Results for all Countries of Self Evaluation for the

OECD Best Practice Guidelines for Biological Resource Centres

Best Practices: Best Practice Guidelines on Biosecurity for BRCs

4. Assessing biosecurity risks of biological material

- Can the BRC ensure that a detailed inventory of the different biological materials it holds is available?
- Did the BRC conduct a risk assessment of the biological materials in their inventories for the purpose of assigning such materials to biosecurity risk levels, which may be assigned as high, moderate, low or negligible?
- Is the level of biosecurity risk of biological material determined according to the best available information on its potential for malicious misuse as well as its virulence?
- Does the risk assessment address the potential of biological materials (should they be obtained and misused by unauthorised persons, to cause harm to the health of humans, crops, livestock or infrastructure)?
- Does the BRC engage in developing expert networks that can contribute to the provision of risk analysis?
- Does the BRC share its experience with other BRCs regarding the results of qualitative risk assessment and the reasons for assigning the biosecurity risk level of a particular biological material and does the BRC make all such documentation available to competent national authorities?
- Does the BRC determine a biological material's biosecurity risk level as a function of its potential for malicious misuse and its virulence?
- Does the BRC assess the potential for misuse based on the following key factors:

  1. Availability: the number of facilities that stock the biological material and their geographical distribution
  2. Amplification: the case with which the biological material can be replicated, for example whether it can be grown in culture and its growth rate
  3. Skills and knowledge: the ubiquity or rarity of the skills and knowledge necessary to amplify and/or genetically modify the biological material
  4. Dispersal: the ease and effectiveness with which the biological material can be dispersed, such as by air, water, food or by other means into the environment. This might include (but not be limited to) a biological material's aerosolisation and inhalation characteristics
  5. Environmental viability: the hardiness of the biological material across a range of temperatures, humidity levels, light exposures
  6. Countermeasures: the existence of and ease of access to prophylaxis, post-exposure treatments and detection and decontamination measures
  7. Economic consequence: the extent to which the biological material may be used to bring about harmful economic consequences for humans, crops, livestock or infrastructure?

- Does the BRC assess virulence based on the following key factors:

  1. Infective dose: the smallest quantity of the biological material necessary to cause infection
  2. Pathogenicity: the disease-causing ability of the biological material
  3. Lethality: the ability of the biological material to cause death to the host.
  4. Transmissibility: the ease with which the biological material can spread either by vector to host or host to host

  Where factors that could materially affect the assessment of a biological material's potential for malicious misuse as well as its virulence are known, does the BRC ensure that due account is taken of them in determining the overall biosecurity risk level of a biological material?

  Does the BRC carry out the risk assessment in such a manner that risk factors are weighed?

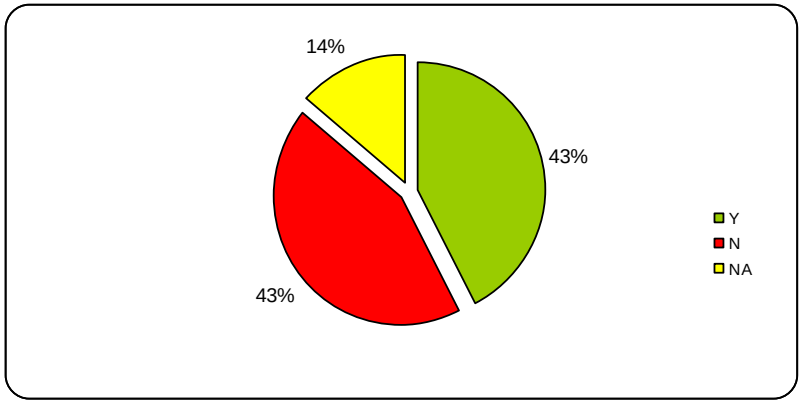
  In conducting the risk assessment, if there is doubt as to whether a particular factor of a biological material should be characterised as high, moderate, low or negligible, does the BRC consider assigning that factor to the higher of the two possible levels?

  Does the BRC see the development of common methodologies for risk assessment as a priority?

