



ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLE VENEZIE

LEGNARO (PD)

DELIBERAZIONE

DELLA DIRETTRICE GENERALE

N. 42 del 13/02/2024

OGGETTO: Approvazione dello schema di ``Data Sharing Agreement`` per la realizzazione del progetto ``MyMIC - Standardization of diagnostic and antimicrobial susceptibility testing and clinical interpretation in animal mycoplasmas``, nell'ambito della ``3rd JPIAMR-ACTION - ERA-NET Cofund - Joint Call 2022``.

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Si sottopone alla Direttrice generale la seguente relazione del Responsabile della S.S. Affari Generali, Anticorruzione e Trasparenza.

Si premette che:

- l'IZSve, nel quadro dei propri compiti istituzionali – di cui all'art. 3 dell'Accordo sulla gestione dell'Istituto Zooprofilattico Sperimentale delle Venezie, approvato dalla Regione del Veneto, dalla Regione Autonoma Friuli Venezia Giulia e dalle Province Autonome di Trento e Bolzano, rispettivamente, con leggi n. 5/2015, n. 9/2015, n. 5/2015 e n. 5/2015 – diretti alla tutela della salute ed alla promozione del benessere animale, provvede all'effettuazione di ricerche di base e finalizzate per lo sviluppo delle conoscenze nell'igiene e sanità veterinaria, nella sicurezza alimentare e nutrizione, secondo programmi e anche mediante convenzioni con università e istituti di ricerca italiani e stranieri, nonché su richiesta dello Stato, delle Regioni, delle Province autonome e di enti pubblici e privati;
- l'IZSve ha sviluppato negli anni diverse metodiche per la diagnosi delle micoplasmosi, istituendo l'“U.O. *Micoplasm*” presso la sezione territoriale “SCTI – Verona”. Tale laboratorio svolge attività diagnostica e di ricerca sui micoplasmi animali, raccoglie ceppi di micoplasmi e funge da laboratorio di riferimento WOAH per la micoplasmosi aviaria;
- in particolare i ceppi di micoplasmi di importanza veterinaria vengono sottoposti a determinazione della MIC (concentrazione minima inibitoria) nei confronti delle principali molecole antimicrobiche comunemente utilizzate in medicina veterinaria. Tale

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attività ha consentito di creare, nel tempo, un *database* di dati di farmaco-sensibilità per le principali specie di micoplasmi, fornendo utili informazioni in termini di approccio alla terapia e controllo delle popolazioni microbiche;

- JPIAMR - *Joint Programming Initiative on Antimicrobial Resistance* è una piattaforma collaborativa internazionale che coinvolge, oltre alla Commissione Europea, 29 nazioni, il cui scopo è la riduzione della resistenza antimicrobica e, a tal fine, sostiene azioni di collaborazione per colmare le lacune relative a tale materia in una prospettiva *One Health*;
- nell'ambito della “*3rd JPIAMR-ACTION Joint Call 2022 – ERA-NET Cofund – Diagnostic and Surveillance Networks*”, l'IZSVE si è determinato a partecipare alla realizzazione della proposta progettuale “*Standardization of diagnostics and antimicrobial susceptibility testing and clinical interpretation in animal mycoplasmas – (MyMIC)*”, il cui obiettivo è l'istituzione di una rete di laboratori che si occupano di diagnostica dei micoplasmi e dello studio della loro suscettibilità agli antimicrobici, allo scopo di confrontare i diversi metodi utilizzati e i risultati delle concentrazioni minime inibitorie (MIC). Ciò porterà, inoltre, alla stesura di linee guida per la standardizzazione della coltura, identificazione e determinazione delle MIC;
- il progetto in parola, coordinato dalla *French Agency for Food, Environmental and Occupational Health & Safety* (ANSES), è stato approvato dal gruppo direttivo di JPIAMR, cd. *Call Steering Group*, e prevede la collaborazione di 13 partner, tra i quali l'IZSVE.

Considerato che, per lo svolgimento del progetto “*MyMIC*”, risulta necessaria la condivisione di dati relativi ai test di determinazione della MIC, ottenuti dai laboratori dei diversi Partner, al fine di definire le condizioni per la condivisione dei dati, dei metadati associati e le procedure per l'ottenimento degli stessi, le Parti hanno condiviso per le vie brevi lo schema di “*Data Sharing Agreement*”, documento che si allega al presente provvedimento quale parte integrante e sostanziale (*allegato n. 1*).

Con *ticket* intranet n. 212607/2024, il dott. Marco Bottinelli, ricercatore veterinario presso la “*SCTI – Verona*”, ha richiesto alla scrivente Struttura di procedere con gli adempimenti necessari alla stipula dell'Accordo sopra citato.

