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MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY BIOBANKING[1]

Paris, 23–25 January 2017

A meeting of the *ad hoc* Group on Veterinary Biobanking was held at the OIE Headquarters in Paris from 23 to 25 January 2017.

1. Opening

Dr Matthew Stone, OIE Deputy Director General, International Standards and Science, welcomed the participants on the second day of the meeting and explained the OIE's interest in developing an OIE virtual biobank.

He pointed out that the creation of an OIE virtual biobank would facilitate searches for biological resources collected and preserved in OIE Reference Centres. These resources include reference materials, such as antisera for use as reference reagents, which are important tools for the development and standardisation of tests for the diagnosis and control of OIE listed diseases.

2. Adoption of the agenda, appointment of a chair and rapporteur

The meeting was chaired by Dr Jane Richardson, and Dr James Watson acted as rapporteur.

The agenda, including the Terms of Reference (ToRs), and the list of participants are presented in Appendices I and II, respectively.

3. Background and discussion on the Terms of Reference

Dr Antonino Caminiti explained the rationale for the meeting and presented the results of the second survey on the capacity for biobanks within the OIE network of Reference Centres (which includes OIE Reference Laboratories and OIE Collaborating Centres). The survey was developed and conducted in 2015 by Dr Maura Ferrari from the OIE Collaborating Centre for Veterinary Biologicals Biobank, which can be found at Appendix III. The survey revealed that i) approximately 35% of respondents did not have a computerised information management system to manage their collection of biological resources and, ii) most of the systems that were in use were not able to interact with other systems. It was noted that these results describe the situation in 2015. As biobanking is a rapidly developing field, these may not accurately reflect the current situation.

The Group considered whether it would be appropriate to revise and expand the Terms of Reference. For example the ToRs did not specify whether the OIE virtual biobank should be open access rather than restricted to OIE Reference Laboratories. Given that OIE Reference Laboratories have a mandate to develop and supply reference reagents, it was reasoned that the information on the location of this material should be accessible to laboratories outside the OIE network, and should definitely include National Reference Laboratories. The

[1] Note: This ad hoc Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the February 2017 report of the Biological Standards Commission because this report provides its considerations and comments. It is available at: http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/laboratories-commission-reports/meetings-reports/

Group suggested two user classes: a core group comprising OIE Reference Laboratories, OIE Collaborating Centres and National Reference Laboratories, which would have full access to the OIE virtual biobank and exchange biobank materials free of charge, and an additional group of users, including industry, academic institutions and research laboratories, which would have a different level of access and would benefit from the sharing of information on resources. In the end, ToRs were not revised.

4. Identify which types of biological material (for OIE listed diseases only) should be included in the OIE biobank

Standards established by the OIE are recognised as international reference standards by the international community. Given that the OIE promotes the preparation and distribution of standard reagents for diagnostic testing, the scope of the OIE virtual biobank should encompass a broad range of diagnostic reagents and reference standards that can be used for diagnosis and control of OIE listed diseases. Of special emphasis, the OIE virtual biobank should include reagents – including, but not limited to, antisera, antigens, plasmids and polymerase chain reaction primers (DNA, RNA) and their derivatives – and reference cultures for the detection of viruses, bacteria, fungi, parasites and protozoa.

5. Define the quality requirements

It was proposed that the quality of biobank materials could be described in discrete quality categories (i.e. two or more distinct groups of biobank materials), depending on the level of characterisation.

The Organisation for Economic Cooperation and Development (OECD) issued the Best Practices Guidelines for Biological Resource Centres in 2007, which are based on the concepts of identity, purity, stability and viability. The Group based the quality classification for the OIE virtual biobank on such guidelines for harmonisation purposes, recognising that the specific parameters in the OECD guidelines may not be fully applicable for OIE biobanking purposes. These resources were used as references: the quality criteria adopted for the European Virus Archive (EVAg) initiative, a project funded under Horizon 2020 (the EU programme for Innovation that runs from 2014 to 2020), straininfo, a world-wide, virtual catalogue integrating the information from catalogues of biological resource centres, the World Federation for Culture Collections (WFCC), an international organisation that operates as a clearing house for information on collections of microbiological specimens, the Best Practices for Repositories issued by the International Society for Biological and Environmental Repositories (ISBER) (human focused), and the International Biobank of Veterinary Resources (IBVR), a biobank hosted at Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna, Italy.