  Does the BRC seek to develop quantitative and qualitative tools and assessments that assist in completing appropriate and comparable risk assessment?

  In developing common tools and methodologies with the broader scientific community, does the BRC draw on appropriate existing tools and methodologies (including international)?

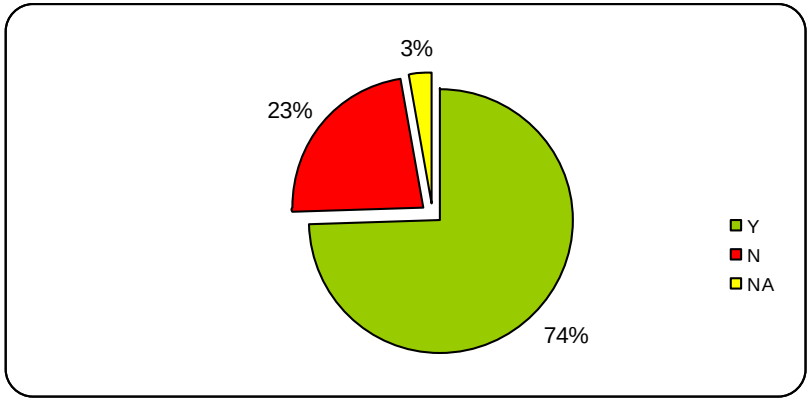
Result for all Countries



5. New acquisitions/ re-assessment of inventory

- Does the BRC make biosecurity risk assessment part of the acquisition process of new biological material?
- When being transferred between BRCs, is a summary of a biological material's risk assessment made available to the recipient of the BRC?
- Is a new risk assessment only then being conducted if, after reviewing the summary, there appears to be new circumstances or information that affects the original assessment?
- Does the BRC re-assess the biosecurity risk level of materials for which there is new information about their virulence or potential for malicious misuse?

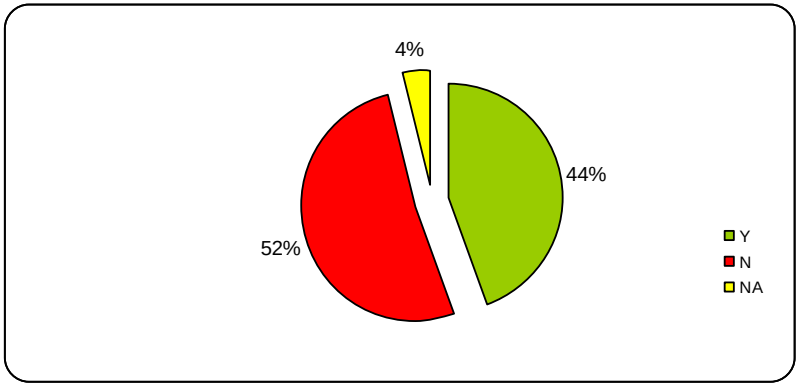
Result for all Countries



6. Biosecurity risk management Practices

- Does the BRC establish a timetable for internal audits to check for the level of compliance with the risk management practices?
- Do such evaluations conform to the rolling audit and review programme as described in the document "General Best Practice Guidelines for all BRCs Section"?
- Does the BRC designate a biosecurity officer at operational level within the BRC, whose responsibility is to ensure internal compliance with the biosecurity best practice guidelines?