Ai sensi dell'Accordo in parola – efficace dalla data di ultima sottoscrizione per un periodo di tre anni – ciascun Partner si impegna a fornire a titolo gratuito i Dati, identificati nell'allegato “*Annex 1 – Definitions*” e con le modalità previste nell'allegato “*Annex 2 – proposed format for the Raw Data*”, ad ANSES e all'IZSVE che, in qualità di “*Recipients*”, raccoglieranno i dati provenienti da tutti i Partner e produrranno un set di dati puliti da utilizzare per ulteriori analisi di dati.

Il costo per la realizzazione delle attività oggetto dell'Accordo rimane a carico di ciascuna delle parti, per la rispettiva competenza, in quanto comprese nell'ambito delle attività facenti parte del mandato istituzionale, per le motivazioni di interesse pubblico esplicitate nelle premesse, che si intendono integralmente trasfuse.

Tutto ciò premesso, sulla base degli elementi riportati dal referente dell'istruttoria, si propone alla Direttrice generale quanto segue:

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1. di approvare lo schema di “*Data Sharing Agreement*” per lo svolgimento del progetto “*Standardization of diagnostics and antimicrobial susceptibility testing and clinical interpretation in animal mycoplasmas - MyMIC*” nell’ambito della “*3rd JPIAMR-ACTION Joint Call 2022 – ERA-NET Cofund – Diagnostic and Surveillance Networks*”, da stipulare tra l’Istituto Zooprofilattico Sperimentale delle Venezie, rappresentato dalla Direttrice Generale e legale rappresentante *pro tempore*, dott.ssa Antonia Ricci, e gli altri partner del progetto “*MyMIC*” individuati nell’Accordo, documento che si allega al presente provvedimento quale parte integrante e sostanziale (*allegato n. 1*);
2. di procedere, per l’effetto, alla sottoscrizione dell’Accordo di cui al punto che precede – efficace dalla data di ultima sottoscrizione fino al completamento delle attività di ricerca – ai sensi degli artt. 15 e 16 del vigente Accordo interregionale sulla gestione dell’Istituto Zooprofilattico Sperimentale delle Venezie, sottoscrizione che avverrà con firma digitale ai sensi dell’art. 15, comma 2-*bis* della L. n. 241/1990, come modificato dall’art. 6, comma 5 del D.L. n. 145/2013, convertito, con modificazioni, dalla Legge n. 9/2014;
3. di prendere atto che, in virtù del predetto Accordo – efficace dalla data di ultima sottoscrizione per un periodo di tre anni – ciascun Partner si impegna a fornire a titolo gratuito i Dati, identificati nell’allegato “*Annex 1 – Definitions*” e con le modalità previste nell’allegato “*Annex 2 – proposed format for the Raw Data*”, ad ANSES e all’IZSVE in qualità di “*Recipients*”;
4. di prendere atto, infine, che il costo per la realizzazione delle attività oggetto dell’Accordo rimane a carico di ciascuna delle parti, per la rispettiva competenza, in quanto comprese nell’ambito delle attività facenti parte del mandato istituzionale, per le motivazioni di interesse pubblico esplicitate nelle premesse, che si intendono integralmente trasfuse.

LA DIRETTRICE GENERALE

ESAMINATA la proposta di deliberazione del Responsabile della S.S. Affari Generali, Anticorruzione e Trasparenza.

PRESO ATTO che il Responsabile della S.S. Affari Generali, Anticorruzione e Trasparenza nel proporre il presente atto attesta la regolarità tecnica ed amministrativa, la legittimità e congruenza dell’atto con le finalità istituzionali dell’Istituto, l’assenza di conflitto di interessi, stante anche l’istruttoria effettuata a cura del suddetto Dirigente.

VISTO il decreto del Presidente della Giunta regionale del Veneto n. 102 del 22 settembre 2020 con il quale è stata nominata la dott.ssa Antonia Ricci quale Direttore generale dell’Istituto Zooprofilattico Sperimentale delle Venezie.

VISTA la DDG n. 141 del 19 aprile 2023 con la quale il dott. Giovanni Cattoli è stato nominato Direttore sanitario dell’Istituto.

VISTA la DDG n. 101 del 10 marzo 2021 con la quale il dott. Massimo Romano è stato nominato Direttore amministrativo dell’Istituto.

ACQUISITO il parere favorevole del Direttore amministrativo e del Direttore sanitario per quanto di competenza, espresso ai sensi dell’art. 15 dello Statuto dell’Istituto, adottato con

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delibera del CdA n. 12 del 24 maggio 2021 e approvato con delibera della Giunta regionale del Veneto n. 1308 del 28 settembre 2021.