The quality of biobank materials would be based on identity, purity, stability, potency, safety and documentation. The proposed quality criteria are defined in Appendix IV. Category 1 biobank materials meet the highest quality standards, while category 2 biobank materials meet the minimum requirements for inclusion of material in the biobank, but have not fulfilled all of the requirements for category 1 biobank materials. Biobank materials may have fulfilled a varying combination of these different criteria. This would be clearly indicated in the metadata reported in the "data sheet", which must accompany all the biobank materials entered into the biobank.

In support of this categorisation, the quality requirements for biobank materials should be set according to the intended use, with OIE reference reagents and standards contained in the highest category, i.e. category 1. It was recognised that the role of the OIE as a standard-setting organisation was of paramount importance, thereby ensuring the quality of reagents and standards as a high priority.

In general, suppliers to the OIE virtual biobank should be OIE Reference Laboratories, which have in place appropriate accreditation and quality management systems. In the absence of an OIE Reference Laboratory for an OIE listed disease, laboratories with appropriate quality management systems may also be able to supply material. The quality parameters for biological samples exchanged through the OIE virtual biobank should be in accordance with the provisions of the OIE Codes and Manuals (e.g. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 1.1.5 Quality Management in Veterinary Testing Laboratories) and associated guidance documents (e.g. OIE Guideline on International Reference Antibody Standards for Antibody Assays) or other international standards with regard to the preparation of diagnostic reagents and laboratory reference standards.

6. Define the metadata attached to the biological material

The metadata to be provided for each biobank material are listed in the Table in Appendix V.

Two major classes of metadata are defined in the Table: material and sample. Additional multivariate fields to link to references, documents and sequence data were outlined. Mandatory fields are also defined, and completion of all mandatory fields represents the threshold for biobank materials to be included in quality category 2.

The Group recommends, wherever possible, to use existing OIE controlled terminologies for describing diseases, animals, etc. Further work would be required to fully define the metadata schema.

Once the metadata schema is defined, it is important that a governance process is established to manage proposals for change and oversee ongoing developments with the OIE virtual biobank.

7. Review the information technology options and propose preferred option

The principal key business requirements and functions for the OIE virtual biobank were outlined in the form of high level requirements and corresponding sub-requirements. The definition of detailed specifications was reserved for a later phase of the project.

The metadata described above should be sourced from the laboratory information systems of the supplier, ideally by a reasonably automated process. Within each supplier organisation, a person responsible for data management should be identified to ensure that responsibility is actively taken for the maintenance of the data and for making data amendments should there be any quality issues.

Technology choices should be made at the implementation phase with consideration given to well established standards and the expertise of the hosting organisation, which would be an OIE Reference Centre.

High level requirements are summarised as follows:

Provide a web-based portal where registered users can search and request reagents or reference material offered by the OIE network, with the following capabilities:

- Allow the user to request access (based on institutional affiliation), create a user profile, and manage individual access to system components based on the registered user's role and authorisation.
- Provide a search interface that allows the user to query within the defined metadata or free text search to retrieve one or more records.
- Enable the user to select a record and view the full description of the material.
- Receive incoming requests for one or more materials to the OIE Reference Centre (by email for the implementation phase; integrated request management within the system for the later phase). All requests would carry the materialID (see Appendix V).
- Store the metadata as listed in Appendix V plus uploaded documents (e.g. permits, Standard Operating Procedures [SOPs], and other supporting materials).
- Include a mechanism for the OIE Reference Centres to add, update, or delete their data, either by manual entry through a portal interface, via upload of a data file or via web services.
- Facilitate the exchange of materials using the standard Material Transfer Agreement (MTA, see Section 8).
- Validate the data uploaded or entered into the database for mandatory fields using controlled terminology, and for data type.
- Provide information to the OIE on user access and metrics (e.g. number of visits).
- Track the history of amendments made.

- Include a form for general enquiries to the system administrator or for contacting technical support.
- Include a user workspace (e.g. save previous queries, bookmark of reagents etc.).
- Include a service that allows subscribers to receive alerts (e.g. new reagents, new features of the system, etc.).
- Generate an exportable catalogue of the reference materials from the system to support laboratories with limited information technology capacity.
- As a minimum the content should be available in English, but where OIE translation exists, information may also be offered in French, Spanish, or other languages.
- The implementation should support multilingual functions provided by web browsers.

Requirements for the hosting system

- It is recommended that the OIE Veterinary Biobank portal and database should be run on a central server(s) with standard backup procedures. The development, management and maintenance should be undertaken by an OIE Reference Centre with previous experience in operating a biobank.