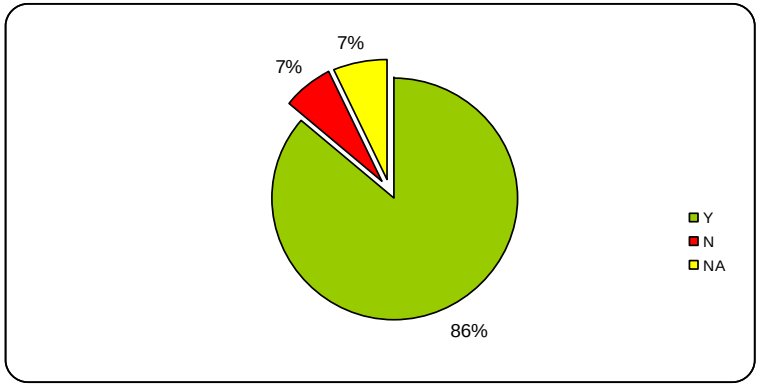
Result for all Countries



6.1 Physical security of BRCs

- Does the BRC conduct all activities with biological materials in an area that corresponds to the appropriate biosecurity risk level resulting from the application of the biosecurity risk assessment?
- Does the BRC supplement the general security area by additional layers of physical security within the facility, if they possess biological material that presents a high or moderate biosecurity risk level?
- Does the biological material present a moderate biosecurity risk being stored and worked with primarily in a restricted area?
- Does the biological material present a high biosecurity risk being stored and worked with in a high security area?

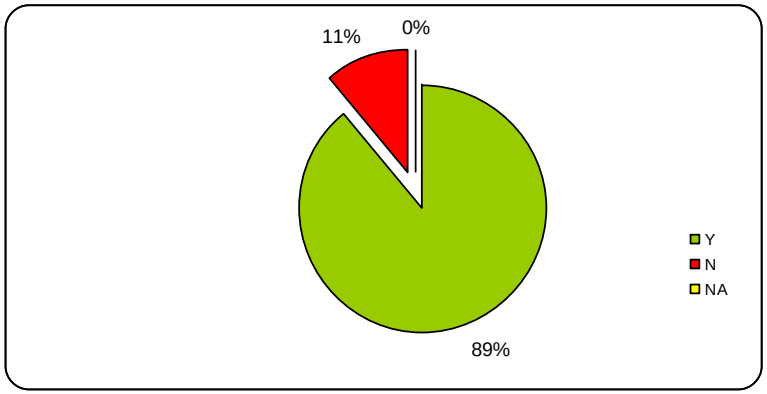
Result for all Countries



6.1.1 Physical security of BRCs: General security area

- Does the BRC implement physical security measures that provide a general security barrier against theft and persons gaining unauthorised access to facilities and the material therein?
- Is the general security barrier equipped with access controls, available to all staff at the facility?

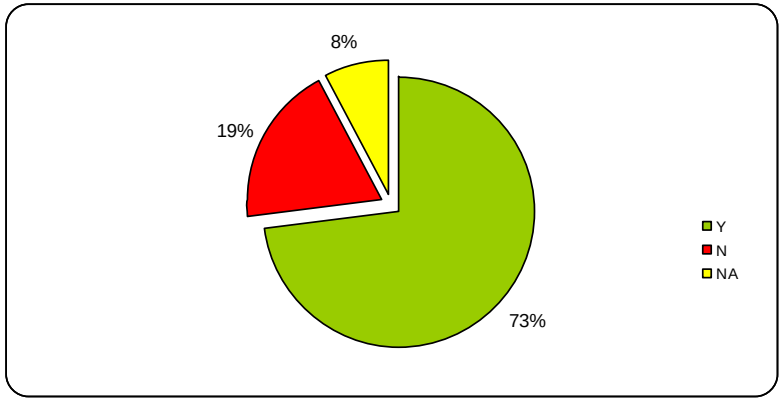
Result for all Countries



6.1.2 Physical security of BRCs: Restricted area

- Is access to a restricted area limited by an additional access item that is only available to individuals who are authorised to access the materials held within?
- Are all restricted areas enclosed on all sides within the general security area? (restricted areas should not share a boundary with a public area)
- Are restricted areas equipped with a 24-hour intrusion detection system?