VISTO l'Accordo per la gestione dell'Istituto Zooprofilattico Sperimentale delle Venezie tra la Regione del Veneto, la Regione Autonoma Friuli Venezia Giulia e le Province Autonome di Trento e Bolzano, approvato dai suddetti Enti, rispettivamente, con leggi n. 5/2015, n. 9/2015, n. 5/2015 e n. 5/2015.

DELIBERA

1. di approvare lo schema di “*Data Sharing Agreement*” per lo svolgimento del progetto “*Standardization of diagnostics and antimicrobial susceptibility testing and clinical interpretation in animal mycoplasmas - MyMIC*” nell’ambito della “*3rd JPIAMR-ACTION Joint Call 2022 – ERA-NET Cofund – Diagnostic and Surveillance Networks*”, da stipulare tra l'Istituto Zooprofilattico Sperimentale delle Venezie, rappresentato dalla Direttrice Generale e legale rappresentante *pro tempore*, dott.ssa Antonia Ricci, e gli altri partner del progetto “*MyMIC*” individuati nell’Accordo, documento che si allega al presente provvedimento quale parte integrante e sostanziale (*allegato n. 1*);
2. di procedere, per l’effetto, alla sottoscrizione dell’Accordo di cui al punto che precede – efficace dalla data di ultima sottoscrizione fino al completamento delle attività di ricerca – ai sensi degli artt. 15 e 16 del vigente Accordo interregionale sulla gestione dell'Istituto Zooprofilattico Sperimentale delle Venezie, sottoscrizione che avverrà con firma digitale ai sensi dell’art. 15, comma 2-*bis* della L. n. 241/1990, come modificato dall’art. 6, comma 5 del D.L. n. 145/2013, convertito, con modificazioni, dalla Legge n. 9/2014;
3. di prendere atto che, in virtù del predetto Accordo – efficace dalla data di ultima sottoscrizione per un periodo di tre anni – ciascun Partner si impegna a fornire a titolo gratuito i Dati, identificati nell’allegato “*Annex 1 – Definitions*” e con le modalità previste nell’allegato “*Annex 2 – proposed format for the Raw Data*”, ad ANSES e all’IZSVe in qualità di “*Recipients*”;
4. di prendere atto, infine, che il costo per la realizzazione delle attività oggetto dell’Accordo rimane a carico di ciascuna delle parti, per la rispettiva competenza, in quanto comprese nell’ambito delle attività facenti parte del mandato istituzionale, per le motivazioni di interesse pubblico esplicitate nelle premesse, che si intendono integralmente trasfuse.

Il presente provvedimento non è soggetto al controllo previsto dall’Accordo per la gestione dell'Istituto Zooprofilattico Sperimentale delle Venezie approvato dagli Enti cogenerenti con le leggi regionali e provinciali citate nelle premesse.

LA DIRETTRICE GENERALE
dott.ssa Antonia Ricci

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Sul presente atto deliberativo ha espresso parere favorevole

Il Direttore amministrativo
dott. Massimo Romano

Il Direttore sanitario
dott. Giovanni Cattoli

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ATTESTAZIONI ALLEGATE ALLA DELIBERAZIONE DELLA DIRETTRICE GENERALE

Il Responsabile della Struttura proponente attesta la regolarità della proposta di deliberazione, presentata per l'adozione, in ordine ai contenuti sostanziali, formali e di legittimità dell'atto e che la stessa:

Comporta spesa	<input type="checkbox"/>	su	Finanziamento istituzionale	<input type="checkbox"/>
			Finanziamento vincolato	<input type="checkbox"/>
			Altri finanziamenti	<input type="checkbox"/>
Non comporta spesa	<input checked="" type="checkbox"/>			

ATTESTAZIONE DI COPERTURA ECONOMICA DELLA SPESA

Il Responsabile del Budget attesta l'avvenuto controllo sulla disponibilità di budget

Evidenziato infine che il responsabile della Struttura proponente, con la sottoscrizione della proposta di cui al presente atto, dichiara, sotto la propria responsabilità ed ai sensi e agli effetti degli artt. 47 e 76 del DPR 28 dicembre 2000, n. 445, che, in relazione alla presente procedura, non si trova in condizioni di incompatibilità di cui all'art. 35 bis del d.lgs. n. 165/2001, né sussistono conflitti di interesse di cui all'art. 6 bis della legge n. 241/1990 e agli artt. 6, 7 e 14 del DPR n. 62/2013.

dott.ssa Giulia Ferriani

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ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLE VENEZIE

Viale dell'Università 10 – 35020 LEGNARO (PD)

DELIBERAZIONE DELLA DIRETTRICE GENERALE

N. 42 del 13/02/2024

OGGETTO: Approvazione dello schema di ``Data Sharing Agreement`` per la realizzazione del progetto ``MyMIC - Standardization of diagnostic and antimicrobial susceptibility testing and clinical interpretation in animal mycoplasmas``, nell'ambito della ``3rd JPIAMR-ACTION - ERA-NET Cofund - Joint Call 2022``.