8. Propose Standard Material Transfer Agreement

It was noted that access to standardised Material Transfer Agreements (MTA) could facilitate the timely exchange of biobank materials in general by simplifying the processes. These MTA templates for biobank materials could be based on MTAs that have previously been adopted by OIE Reference Laboratories for the exchange of materials within the network, and for providing materials in response to other requests for research or commercial use.

The drafting of a single standard MTA was proposed for use in transfers of materials between the OIE Reference Centres and national laboratories of OIE Member Countries. This MTA could be integrated within the OIE virtual biobank portal. This could remove some of the issues identified in two previous surveys (survey 1 and survey 2 in Appendix III). The MTA template should be agreed by OIE Member Countries at the OIE General Assembly. With regard to transfers of material outside the OIE network, laboratories may use their own MTAs with clear specifications about commercial use.

With reference to Article 4 of the Nagoya protocol, the MTA is intended to establish a culture for the open exchange of biobank materials among the participating laboratories and to constitute Prior Informed Consent (PIC) on Mutually Agreeable Terms (MAT), while avoiding as much as possible the potential adverse impacts of the Nagoya requirements.

The standard MTA text should be drafted and reviewed by the OIE legal department.

It is proposed that the following elements be included in the standard MTA:

- Parties (sender scientist and recipient scientist, and their institutions);
- Material (material comprises any of the biological samples listed in the OIE virtual biobank);
- Intended use (material should be used for the diagnosis and control of designated pathogens or diseases as defined in the ToRs of OIE Reference Laboratories. Any other use should be negotiated independently; the standard MTA would not allow for commercial use);
- Ownership (the sender retains ownership and intellectual property rights);
- Distribution (e.g. transfer to third parties). As the OIE virtual biobank should facilitate rapid transfer of material between the centres of the OIE network, transfer to third parties would not be permitted under this MTA;
- Confidentiality (the parties should respect each other's confidential information);

- Each party should accept liability for their own actions with the providing laboratory only liable for the cost of preparing the reagents;
- Publication (the supplier must be acknowledged in any publications and under this MTA inclusion in acknowledgement is pre-agreed);
- Misuse/Dual use (the recipient is responsible for safe use of material and the use complies with all legal requirements; not for use in humans);
- Termination (the MTA is in effect for 2 years unless an extension is mutually agreed. Any remaining material should be destroyed as biomedical waste after this period);
- Dispute resolution (in the first instance the OIE should act as an arbitrator in any dispute between the OIE Reference Centres).

9. Define the steps that are needed for implementation of the biobank database

- Review of this report by either internal or external experts;
- Refine data definitions and technical specifications;
- Raise awareness including presentation to national OIE Laboratories Focal Points;
- Form a governance structure for the OIE virtual biobank;
- Identification of candidate laboratory to host the portal;
- Identification of laboratories for participation in a pilot phase.

10. Final remarks

It was not clear whether or not the participating OIE Reference Laboratories should be allowed to supply biobank materials for diseases for which they are not a designated OIE Reference Laboratory.

It was emphasised that the purpose of the OIE virtual biobank may go beyond only supplying validated reference materials. This might encourage other laboratories to offer access to biological samples that meet the minimum quality criteria. This is particularly important for emerging diseases for which an OIE Reference Laboratory may not have been established at the time of an outbreak, but for which a rapid sharing of samples would still be necessary.

It was noted that for some databases, the provision of a link to publicly accessible SOPs is part of the metadata associated with a sample. It was pointed out that various SOPs for quality, storage, and security are available. OIE Reference Laboratories should be encouraged to share these SOPs within the OIE network, and to develop their own using SOPs provided by other OIE Reference Laboratories as a template.

11. Adoption of the report

The Group adopted the report.

12. Glossary

Biobank: A biobank is a facility for the collection, preservation, storage and supply of biological samples and associated data, which follows standardised operating procedures and provides material for scientific and clinical use.

OIE Reference Centre: an OIE Reference Laboratory or an OIE Collaborating Centre.

MTA: Material Transfer Agreement.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY BIOBANKING

Paris, 23 – 25 January 2017

Background

A biobank is an organised collection of biological samples and associated data, the existence of which is a critical prerequisite for high-quality research and advances in life science. The creation of a virtual biobank, an electronic database of biological specimens and related information, would increase the number of accessible collections by providing access independent of geographical limitations. A virtual biobank would also be an opportunity for cooperation and sharing of biological resources, including reference reagents, among the OIE Reference Centres.