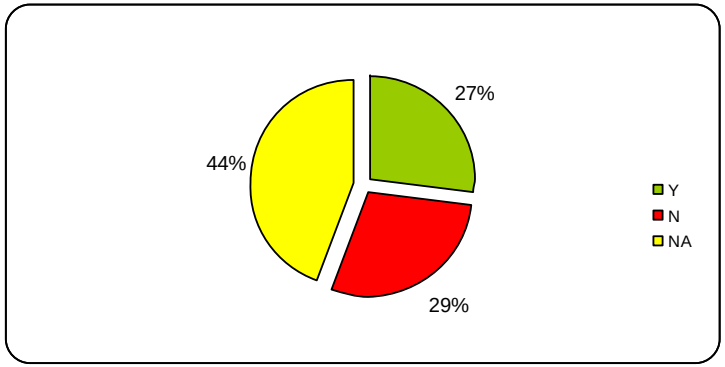
Result for all Countries



6.1.3 Physical security of BRCs: High security area

- Is the high security area nested within a restricted area? (it should not under any circumstances share a physical boundary with the general security area)
- Is the access to the high security area limited by an additional access item that is only available to individuals who are authorised to access the materials held within?
- Does the access item signal that the individual has a different level of access than staff with access to only general or restricted areas?
- Is the high security area equipped with a 24-hour intrusion detection system?
- Is the construction of restricted and high security areas as such that any apertures (windows, ventilation, shafts) that are sufficiently large for a person to gain entry through are secured to prevent this?
- Are emergency exit doors releasable only from the inside, unless prevailing safety codes provide otherwise?
- Does the BRC maintain equipment /facility maintenance logs of the security areas, including names and affiliation of maintenance personnel?

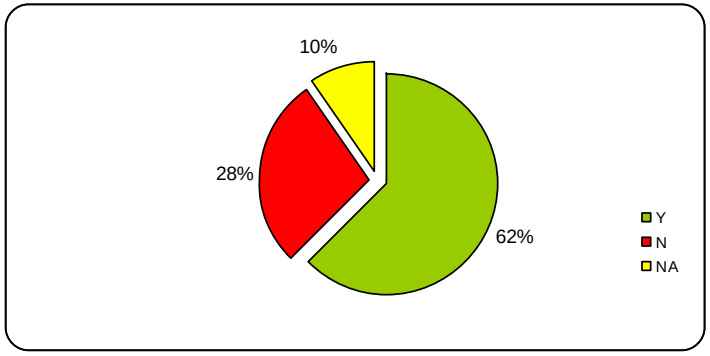
Result for all Countries



6.2 Security management of personnel

- Does the BRC manager ensure that attentive management practices in the supervision of staff are the norm?
- Does the BRC institute security screening, in line with national privacy law, and set in place best practice guidelines describing how decision on appointments should be taken according to the nature of the facts that emerge about the individual?
- Are background checks of staff whose duties require them to have access to material that presents a high or moderate biosecurity risk conducted prior to the granting of access to such biological materials?
- Has all staff been issued with an identification token? (preferably equipped with a photograph of its issued holder and providing information as to their level of access)
- Are identification tokens being worn at all times, except in circumstances where doing so would present a health and safety risk (when wearing a biohazard)?
- re identification tokens being surrendered upon termination of employment at the BRC?
- Does BRC keep records of current and former employees, while paying due respect to their privacy?