Publicata dal 13/02/2024 al 28/02/2024

Atto immediatamente esecutivo

Il Responsabile della Pubblicazione
Benedetta Mazzucato

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Elenco firmatari

Questo documento è stato firmato da:

Dott.ssa Giulia Ferriani - Servizio Affari generali, anticorruzione e trasparenza

Dott. Massimo Romano - Direzione Amministrativa

Dott. Giovanni Cattoli - Direzione Sanitaria

Dott.ssa Antonia Ricci - Direzione Generale

Benedetta Mazzucato - Gestione Atti

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JPIAMR 2022 – DIAGNOSTIC AND SURVEILLANCE NETWORKS

MyMIC – STANDARDIZATION OF DIAGNOSTIC AND ANTIMICROBIAL SUSCEPTIBILITY TESTING AND CLINICAL INTERPRETATION IN ANIMAL MYCOPLASMAS

DATA SHARING AGREEMENT

BETWEEN

The French Agency for Food, Environmental and Occupational health & Safety,

a public organisation of an administrative nature

with registered offices at: 14 rue Pierre et Marie Curie, 94701 Maisons-Alfort cedex, France, represented by Pr Benoît Vallet, hereinafter referred to as “**ANSES**”

AND

Istituto Zooprofilattico Sperimentale delle Venezie (IZS),

a public veterinary Institute with offices at Viale dell’Università 10, 35020 Legnaro (PD), Italy, fiscal code and VAT n. 00206200289, represented by its Director General, Dr. Antonia Ricci, hereinafter referred to as “**IZSve**”

AND

Gezondheidsdienst voor Dieren B.V.,

a corporation with limited liability incorporated under the laws of The Netherlands with registered offices at: Arnsbergstraat 7, 7418 EZ Deventer, The Netherlands, represented by its CEO Prof. Dr. Y.H. Schukken, hereinafter referred to as “**GD**”

AND

Swedish Veterinary Agency / Statens veterinärmedicinska anstalt, an expert authority under the Ministry of Rural Affairs and Infrastructure with registered offices at SE-751 89 Uppsala Sweden, represented by its Director General, Ann Lindberg, hereinafter referred to as “**SVA**”

AND

Finnish Food Authority, with registered office at P.O. Box 100 FI-00027 Ruokavirasto, Finland, represented by Head of Animal Health Diagnostic Unit Riikka Holopainen, hereinafter referred to as “**FFA**”

AND

Universiteit Gent - Ghent University, public institution with legal personality, having its administrative offices in Belgium, B-9000 Gent, Sint-Pietersnieuwstraat 25, company registration number 0248.015.142, for whom Prof. Dr. Rik Van de Walle, rector, acts by delegation pursuant to the Board of Governors' decision, who entrusts the execution of the present agreement dr. Bart Pardon, Department of Internal Medicine, Reproduction and Population Medicine, Promoter and to Prof. dr. Frank Pasmans, Department of Pathobiology, Pharmacology and Zoological Medicine (hereinafter referred to as “**UGent**”);

AND

Universidad de Las Palmas de Gran Canaria, with registered offices at: Calle Juan de Quesada 30, Las Palmas de Gran Canaria, 35001 Las Palmas de Gran Canaria, España, with fiscal code C.I.F. Q3518001G, represented by its Rector Dr. Lluís Serra Majem, hereinafter referred to as “**ULPGC**”

AND

University of Veterinary Medicine Vienna (Vetmeduni), a public institution with registered office at Veterinaerplatz 1, 1210 Vienna, Austria, represented by its Rector A.-Prof. Dr. Petra Winter, hereinafter referred to as “**Vetmeduni**”

AND

Veterinary Medical Research Institute

Hungária körút 21.

Budapest, 1143, Hungary, represented by Tibor Magyar, hereinafter referred to as “**VMRI**”

AND

Kimron Veterinary Institute, with registered offices at POB 12 Bet Dagan, 50250, Israel represented by Dr. Monica Leszkowicz Mazuz (Director of KVI from 1/12/23) hereinafter referred to as “**KVI**”

AND

University of Bern with its Institute of Veterinary Bacteriology (IVB), public institution with registered office at Länggassstrasse 122, 3012 Bern, Switzerland, represented by its director Prof. Dr. Jörg Jores, hereinafter referred to as “**UniBE**”

AND

National Veterinary Research Institute (NVRI), a governmental research institute supervised by the Minister of Agriculture and Rural Development, with headquarters at Aleja Partyzantów 57, 24-100 Puławy, Poland represented by its Director General, prof. Stanislaw Winiarczyk , hereinafter referred to as “**NVRI**”