Terms of Reference

1. Identify which types of biological material (for OIE listed diseases only) should be included in the OIE biobank;
2. Define the quality requirements;
3. Define the metadata attached to the biological material;
4. Review the Information Technology options and propose preferred option;
5. Propose standard Material Transfer Agreement;
6. Define the steps that are needed for implementation of the biobank database.

Provisional Agenda

1. Opening
2. Designation of the chair and rapporteur
3. Adoption of agenda
4. Consideration of Terms of Reference
5. Other business
6. Adoption of report

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY BIOBANKING

Paris, 23–25 January 2017

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Appendix III

SUMMARY OF RESPONSES TO 2ND SURVEY ON BIOBANKS FROM THE OIE REFERENCE LABORATORIES

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Summary of Responses to 2nd Survey on Biobanks from the OIE Reference Laboratories

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First meeting of the *ad hoc* Group on Veterinary Biobanking, Paris 23 January 2017

Background

First survey in 2014

Survey on availability of biological resources including reference reagents

267 Ref Centres in 2014
88 respondents (33%)
Details in 'Presentation Dr Ferrari'

Second survey in 2015

Survey on IT systems and development of spreadsheet

Sent to the 88 Ref Centres which had responded to the first survey
36 respondents (40%)

Questions (2015)

1 Do you have a computerised management system for your biological resources?

2.a Is your system able to communicate with other systems through the internet?

2.b If yes, do you have the technical capability to export your data to another database?

3.a Is the facility involved in a collaborative biobank project?

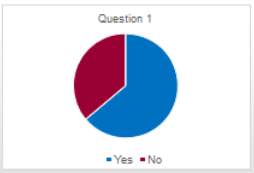
3.b If yes, please indicate the platform system (e.g. Apache, IIS, etc.).

3.c Please also indicate the database management system platform that you are using (MySQL, Oracle, MS SQL, etc.).

4. Have you developed a data sheet with the characteristics of each of your biological resources?

1. Do you have a computerised management system for your biological resources?

Answer	N	%
Yes	23	63,9
No	13	36,1
Total	36	



2.a Is your system able to communicate with other systems through the internet?

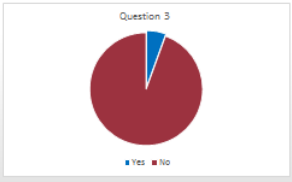
Answer	N	%
Yes	2	5,6
No	34	94,4
Total	36	

2.b If yes, do you have the technical capability to export your data to another database?

Answer	N	%
Yes	6	16,7
No	30	83,3
Total	36	

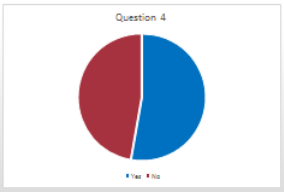
3.a Is the facility involved in a collaborative biobank project?

Answer	N	%
Yes	2	5,6
No	34	94,4
Total	36	



4. Have you developed a data sheet with the characteristics of each of your biological resources?

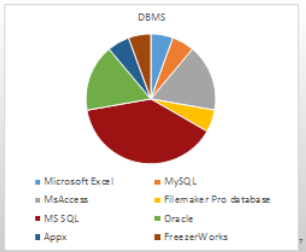
Answer	N	%
Yes	19	52,8
No	17	47,2
Total	36	



3.b If yes, please indicate the platform system (e.g. Apache, IIS, etc.).

3.c Please also indicate the database management system platform that you are using (MySQL, Oracle, MS SQL, etc.).

DBMS	N	%
Microsoft Excel	1	5,6
MySQL	1	5,6
MsAccess	3	16,7
Filemaker Pro database	1	5,6
MS SQL	7	38,9
Oracle	3	16,7
Appx	1	5,6
FreezerWorks	1	5,6
Total	18	100



Summary

- 35% of respondents did not have a management system in place
- Most of IT systems are not able to interact with each other
  Security consideration or technical limitation?
- Results are from 2015

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Thank you for your attention

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Appendix IV Quality requirements for biobank materials

