Standard Operation Procedures	SOP_004
Effective Date: 09/01/2024	**Public**

European Union Summary Reports Delivery

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Process Responsibility	Process owners are accountable this procedure being adhered to within their respective or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document.

SCOPE AND OBJECTIVES

This SOP covers the process for managing the delivery of annual Scientific Reports. These reports are: 1) EU One Health Zoonoses Report (EUOHZ), 2) EU Summary Report (EUSR) on Antimicrobial Resistance (AMR), 3) EUSR on Transmissible Spongiform Encephalopathies (TSE), 4) Annual Report on veterinary medicinal product residues and other substances in live animals and animal products (ARVMPR), 5) Annual Report on Pesticide Residues (ARPR). This procedure describes steps relevant to the variants of the process EPA 04.01 – GENERIC MANDATES

RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

1. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safetyin particular (Article 33)
2. Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC, in particular Article 9(2) for EUOHZ and EUSR AMR
3. Commission Implementing Decision (EU) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU for EUSR AMR
4. Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
5. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC in particular Article 32, for the ARPR
6. Decision of the Management Board concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission
7. SOP_007 Risk assessment of Generic Mandates
8. SOP_008_ Data collection and validation
9. Definitions of EFSA Scientific Outputs and Supporting Publications
10. Information Management Policy
11. SOP_010_ Scientific Cooperation, Grants and Procurements, Planning, Launch, Evaluation, Award and Implementation
12. SOP_20_ Processing of confidentiality claims received by EFSA in the context of its scientific operations
13. Publication of scientific data from EU-coordinated monitoring programmes and surveys – Technical Report
14. WIN_SOP08/10a_Catalogue Management_Annual Revision
15. WIN_SOP_004_S/01 Collecting and validating data within the framework of the annual EU One Health Zoonoses Report and the annual EU Summary Reports on Antimicrobial Resistance and on Transmissible Spongiform Encephalopathies
16. WIN_SOP_004_S/02 Review and approval of external scientific reports supporting the annual EU One Health Zoonoses Report, and the annual EU Summary Reports on Antimicrobial Resistance and on Transmissible Spongiform Encephalopathies
17. WIN_SOP_004_S/03 Preparation, review and approval of the annual EU One Health Zoonoses Report, and the annual EU Summary Reports on Antimicrobial Resistance and on Transmissible Spongiform Encephalopathies
18. WIN_SOP014_05 Avoiding Plagiarism Guidelines
19. WIN-SOP 14-08 Publishing catalogue
20. WIN_SOP_020_01 Practical implementation of SOP_020
21. WIN_SOP_020_02 Practical implementation of SOP_020
22. WIN_SOP_020_03 Practical implementation of SOP_020

ABBREVIATIONS AND DEFINITION	
AMR	Antimicrobial Resistance
AR	Annual Report – generic term used in this SOP. The term covers the Annual Scientific Reports that are produced by EFSA in the remit of process 04.01 Generic Mandates, e.g. EUOHZ, EUSR AMR, EUSR TSE, ARPR, ARVMPR[1]; the deliverable can be either a Scientific Report of EFSA or a Technical Report[2].
ARPR	Annual Report on Pesticide Residues
ARVMPR	Annual Report on veterinary medicinal product residues and other substances in live animals and animal products
BIOHAW Unit	Biological Hazards and Animal Health and Welfare Unit
Case Management Tool	EFSA's case management tool is built on APPIAN and it ensures the automation of the relevant scientific production processes as well as EFSA to store a great deal of mandate information and consolidate that into one database.
ChemMon	Chemical Monitoring data collection
CO	Communication Officer
ENGAGE	Communication and partnership department
IDATA unit	Integrated Data Unit
DCF	Data Collection Framework
DO	Data Officer
DWH	Data Warehouse
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EUOHZ	European Union One Health Zoonoses Report
EURL	European Union Reference Laboratory
EUSR	European Union Summary Report
FIN	Finance Unit
HoD	Head of Department
LU	Leading Unit
MS	Member State

[1] At the date of SOP approval, the Leading unit for EUOHZ, EUSR AMR and EUSR TSE is BIOHAW Unit and for ARVMPR and ARPR is IDATA Unit.
[2] For EFSA output types see: http://www.efsa.europa.eu/en/efsajournal/scdocdefinitions