AND

The University of Melbourne [ABN 84 002 705 224] of Parkville, Victoria 3010, a body politic and corporate established in 1853 and constituted under the provisions of the University of Melbourne Act 2009 (Vic) of Melbourne, VIC 3010, hereinafter referred to as “**UoM**”

IZSve and **ANSES** hereinafter the “**Recipients**” of raw data as leaders of WP2

ANSES, IZSve, GD, SVA, FFA, UGent, ULPG, Vetmeduni, VMRI, KVI, UniBE, NVRI, UoM hereinafter collectively the “**Parties**”, as they provide raw data, and each a “**Party**”;

WHEREAS:

- Animal mycoplasmas are major pathogens causing various diseases in livestock and pets, with significant economic losses for farmers. Their control relies largely on antimicrobial (ATB) use. Inappropriate and sustained use of ATB can select for resistance in the targeted bacteria, hence hampering treatment efficacy, but non-target microorganisms are also affected, including zoonotic/food-borne bacteria with significant impact on human health.
- The efficacy of ATBs in vivo can be indirectly assessed by in vitro susceptibility testing. However, existing standard procedures for AST could not be used for mycoplasmas, because of their different culture requirements and growth. The lack of standardized consensus procedures and quality control strains makes comparisons between studies difficult or impossible. Moreover, there are no clinical breakpoints or epidemiological cut-off (ECOFF) values determined specifically for animal mycoplasmas, which complicates the interpretation of results.
- Parties have amongst other institutions applied for the JPIAMR NETWORK CALL 2022 regarding “Diagnostics and Surveillance Networks” (hereinafter “the MyMIC project”). The objective of the MyMIC project is to set up a network of laboratories working on mycoplasma diagnostics and their susceptibility to ATBs to compare the different methods used and the results of minimum inhibitory concentrations (MIC). This project will lead to the drafting of guidelines for a standardized culturing, identification and determination of MICs. The aggregation of MIC data obtained by the different partner laboratories (Data as described in Annex2) will be helpful to determine the first tentative ECOFFs for some *Mycoplasma* species to help clinical interpretation of MICs, and guide veterinarians toward a reasonable use of ATBs (hereinafter “the Purpose”).

NOW, THEREFORE

in consideration of the covenants and obligations hereinafter set forth, the Parties hereto, individually and by their respective agents and representatives, hereby agree as follows:

ARTICLE 1: PURPOSE OF THE AGREEMENT

The purpose of this Agreement is to define the conditions for data sharing as part of the MyMIC project that aims to generate analyses of MIC data generated by the different Parties, as well as the associated metadata and procedures to obtain these MIC data. Parties own and/or control the Data as described in Annex 1 and control certain valuable technical and proprietary information relating to this Data and are willing to share them for the Purpose.

ARTICLE 2: DATA OWNERSHIP

1. Each Party makes the Data described in Annex 2 available free of charge to the Recipients solely for the Purpose. The provision of the Data under this Agreement does not constitute a transfer of ownership, in whole or in part, to the benefit of the Recipients. Each Party guarantees that, to its best reasonable knowledge, the Data transmitted (i) are its property, and (ii) that their provision and use do not infringe the rights of third parties.
2. The recipient Parties shall in all cases be entirely and solely liable for the use they make of the Data. No warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.
3. Subject to the terms and conditions herein, all Parties grant to each other a royalty-free, non-exclusive license to use the harmonized Data solely for the Purpose described in this Agreement.
4. The Parties will refer any request for the Data coming from anyone other than those persons working under their organization.
5. Each Party shall ensure that its employees, students and agents using the Data agree to be bound by the terms of this Agreement.
6. Each Party shall decide what kind of data it will and/or is able to share under this Agreement.
7. A data collection template for raw data is provided in Annex 2 for further details.

ARTICLE 3: TYPE OF DATA BEING SHARED AND DATA TRANSFER PROCEDURE

1. All Parties will share the Data as set out in details in the template in Annex2.
2. Data will be anonymized by each Party before they are shared, so that the data cannot be derived from anyone, that all personal data in the dataset has been deleted and that it is therefore impossible to identify a natural person or trace back to, for example, a pet owner or a farm of origin. No personal data will be shared between the Parties.
3. Data will be transferred to ANSES and IZSve, acting as recipients. ANSES and IZSve as leaders of WP2 of the MyMIC project will compile the data from all participating Parties. With support and expertise from all participating Parties, ANSES and IZSve will produce a cleaned dataset to be used for further data analysis. The raw data sets, as well as the cleaned dataset and the results of the data analyses (hereinafter "the Results") will be stored on a secured extranet platform hosted by ANSES, to which all Parties will have restricted access.
4. A data collection template is provided in Annex 2 for further details. Wherever available, raw Data (i.e. where one row of the dataset = one bacterial strain) will be preferred to aggregated data.
5. Each Party shall decide what kind of data it will and/or is able to share under this Agreement. Parties are not obliged to provide all the data asked in the data collection template.
6. Each Party shall ensure that the Data it is sharing under this Agreement does not include any personal data that would fall under the scope of General Data Protection Regulation (EU 2016/679).