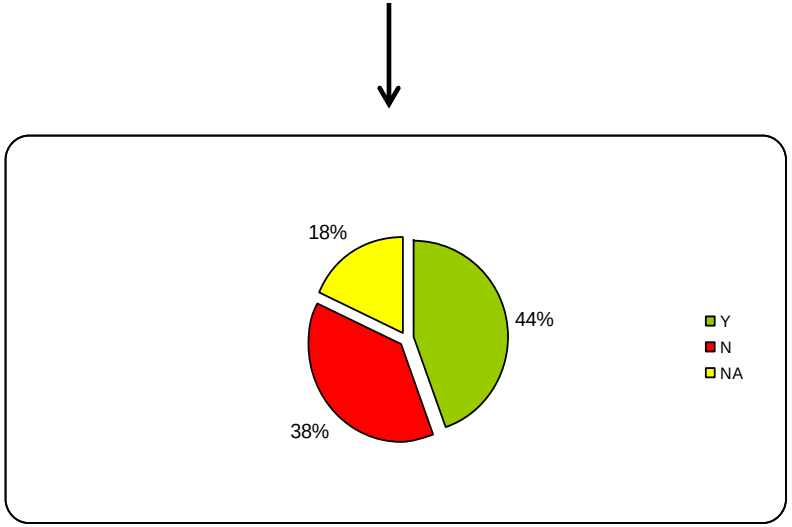
Result for all Countries



6.3 Security management of visitors

- Has the BRC established a system of security controls for visitors?
- Does the BRC system of security controls include a list of the types of visitors that are allowed to enter the facility and does it classify whether the visitor should be escorted or not?
- Are unescorted visitors subject to the same security management procedures as BRC personnel?
- Does the BRC alternatively choose to accept the security clearance conferred to the visitor by a government agency, or other appropriate body, provided that security clearance is current?
- Do escorted visitors have access to restricted or high security areas?
- Does the BRC maintain visitor logs to ensure that visitors do not enter the facility with prohibited items?
- Does the BRC issue colour coded badges for visitors, according to the level of biosecurity risk to which they have access?
- Do these badges either automatically expire when the visitor leaves or is it taken from the visitor on exiting?
- Have appropriate visitor-to-escort ratios been established for different security areas?
- Is the permission to visit the facility being granted by the manager of the BRC or a designee?
- Are decisions on visits to restricted and high security areas being taken in consultation with the biosecurity officer?
- Are visitors within restricted and high security areas being only escorted by personnel with an appropriate level of access?

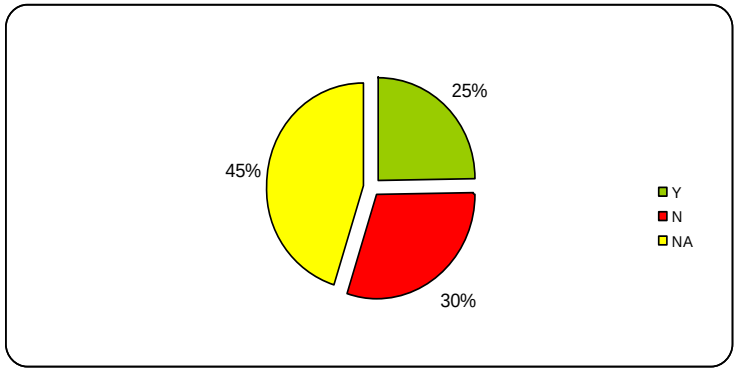
Result for all Countries



6.4 Incident response plan

- Does the BRC devise and adopt an incident response plan, which sets forth a protocol to be followed by the BRC staff for recording, reporting and investigating security breaches?
- Has the BRC determined how to report investigations of security breaches, guided by applicable laws?
- Has the BRC ensured that every staff member is fully notified of the incident response plan and trained in the actions they should take in the event of a security breach?
- Does the incident response plan indicate the reporting requirements in case of a security breach?
- Has the BRC alerted the responsible national authorities if a security breach involving biological material with a high or moderate biosecurity risk level has occured? In such a case, is the BRC prepared to communicate information on associated risks to the local community if so requested by competent national authorities?
- For security breaches involving biological material with a high or moderate biosecurity risk level, does the internal response plan identify the internal staff and external national authorities to whom the security breach is to be reported, in what order and any other actions they need to take?
- Do these actions include immediately instigating appropriate biosafety measures to reduce any health and safety risks to laboratory staff and the local community arising from the breach and to avoid disturbing the scene of the breach and any evidence until authorities arrive?
- Does the incident response plan identify individuals responsible for retrieving and compiling information that may assist investigating authorities, including where relevant, a list of people who have legitimate access to the material, the biosecurity risk level assigned to the biological material or compromised data and the inventory of requests received for the material?