RAL	Risk Assessment Logistics Unit
RC	Reporting countries: EU MSs and EFTA[3] and pre-accession countries.[4] *Note: EFTA and pre-accession countries attend network meetings as observers, with no voting rights in Networks' decisions; however, these countries are participating in the data collection process and usually observe the Networks' agreed decisions.*
SO	Scientific Officer
SOP	Standard Operating Procedure
TSE	Transmissible Spongiform Encephalopathies
PROCEDURE	
	Previous SOPs in the process:
Step 1	**1.0 Agreement on dates for: data collection, data validation, draft report consultation and fixed publication date**
SO, DO, CO, RAL Unit Administrative Staff	1.1 Data collection is launched annually for collecting information gathered for the reporting year. To ensure smooth planning, the year before launching the data collection the SO and DO agree with the MSs and the EC the following: data collection launch and closure dates, data check and validation and draft report consultation dates, in accordance with applicable legal framework. This agreement is recorded in the minutes of the relevant network meeting – i.e., the Scientific Network for Zoonoses Monitoring Data for EUOHZ and EUSR AMR, and the Chemical Monitoring Network for ARVMPR and ARPR, or is sent by email or communicated through Teams to MSs and EC for EUSR TSE. 1.2 SO informs CO of the publication date whenever agreed, if possible in accordance with publication deadlines stipulated within the applicable legal framework, for work planning reasons and for consideration of communication-related activities, e.g., web story, press release, data visualization, etc. 1.3 SO communicates the dates of the Tollgates 1, 2 and 3, as applicable (for details please see steps below), to the relevant responsible in RAL who records them in the Case Management Tool/Appian. SO informs the relevant DO of the changes to be performed on the data pipeline (from data ingestion to data validation and data sharing).
Step 2	**2.0 Preparation of the data collection supporting materials**

[3] https://www.efta.int/
[4] Info on pre-accession countries at: https://www.efsa.europa.eu/en/partnersnetworks/international

DO, SO	2.1 Before launching the data collection (see step 3.1) and at the latest by the first quarter of the year following the reporting year, DO and SO publish updated supporting documents (e.g., manuals, catalogues, data dictionaries and mapping tools), where applicable, to assist the RCs with the data collection exercise. These supporting documents are based on specific legislative requirements, scientific considerations, technical requisites, and on the experience gained (feedback collected from RCs) from previous data collection exercises. 2.2 By the first quarter of the year following the reporting year, planned procurement procedures (see SOP_010_Scientific Cooperation, Grants and Procurements, Planning, Launch, Evaluation, Award and Implementation) are launched or framework contracts implemented for drafting the AR, or for reviewing specific chapters of the AR, or for producing data visualization tools. This step applies only to EUOHZ, EUSR AMR and EUSR TSE. SO provides to DO updated annual population data (EUROSTAT), which needs to be inserted in the EFSA DWH and which serves the purpose of calculating specific statistics. This step applies only to EUOHZ.
Step 3	**3.0 Data collection and data validation**
DO, SO	3.1 DO launches the data collection via EFSA DCF as agreed with MSs in the pre-defined calendar. 3.2 RCs submit data in accordance with the data collection rules and by the agreed/legal deadline – see step 1.1. 3.3 During data transmission: • The data ingestion system automatically applies previously defined data validation rules, which are business rules in the DCF (see also SOP_008_ Data Collection and Validation). • SO carries out scientific data validation for the reports within their remit, unless this activity is fully outsourced, as mentioned in step 2.2. 3.4 At the end of the data collection period the DO closes the data collection in DCF. Data collected is made available to the SO and the contractor, when applicable, via the agreed formats/templates e.g., reports in MicroStrategy, flat files, dashboards, maps etc. In case one or more confidentiality requests were received via the Portalino in the context of a call for data, LU informs LA when the call is closed and assigns a Question Number to the relevant Portalino submission. Confidentiality requests received in the context of a call for data are assessed by LA applying Procedure 1 of SOP_020_Confidentiality assessment, implementation and publication of documents.
Step 4	**4.0 Data analyses and AR structure**
SO, DO	4.1 SO assigned to the AR or the contractor (in case of full outsourcing) assesses the overview reports available in the MicroStrategy and performs analyses. The SO can ask the DO to produce related tables, graphs and maps.