Material Type		Identity	Purity	Stability	Potency	Biosafety/Biosecurity	Documentation
Principle – Live material		*That the organism or cell is what it is stated to be.*	*That the material is free from significant adventitious agents.*	*That the material remains viable for a known time*	*That a known concentration of organisms or cells is present*	*Assess risks associated with organism*	*The critical attributes of the material are adequately described.*
Principle - reagents		*That the material is derived from the stated parent organism.*	*That the material does not have any significant cross reactions.*	*That the material retains expected reactivity for a known time.*	*That the material is of a known reactivity or concentration*	*Assess risks of material directly, or due to contamination*	*The critical attributes of the material are adequately described.*
Reference organisms							
Viruses	1	Full genome has been sequenced	No adventitious agents detected	Periodic testing to confirm viability	Measure TCID50[1] or equivalent	Document Risk Group	Complete metadata
	2	Partial sequence or specific assays used to identify	Not tested for known adventitious agents	Expected period of stability documented	Potency described quantitatively		Partial metadata
Bacteria	1	16S sequencing	No adventitious agents detected	Periodic testing to confirm viability		Document Risk Group	Complete metadata
	2	Other assays used to identify	Not tested for known adventitious agents	Expected period of stability documented	Potency described quantitatively		Partial metadata
Fungi	1	Barcode or other identifying sequence	No adventitious agents detected	Periodic testing to confirm viability		Document Risk Group	Complete metadata
	2	Other assays used to identify	Not tested for known adventitious agents	Expected period of stability documented	Potency described quantitatively		Partial metadata
Parasites	1	Barcode or other identifying sequence	No adventitious agents detected	Periodic testing to confirm viability		Document Risk Group	Complete metadata
	2	Other assays used to identify	Not tested for known adventitious agents	Expected period of stability documented	Potency described quantitatively		Partial metadata
Reagents							
Antisera/Monoclonal antibodies	1	Detects parent organism	Free from significant cross reactions	Periodic testing to confirm potency	Reactivity documented against known standard	Free of viable pathogens	Complete metadata
	2			Expected period of stability documented	Reactivity described qualitatively		Partial metadata

Material Type		Identity	Purity	Stability	Potency	Biosafety/Biosecurity	Documentation
Inactivated organisms	1	Reacts appropriately in validated assay	Free from significant cross reactions	Periodic testing to confirm potency	Reactivity documented against known standard	Sterility tested	Complete metadata
	2			Expected period of stability documented	Reactivity described qualitatively	Documented inactivation by appropriate method	Partial metadata
Nucleic acids	1	Reacts appropriately in validated assay	Free from significant cross reactions	Periodic testing to confirm potency	Reactivity documented against known standard	Sterility tested	Complete metadata
	2			Expected period of stability documented	Reactivity described qualitatively		Partial metadata
Fixed tissues	1	IHC[2] or ISH[3] confirmation of target organism	Free from significant cross reactions	Periodic testing to confirm potency			Complete metadata
	2			Expected period of stability documented			Partial metadata
Proteins/Antigens	1		Free from significant cross reactions	Periodic testing to confirm potency	Reactivity documented against known standard	Sterility tested	Complete metadata
	2			Expected period of stability documented	Reactivity described qualitatively		Partial metadata
Cell cultures / Hybridomas	1	Genetic characterisation of cells	No adventitious agents detected	Periodic testing to confirm viability	Concentration		Complete metadata
	2	Species of origin or less definitive check of identity	Not tested for known adventitious agents	Expected period of stability documented			Partial metadata

1 $TCID_{50}$, median Tissue Culture Infectious Dose, amount of a pathogenic agent that will produce pathological change in 50% of cell cultures inoculated.
2 IHC, ImmunoHistoChemistry
3 In Situ Hybridisation

Appendix V Metadata associated to biobank materials

	Name	Description	Class	Mandatory	Repeatable	Valid Entries	Notes
1	**MaterialType**	Type of Material	Material	Y	N	Cells, antisera, hybridoma, inactivated organism, nucleic acid, fixed tissue, protein, antigen, virus, bacteria, fungi, protozoa, parasite	
2	**SourceLab**	Laboratory	Material	Y	N	OIE laboratory identifier	
3	**MaterialID**	Unique identifier OIE biobank	Material	Y	N	Unique identifier for the biological sample within the OIE virtual biobank. This code would be used for specifying requests to the supplier	
4	**SourceID**	Unique identifier supplier laboratory	Material	Y	N	Unique identifier for the biological sample from the supplying laboratory database	
5	**MaterialName**	Name of the reference material	Material	Y	N	Free text detailing the name of the reagent	
6	**MaterialTaxon**	Taxonomic Identifier	Material	N	N	Select from predefined list of species and subtypes to be defined for all OIE listed diseases	
7	**MaterialDesc**	General description of the material	Material	Y	N	Free text providing a description of the material. This should be used to provide critical information to the requestor regarding the nature, history, and special requirements for the use of the material	
8	**OIEDisease**	OIE disease (species, subtype)	Material	Y	N	Reference to the OIE Code	
9	**DiseaseRiskGroup**	Risk group	Material	N	N	Nil	Null field, entries not defined
10	**Reference**	Literature	Material	N	Y	Citation/s for relevant literature describing the Material	Allows multiple references to be listed
10,1	**ReferenceDOI**	Literature	Reference	N	N	Digital object identifier (DOI) for reference	
10,2	**ReferenceURL**	Literature	Reference	N	N	Uniform Resource Locator (URL) for reference	
11	**MaterialContactName**	Contact information	Material	Y	N	Name of contact for requests	
12	**MaterialContactEmail**	Contact information	Material	Y	N	Email of contact for requests	