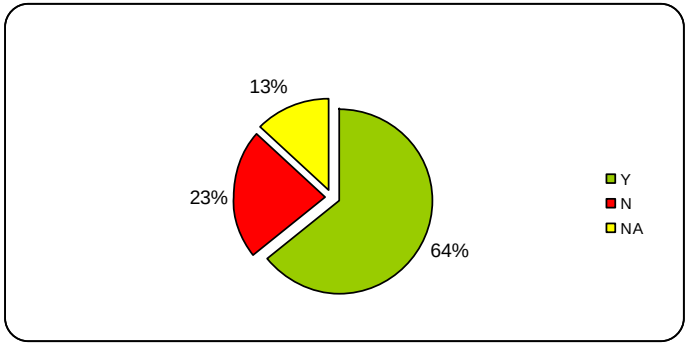
Result for all Countries



6.5 Staff training and developing a biosecurity-conscious cultur

- Has the BRC devised and implemented a biosecurity training course to instruct relevant staff in the biosecurity procedures of the facility?
- Does the training course explain to staff the key elements of the Risk Management Practices and ensure that staff are aware of their responsibilities and procedures that should be followed during the course of their work?
- Does the course give staff specific instruction on what constitutes a breach of security procedures and if appropriate, provide information about disciplinary sanctions that will be applied if a staff member deviates from the BRC's biosecurity policy?
- Does the course particularly instruct on the Incident Response Plan, ensuring that all staff are fully aware of the actions they should take if they detect a security breach, or witness activity that they deem suspicious on security grounds?
- Does the biosecurity training course comprise one element of the general orientation course that new staff typically undergo?
- Does the BRC also concern itself with appropriate risk communication and the creation of a biosecurity conscious culture?
- Does the BRC conduct its activities in a transparent manner and does it strive to build trust with the local community?

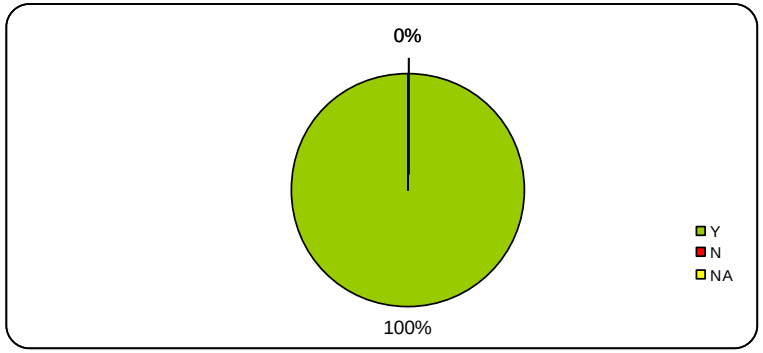
Result for all Countries



6.6 Material control and accountability

- Has the BRC established a system of material control and accountability, which includes conducting and maintaining inventories of biological materials in their collections and identifies individuals who have access to or custody of biological materials at any point in time?
- Does the system provide accurate knowledge of what biological materials exist in a BRC, where those materials are and who has access to them or custody of them at any given time?
- Does the BRC respect the principles of material control and accountability, that apply to all biological material held by the BRCs, including those with only negligible or low biosecurity risk associated with them?

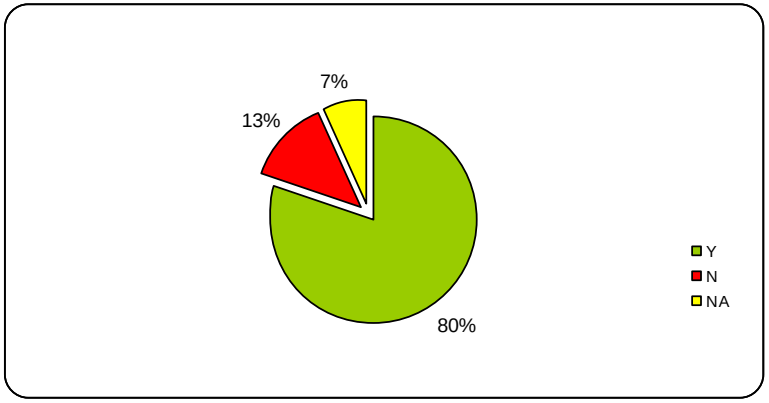
Result for all Countries



6.7 Supply of material

- Does the BRC grant requests from facilities that seek to acquire, use and maintain biological material that presents a negligible or low risk, subject to national legislation?
- Is biological material that presents a moderate or high biosecurity risk only being transferred to facilities that ensure biosafety and where biosecurity measures appropriate to handle such material are in place?
- Does the BRC document all acquisition requests, in particular for high and moderate biosecurity risk level materials, including requests refused and the reason for refusal?
- Is the BRC able to provide competent national authorities with a record of all acquisition requests for such materials, whether the request was accepted or declined , if requested by such national authorities?
- Does the BRC condition the dispatch of biological material with a high or moderate biosecurity level upon agreement of the receiving party to provide notice of successful receipt in their as agreed timeframe?

