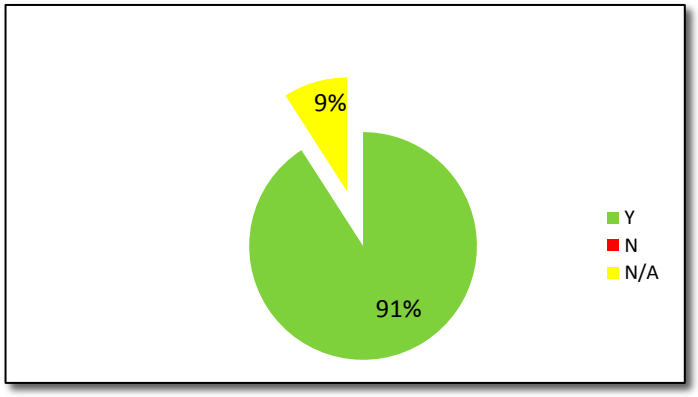
**Result for all Countries**



## 12.6 Traceability of biological materials supplied

- Does the BRC keep records of all requests for biological materials, including those requests refused for any reason- showing the biological material, method and date of shipment, and name and adress of the person to whom sent?
- Are records of shipment receipts maintained? Do these records meet national law, regulations and policies?

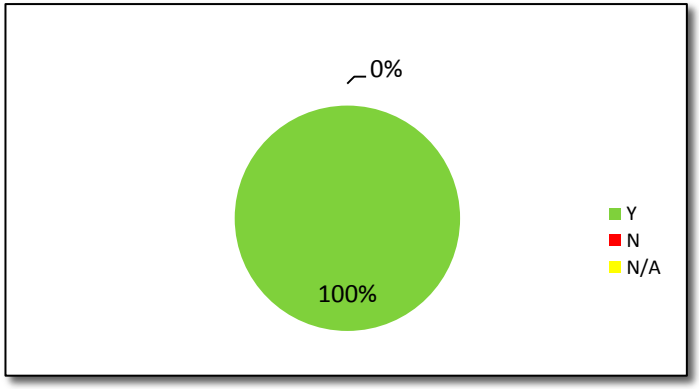
**Result for all Countries**



## 12.7 Handling complaints and anomalies

- Can the BRC effectively record all user queries or complaints and acknowledge them as soon as possible by fax, telephone or e-mail?
- Does the BRC investigate the complaints as soon as received and implement the necessary corrective actions? Are all complaints being included in regular trend analysis?
- Are records of responses/solutions being stored?

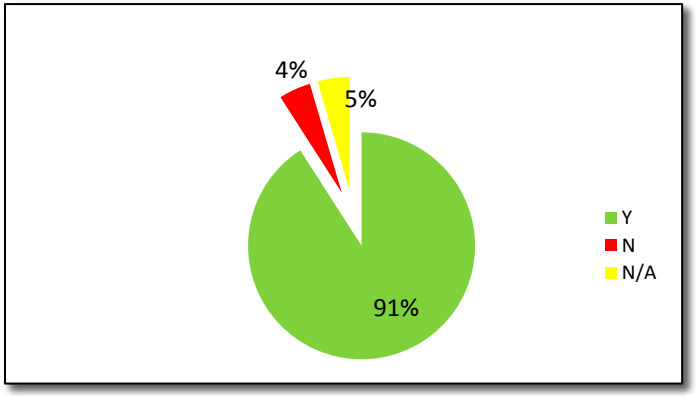
**Result for all Countries**



## 12.8 Refunds

- If the user is not deemed at fault, is the normal policy being followed by providing the user with a replacement free of charge where this is possible?
- If considered appropriate, are refunds being given?

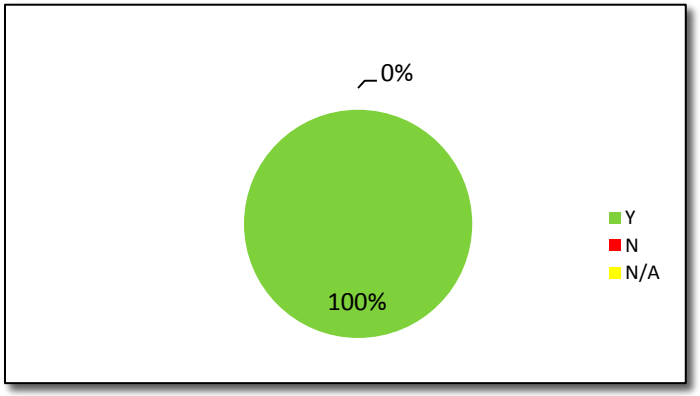
**Result for all Countries**



## 12.9 Confidentiality

- Is all work carried out by a client being treated as strictly confidential to that client unless national requirements apply?
- Does this apply to all requests for biological materials, safe and patent deposits, information supplied relating to these and to the fact that the product or service was requested in accordance with national law, regulations and policies?
- Are the names of past and present clients only revealed with the clear permission of the client?