	Name	Description	Class	Mandatory	Repeatable	Valid Entries	Notes
13	**MaterialInfo**	Any other information	Material	N	N	Free text	
14	**MaterialDocName**	Associated document	Material	N	Y	Document/s name/description	Allows multiple documents to be listed
14,1	**MaterialDocType**	Associated document	Document	N	N	Certificates of Analysis (CoA), Material Safety Data Sheet (MSDS), Permit, Other	
14,2	**MaterialDocRef**	Associated document	Document	N	N	Internal reference to document (these documents should be uploaded into the OIE virtual biobank)	
15	**MaterialParent**	Parent sample	Material	N	N	Material identification data (ID) of parent	
16	**MaterialSource**	Provenance	Material	N	N	The supplying laboratory's source for the material	
17	**MaterialHost**	Host	Material	N	N	OIE identifier for the species that is the matrix of the material	
18	**MaterialDate**	Accession date	Material	Y	N	The date the supplying lab received the material	
19	**MaterialSeq**	Sequence	Material	N	Y	Link/s to sequence information (e.g. GenBank)	
20	**MaterialAvailability**	Availability	Material	Y	N	In stock/Special order	
21	**SampleName**	Name of the reference material	Material	N	Y	Free text detailing the name of the reagent. Sample information describes available batches in the supplier's storage system	Allows multiple sample lots for each material type. Not mandatory, as you could list a material with no currently available lots
21,1	**SampleDesc**	General description of the material	Sample	Y	N	Free text providing a description of the material. This should be used to provide critical information to the requestor regarding the nature, history, and special requirements for the use of the sample	
21,2	**SampleSupplyQuantity**	Supply Unit	Sample	Y	N	Number	
21,3	**SampleSupplyUnit**	Supply Unit	Sample	Y	N	Unit	
21,4	**SampleQAIdentity**	Quality Assurance level for Sample Identity	Sample	Y	N	1, 2, 0	Quality Assurance level as referenced in Appendix IV "Quality requirements for biobank materials"
21,5	**SampleQAPurity**	Quality Assurance level for Sample Purity	Sample	Y	N	1, 2, 0	Quality Assurance level as referenced in Appendix IV "Quality requirements for biobank materials"

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	Name	Description	Class	Mandatory	Repeatable	Valid Entries	Notes
21,6	**SampleQAStability**	Quality Assurance level for Sample Stability	Sample	Y	N	1, 2, 0	Quality Assurance level as referenced in Appendix IV "Quality requirements for biobank materials"
21,7	**SampleQAPotency**	Quality Assurance level for Sample Potency	Sample	Y	N	1, 2, 0	Quality Assurance level as referenced in Appendix IV "Quality requirements for biobank materials"
21,8	**SampleQASafety**	Quality Assurance level for Sample Safety	Sample	Y	N	1, 2, 0	Quality Assurance level as referenced in Appendix IV "Quality requirements for biobank materials"
21,9	**SampleDate**	Creation Date	Sample	Y	N	Date	
21,1	**SampleStorage**	Storage conditions	Sample	N	N	Description of critical storage requirements, e.g. temperature, humidity	
21,11	**SampleBatch**	Batch information	Sample	N	N	Batch numbers. This number could be used for specyfing requests to the supplier	
21,12	**SampleForm**	Form of supply	Sample	Y	N	Frozen, freeze dried, etc.	Defined list
21,13	**SampleGrowth**	Conditions of growth	Sample	N	N	Description of critical growth requirements	
21,14	**SampleInfo**	Any other information	Sample	N	N	Free text	