ARTICLE 4: AUTHORIZED USE OF THE DATA

- 1 Shared Data will be analysed and interpreted in collaboration with all Parties, in the respect of Data ownership (Article 2). This includes the preparation of cleaned and consolidated dataset, the implementation of descriptive analyses and comparability assessment of Data being shared under this agreement as well as generation of tentative ECOFF in the framework of WP3.
- 2 The joint analysis and interpretation of the Data shall lead to the production of joint reports as well as joint scientific/academic publications of the involved Parties based on Principles of Scientific Practice. An indication of the Data sources (country, institute, framework...) must be included in these reports/publications. The regulation of co-authorships regarding such publications is subject to the international requirements on authorship of the International Committee of Medical Journal Editors (<http://www.icmje.org/>).
- 3 Any publication or disclosure of the Results from the MyMIC Network shall require the written agreement of all Parties.
- 4 Prior notice of any planned publication shall be given to the other Parties at least 45 calendar days before the publication. Any objection to the planned publication shall be made in writing to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.
- 5 An objection is justified if :
 - a. the protection of the objecting Party's data would be adversely affected
 - b. the objecting Party's legitimate interests in relation to the data would be significantly harmed.
- 6 The objection has to include a precise request for necessary modifications.
- 7 If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.
- 8 The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted.
- 9 A Party shall not include in any dissemination activity another Party's data without obtaining the owning Party's prior written approval, unless they are already published.

ARTICLE 5: NON-AUTHORIZED USE OF THE DATA

- 1 The Data provided within the framework of this Agreement may not be used for other purposes than the specific "Purpose".
- 2 Any further distribution to third parties of Data or a subset of Data made available by the other Parties is forbidden unless agreed to in writing. The solicited Party shall communicate its decision within 30 days. In the absence of any response in given time the permission shall be deemed to have not been given.
- 3 All Parties agree that the Data:
 - a. will not be used for Commercial Purposes; any commercial use of the Data is strictly forbidden. The Parties undertake not to sell, disclose, transfer, give or distribute the Data to any third party;
 - b. will be used only at the Parties organizations and only in the respective offices under the direction of the authorized employees;
 - c. will not be further transferred without the Parties prior written consent.

ARTICLE 6: LIABILITY AND WARRANTY

- 1 Recipients acknowledge that the Data are experimental in nature and is provided "as is" with no warranties, express or implied, including any warranty of merchantability, accuracy, title or fitness for a particular use.

- 2 By signing the Agreement, the Parties accept responsibility for the proper handling of the Data in accordance with the effective legislation of the country in which they are used.
- 3 All Parties shall guarantee the security of the Data, appropriate technical and organizational measures shall be implemented to ensure a level of security appropriate to the risks represented by the nature of the Data.
- 4 Measures shall be undertaken with the aim of preventing an unauthorized person from gaining access and preventing any unauthorized reading, copying, alteration or removal of the Data.
- 5 Each Party shall in all cases be entirely and solely liable for the use to which it puts the Data. No warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purposes nor as to the absence of any infringement of any proprietary rights of third parties.

ARTICLE 7: CONFIDENTIALITY

- 1 Each Party recognizes the confidential nature of the Data being shared and accepts:
 - a. to provide Data only to staff members needing such access and who agree to abide by the provisions of this Agreement;
 - b. to take all reasonable measures to prevent staff from disclosing all or part of the shared Data to third parties.
- 2 Each Party assumes responsibility for enforcing the obligations of this Agreement among its staff having or having had access to the data.
- 3 The confidentiality obligations of the Parties to this Agreement do not apply to Data:
 - a. which were in the public domain at the time of disclosure by one of the Parties;
 - b. which would have fallen into the public domain without any violation of any of the provisions of this Agreement;
 - c. which were legitimately provided by a third party not subject to confidentiality obligations;
 - d. which were already known before the entry into force of this Agreement without having been communicated, directly or indirectly, by one of the Parties to this Agreement;
 - e. that one of the Parties is legally obliged to communicate according to effective legislation in the respective Party's country.
- 4 This Article 7 shall not preclude the right of the scientists of each Party to publish articles on their research work or to present at conferences, in the area of this Agreement as defined in Article 1, as long as they do not disclose confidential information.
- 5 The commitments under this Article shall remain in force for the duration of this Agreement and for the five (5) years following its termination or its term.
- 6 However, they shall not be an obstacle to the registration of industrial property rights (if any).