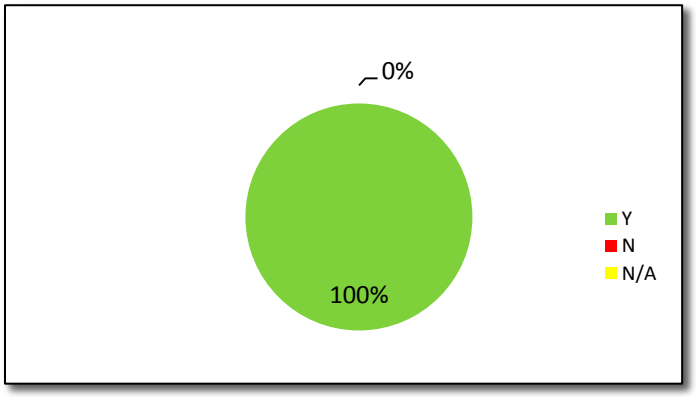
**Result for all Countries**



## 13. Quality audit and quality review
## 13.1 Purpose

- Are periodic audits being carried out by management to ensure that BRC policies and procedures, as set out in these best practice guidelines and the supplemental domain specific best practice guidelines ?

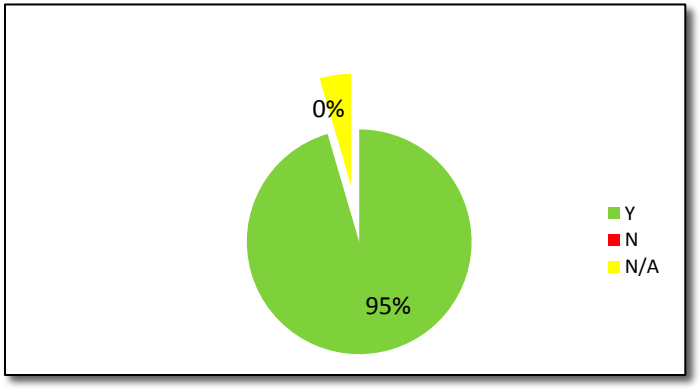
**Result for all Countries**



# 13.2 Responsibility

- Does the BRC manager or a delegate carry out an assessment of the effectiveness of procedures and organise the audit Programme?
- Does the Quality Manager ensure that reviews are recorded and that any actions are implemented?

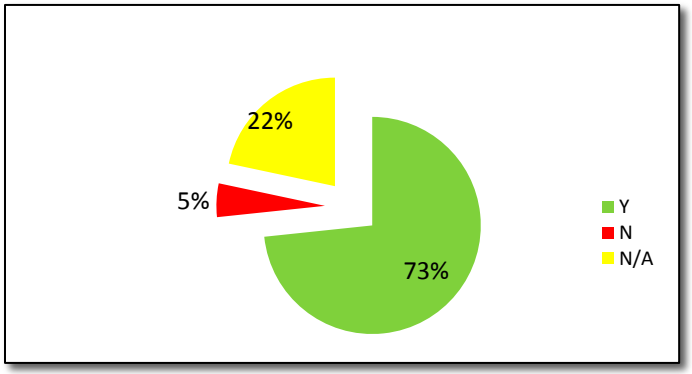
**Result for all Countries**



## 13.3 Implementation

- Does the BRC staff undertake at least one audit each year according to the schedule described in the Rolling Audit Programme?
- Does this Programme entail the review of all BRC activities (documentation, supply, accession, database, training records, equipment and maintenance, enquiries and complaints records and external support services)?
- Does this review additionally include a strain deposit trail through to storage and a supply trail from receipt of order to supply? Are these chosen at random?
- Are the Day Work Books, enquiry records and database records also reviewed?
- Are the results of the audit and record reviews recorded and faults rectified?
- Does an external independent qualified person carry out a Third-Party Audit of the procedures, preferably each year?
- Does this audit also include a biological material deposit trail through to storage and a supply trail from receipt of order to supply? Are these chosen randomly?
- Are The Day Work Books, enquiry records and database records also reviewed?
- Are the results of the Third-Party Audit and record reviews recorded and faults rectified?
- Is a meeting of all audit staff, BRC staff and line management being held annually in order to review the audit reports, enquiries and complaints received and discuss potential improvement in procedures and monitoring?
- Are the results of the review recorded and is the Quality Manager responsible for implementation of actions prescribed?

**Result for all Countries**



## 13.4 Method and procedure for quality checks

- Are all methods and procedures subject to in-use quality checks?
- Are such checks included in the individual documented procedures?

**Result for all Countries**