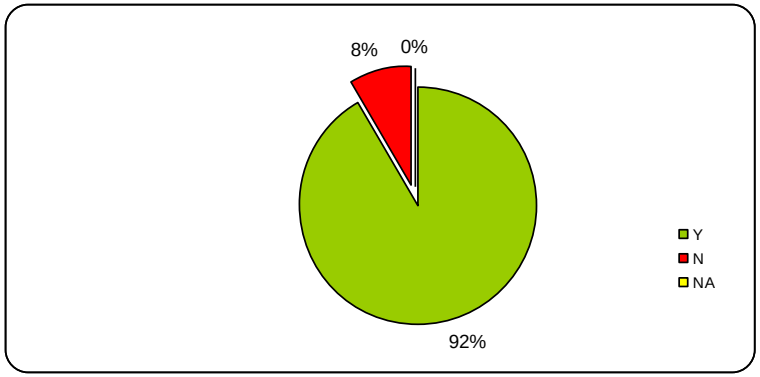
Result for all Countries



6.8 Transport security

- Does the BRC institute procedures that secure material during packaging and transport to reduce the risk of theft?
- For internal and external transfers of biological material that present a negligible or low biosecurity risk, does the BRC apply the required national or regional/international regulations?

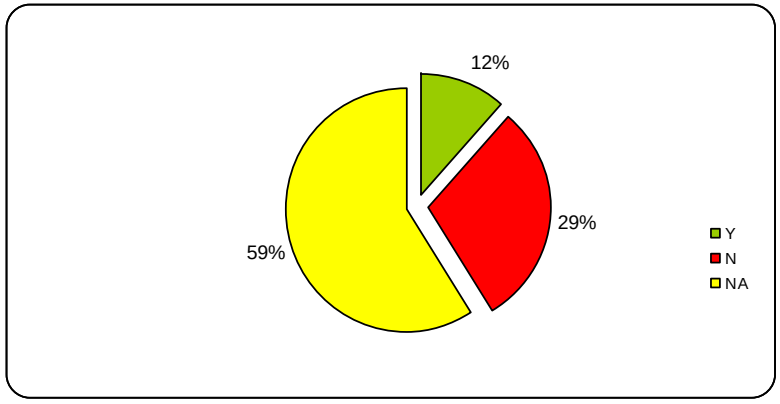
Result for all Countries



6.8.1 Transport security: Internal transport

- Has the biological material that poseses a high biosecurity risk been left unattended or temporarily stored outside the high security area?
- Has the BRC employed a strict chain of custody approach to the internal transfer of biological material that presents a moderate or high biosecurity risk and movement from one high security or restricted area, via a restricted or general security area, to another high security or restricted area?
- Has the BRC worked on making this procedure as minimally burdensome as possible while allowing subsequent analysis of the transactions and transfers made within the scope of the preceding paragraph?