ARTICLE 8: DURATION

- 1 This Agreement is concluded for a period of 3 years from the date on which all Parties have signed it.
- 2 Any prolongation will need an amendment to this Agreement.

ARTICLE 9: APPLICABLE LAW - DISPUTES

- 1 This Agreement shall be construed in accordance with and governed by the laws of the defendant party or Belgium law by default. In the event of any difficulty concerning the execution, validity, termination or interpretation of this Agreement, the Parties shall endeavour to resolve their dispute amicably.
- 2 Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the rules of the World Intellectual Property Organization

(WIPO) Arbitration and Mediation Center. The place of mediation shall be Brussels unless otherwise agreed upon. The language to be used in the mediation shall be English.

- 3 If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 90 calendar days of the commencement of the mediation, the courts of the defendant party or by default Belgium shall have exclusive jurisdiction.

ARTICLE 10: TERMINATION

- 1 Each (single) contracting Party may terminate this Agreement following six (6) months period of notice. The notice of termination must be issued in writing.
- 2 In the event that a Party identifies a breach by another Party of its obligations under this Agreement, the Party may give formal notice to such Party requiring that such breach will be remedied within 30 calendar days from the date of receipt of the written notice by the Party. If such breach is substantial and is not remedied within that period or is not capable of remedy, the Parties may in a meeting of all Parties decide to declare the Party to be a defaulting party and to decide on the consequences thereof that may include termination of its participation.
- 3 The execution of this right of termination does not exempt the defaulting Party from fulfilling the obligations contracted up to the effective date of termination, subject to any damage suffered by the complaining Party because of the anticipated termination of the Agreement.
- 4 The rights to the data granted to a defaulting Party shall cease immediately upon the effective date of termination. A non-defaulting Party leaving voluntarily shall have access rights to the data until the date of the termination of its participation. Other Parties will not have the right to use the data provided by the leaving Party since the beginning of the Agreement, and all the data that have been provided by the leaving Party since the beginning of the Agreement will be deleted and removed from the data collection
- 5 Any delay or failure of performance by all parties shall not constitute default or give rise to any claim for damages if and to the extent that such delay or failure is caused by events unforeseeable and beyond its reasonable control; provided however that the Party seeking relief notifies the other Parties thereof promptly after such a circumstance has occurred.

ARTICLE 11: PERSONAL DATA PROTECTION

- 1 The Parties agree to comply with the applicable legislation on the protection of personal data and respect for private life, and in particular Regulation (EU) 2016/679 of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).
- 2 The Parties guaranties that all necessary measures in order to comply with the GDPR and other data protection regulation that the data transferring parties are subject to has been implemented before data is transferred or made available to the Parties.

ARTICLE 12: MISCELLANEOUS

- 1 **Force Majeure:** Each Party will not be held responsible for the failure, the inaccurate or delayed fulfillment of the obligations of this Agreement, where the same has been caused, directly or indirectly, by unforeseeable circumstances, force majeure or any other cause not attributable to the same. In the event of such force majeure, the affected Party thereby shall promptly notify the other Parties in writing. If the force majeure lasts more than ninety (90) days, the Party shall have the right to terminate the Agreement; the notice of termination shall be made according to the present Article 10.
- 2 **National legislation:** An act or procedure of a Party shall not be considered a breach of the Agreement if the Party's proceedings arise from compelling legislation or a written authority order or similar order based on compelling legislation in the Party's domestic country
- 3 **Entire Agreement:** This Agreement constitutes the entire understanding of the Parties with respect to the matters contained herein, superseding all prior oral or written understandings or communications

between the Parties relating to the present Agreement. This Agreement may be amended, modified, superseded or canceled, only by a written instrument executed by each Party's duly authorized representatives.

- 4 **Notices:** All notices and communications related to this Agreement shall be made by registered or certified letter, return receipt requested, electronic transmission confirmed in writing by registered mail and shall be addressed as follows (or to other address as may hereafter be designed by written notice):

If to ANSES: Dr. Florence TARDY – email: Florence.tardy@anses.fr

If to IZSVE: Dr. Marco Bottinelli - email: MBottinelli@izsvenezie.it

If to GD: Dr. Annet Heuvelink or Anneke Feberwee - email: a.heuvelink@gddiergezondheid.nl or a.feberwee@gddiergezondheid.nl

If to SVA: Dr. Märit Pringle or Emma Hurri - email: marit.pringle@sva.se, emma.hurri@sva.se

If to FFA: Dr. Tiina Autio or Tarja Pohjanvirta – email: tiina.autio@ruokavirasto.fi, tarja.pohjanvirta@ruokavirasto.fi