	Based on the available data, the SO or the contractor (in case of full outsourcing) defines the structure of the AR, the format of the tabulated and graphical outcomes, and determines the main lines of emphasis of each AR based on main findings. SO ensures delivering (by contractor in case of full outsourcing) an approved 'Plan of analysis', which constitutes Tollgate #1 in Appian.
Step 5	**5.0 Reports drafting and RC consultation**
SO, DO, FIN, RAL Unit Administrative Staff	5.1 SO from the LU, also with the support of other units, as needed, drafts the AR chapters. For the EUOHZ, EUSR TSE and EUSR AMR that are supported by procurement procedures, coordination by the SO with the contractor takes place, with the support of FIN where necessary. 5.2 One week in advance of launching the consultation, the RAL Assistant ensures that the proper access rights for the consulted experts are set in the collaboration tool in use in EFSA. 5.3 When the draft report is ready for the consultation, the responsible SO(s) check(s) the quality, completeness and consistency of the draft scientific output (or parts thereof) and decide(s) whether it is ready for finalisation (see Step 11 in the SOP_007_ Risk assessment of Generic Mandates), which constitutes Tollgate #2 in Appian. 5.4 Subject to the conditions set out in Article 16 of the Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning transparency and confidentiality, the preliminary draft AR is shared by SO for consultation with RCs directly or through the relevant Network and/or EURLs, and/or EFSA Scientific Panels, and with the EC, for verifying if data provided are included, and if there is any need for data correction or for adding any missing data. This is done in the last quarter of the year for EUOHZ and EUSR AMR, in the third quarter for the EUSR TSE, and in the first quarter of the following year for ARVMPR and ARPR . 5.5 Comments are received from the consulted organisations by the deadline agreed, including submission by the RCs of the amended data through the DCF in case of EUOHZ, EUSR AMR and EUSR TSE. In the case of ARVMPR and ARPR, validated data should have been amended in DCF at an earlier stage, as per the procedure described in SOP_008_ Data collection and validation process. 5.6 The SO, or the contractor when applicable, addresses the comments received during the consultation and considers the amended data by incorporating them in the AR. Subject to the conditions set out in Article 16 of the Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning transparency and confidentiality, the amended AR can be sent for a final short consultation with the concerned RCs During the short consultation, DCF revision of data can be made, if needed, only for EUOHZ, EUSR AMR and EUSR TSE. Comments and the way these were addressed are stored on the DMS by SO. For the ARVMPR and ARPR the comments are collected by the

	SO and published as Annex together with the AR by the RAL Assistant. Before the final approval, the RAL Assistant receives the link to the final AR from the SO for submitting it for plagiarism check and/or language edit with a view to improve clarity and readability.
Step 6	**6.0 Preparing the report for approval and publication**
SO, DO, RAL Unit Administrative Staff	6.1 After addressing the comments received during the consultation rounds, the responsible SO(s) decide(s) if the scientific output is ready for approval by the HoU/HoD (see Step 11 in the SOP 007 S). 6.2 Then the link to the finalised AR is submitted for approval purposes to the RAL Assistant in accordance with SOP 007 S – Risk assessment of Generic Mandates, and for setting the passing date of Tollgate #3 in Appian. 6.2.1 For EUOHZ and EUSR AMR which are joint interagency EFSA-ECDC scientific reports, the SO liaises with the ECDC SO for the joint approval. 6.3 The SO liaises with ENGAGE CO during the last quarter of the year (in case of EUOHZ and EUSR TSE) or in the first quarter of the following year (in case of EUSR AMR, ARVMPR and ARPR) to plan communication-related activities, e.g., web story, press release, data visualisation, etc. at the time of publication. 6.4 The approved AR is sanitized by implementing relevant confidentiality decisions, if any, pursuant to and Procedure 5, Step 1.2 of SOP_020_Confidentiality assessment, implementation and publication of documents. In case the confidentiality assessment has not been finalized at this stage, provided the blackening proposed by the data providers with regard to the AR is not excessive, proceed with step 6.5. The approved AR is prepared for publication on the EFSA website and, for EUOHZ and EUSR AMR, also on the ECDC website, pursuant to Procedure 10 of SOP_020_Confidentiality assessment, implementation and publication of documents.
	Following SOPs in the process: SOP_014_Publishing a scientific output in the EFSA Journal and Supporting Publications SOP_007_Risk assessment of Generic Mandates