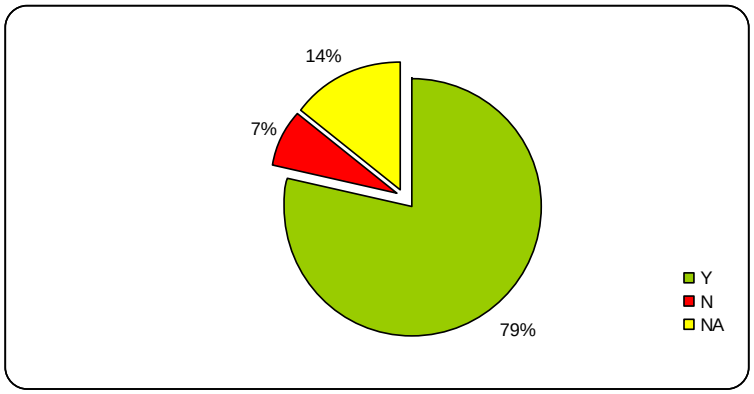
Result for all Countries



6.8.2 Transport security: External transport

- Does the BRC follow the WHO Guidelines on International Regulations for the Packaging and Transport of Infectious Substances to ensure safe and secure packaging and transportation of biological material?
- Is biological material exempt from the WHO Guidelines if it is sent by (air) mail or other means of transport according to the Universal Postal Union requirements?
- Does the BRC follow the International Air Transport Association Dangerous Goods Regulations and other applicable regulations including those for road transport, to ensure that all regulations 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 to comply with applicable national and regional / international laws and regulations?
- Does the staff responsible for the distribution of dangerous goods via air have the shipper's training certificate in possession as required by IATA?

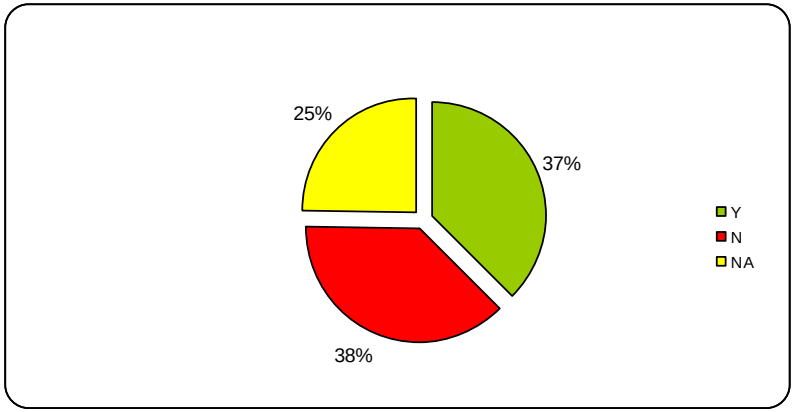
Result for all Countries



6.9 Security of information

- Has the BRC undertaken an information risk assessment, to determine what information presents a biosecurity risk and taken steps to protect information that could reasonably be used to facilitate the theft of high or moderate biosecurity risk material?

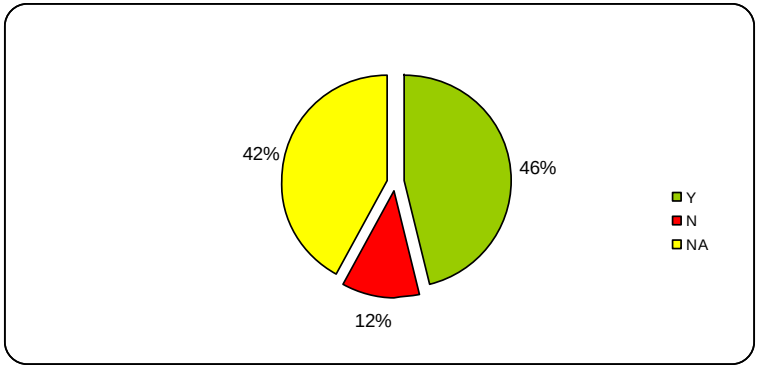
Result for all Countries



6.9.1 Security of information: Information that relates to access to materials

- Is information that could be reasonably used to facilitate the loss or theft of biological materials with a high or moderate biosecurity risk level being protected by proportionate measures to ensure the security of this information?
- Is the information being secured against unauthorised access by appropriate physical and/or electronic means (depending on the format in which the information is stored and the resources available to the BRC)?
- Is access to information pertaining to biological materials associated with high or moderate biosecurity risk levels being granted on a need-to-know basis and only to those individuals with security clearance to access material at the same biosecurity level as the information sought?

Result for all Countries



6.9.2 Security of information: Information that relates to the collection

- Has the BRC developed a policy to guide it in deciding what kinds of information relating to the collection should purposefully be withheld from entering the public domain?
- Is the BRC staff aware of the fact that its repository of knowledge could present a security risk?
- Has the BRC encouraged staff to adopt a code of conduct specific to biosecurity?

Result for all Countries