If to UGent: Prof. Dr. Bart Pardon - email: Bart.Pardon@ugent.be and Prof. dr. Frank Pasmans : - email: frank.pasmans@ugent.be

If to ULPGC, Dr. Ana S. Ramírez Corbera –email: anasofia.ramirez@ulpgc.es

If to Vetmeduni, PD Dr. Joachim Spargser _ email: joachim.spargser@vetmeduni.ac.at

If to VMRI, Dr. Miklós Gyuranecz – email: m.gyuranecz@gmail.com

If to KVI, Dr Inna Lysnyansky _ email: innal@moag.gov.il

If to UniBE, Dr. Gudrun Overesch - email: gudrun.overesch@unibe.ch

If to NVRI, Dr. Katarzyna Dudek – email: katarzyna.dudek@piwet.pulawy.pl

If to UoM, Dr. Nadeeka Wawegama – email: nadeekaw@unimelb.edu.au

Negotiation:This Agreement has been freely negotiated between the Parties hereto and represents their willingness as duly and clearly shown in the content hereof and properly considered.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives.

This Agreement is made at the date and place of the last signature.

Party	Date	Name and signature
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ANSES		
IZSVE		
GD		
SVA		
FFA		
UGent		
ULPGC		
Vetmeduni		
VMRI		
KVI		
UniBE		
NVRI		
UoM		

ANNEX1: DEFINITIONS

The above-mentioned words have the following meanings in this Agreement:

“Data”: includes Raw Data, i.e. Minimum Inhibitory Concentration of specific antimicrobials versus specific strains belonging to different Mycoplasma species as well as details on the methodology used to obtain these data (as set in Annex2) as well as cleaned Data sets elected out of Raw Data for their eligibility to define Ecoff

“Commercial Purposes”: the application of patent, the sale of products or services, lease, license, or other transfer of the Data for any commercial purpose or for the direct benefit of any legal entity, including use of the Data by any organization to perform research for third parties who obtain rights in research results, to screen compounds, to produce or manufacture products for general sale, or to conduct any research activities that result in any sale, lease, license, or transfer of the Data to a legal entity.

“Confidential Information”: Information of any nature protected or not by an intellectual property right (for example data, documents, methods, know-how, etc.) whatever their subject, transmission mode, origin, communicated within the frame of this Agreement. The Data is Confidential information.

Confidential information does not include information that:

- a) is a part of the public domain at the date of this Agreement or became available following the aforementioned acquisition by act or behavior not prohibited by the Receiving Party;
- b) is known or can be demonstrated that they it was known by the Receiving Party at the time of transmission;
- c) is disclosed to the Receiving Party and explicitly defined as non-confidential;
- d) have been independently developed by the Receiving Party without using any of the confidential information;
- e) is revealed to the Receiving Party by someone other than the Revealing Party that has no obligation to secrecy under the terms and conditions of the present Agreement; or else, information which becomes available to the is disclosed to the Recipient Party by any other means not ascribable to the present Agreement;
- f) is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by the Receiving Party, provided, however, that such Receiving Party (A) gives, to the extent possible according to effective legislation in the Party’s country, the disclosing Party sufficient advance written notice to permit it to seek a protective order or other similar order with respect to such Confidential Information and (B) thereafter discloses only the minimum information required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by such disclosing Party;
- g) have been previously agreed upon in written form by the Provider of such information.

“Patent rights”: any patents, patent applications, trade secrets or other proprietary right of one Party having claims relating to the Data, including any altered forms of the Data made by another Party, and any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protections certificates and the like, or provisional applications of any such patents and patent applications, or foreign equivalent thereof.

ANNEX 2 : proposed format for the Raw Data

This is a copy paste of one excel sheet that need to be used for data exchanges. One sheet has to be filled in by species and one raw has to be filled in per isolates. The template excel files will be sent to all parties

Provider : Mycoplasma species : AST method (agar dilution, broth dilution) : Medium use : QC strain use : Incubation time before reading : Inoculum density:		Anses M. bovis agar dilution INDICIA F12000 5 days for all ATB 1µL at 10 ⁷ cfu/mL		Please fill in one sheet per species									
Strain number / name. Please specify if it is the QC strain		Country of origin		Year of isolation		Isolation context (clinical or screening + animal host, origin of sample (eg milk, lung))		If published, please provide doi, if not put n.p. for not published		MIC per antimicrobial tested [please indicate the range tested] (in µg/ml)		Add as many molecules of interest to you. If you don't test a molecule, just put nd "not done" in the corresponding cell	
F12000 (QC)	France	2023	cow, mastitis	n. p.	[2-64]	[2-256]	[0.25-64]	[0.06-128]	[0.06-128]	[1-32]			
F15000	France	2022	veal, pneumonia, nasal swabs	n. p.	16	8	2	128	nd	8			