European Food Safety Authority

BIOCONTAM and DATA UNITs

Scientific Network for Zoonoses Monitoring Data – Antimicrobial Resistance Meeting

Minutes of the 3rd meeting

Held on 27-28 February 2014, Parma

(Agreed on 31/03/2014)

Participants

- **Network Representatives of Member States and Norway and Switzerland:**

Country	Name	Country	Name
Austria	Peter Much	Latvia	Andra Utinane
Belgium	Nadine Botteldoorn	Lithuania	Asta Pereckiene
Bulgaria	Hristo Daskalov	Luxembourg	Joseph Schon
Croatia	Dražen Kneževic	Netherlands	Rob Van Oosterom
Czech Republic	Kateina Zemánková	Norway	Anne Magrete Urdahl
Denmark	Vibeke Frøkjær Jensen	Poland	Kinga Wieczorek
Estonia	Jelena Sõgel	Portugal	Maria Fatima Cordeiro Silva
Finland	Katariina Pekkanen	Romania	Ioana Neghirla
France	Sophie Granier	Slovakia	Andrea Brtkova
Germany	Bernd-Alois Tenhagen	Slovenia	Majda Golob
Greece	Tzani Myrsini	Spain	Cristina De Frutos Escobar
Hungary	Katalin Czeibert	Sweden	Bjorn-Olof Bengtsson
Ireland	Caroline Garvan	Switzerland	Sabina Buettner
Italy	Antonio Battisti	United Kingdom	Lesley Larkin

- **Hearing experts intervening in their private capacity:**
  - Heather Tate – US Food and Drug Administration (FDA)
  - Christopher Teale – UK Animal Health and Veterinary Laboratories Agency

- **World Organisation for Animal Health (OIE):**
  - Daniel Chaisemartin

- **EFSA:**
  - Pierre-Alexandre Belœil (BIOCONTAM, Chair), Mary Gilsenan* (DATA), Ernesto Liebana Criado* (BIOCONTAM), Frank Boelaert (BIOCONTAM), Francesco Vernazza* (DATA), Stefano Cappè (DATA), Anca Stoicescu (DATA, scientific secretary), Kenneth Mulligan* (DATA), Francesca Riolo (DATA), Verena Spiteller (DATA), Klaudia Chrzastek (DATA), Simona Fusar Poli* (DATA).

*: Partial attendance at specific points of the agenda

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1. Welcome and apologies for absence

The meeting was opened by welcoming the members of the Scientific Network (SN). Apologies were received from Iceland, Malta, the European Centre for Disease Prevention and Control (ECDC) and the European Commission (EC).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, members of networks, peer review meetings, networking meetings and their alternates shall be invited to complete and submit an Annual Declaration of interest (ADoI). EFSA screened the ADoI filled in by the experts invited to the meeting. No conflicts of interests related to the issues discussed at this meeting were identified during the screening process nor at the Oral Declaration of interest (ODoI) at the beginning of this meeting. The Chair thanked the representatives who submitted ADoIs.

4. Reorganisation of the Risk Assessment and Scientific Assistance Directorate (RASA)

Mary Gilsenan, head of the DATA Unit, presented the remit of the RASA Directorate and summarised the purpose of the restructuring - to gain efficiency by introducing a project management approach and strengthened collaboration between the reorganised units. The tasks and the structure of the four new RASA units were outlined. In addition, Ernesto Liebana Criado, acting head of BIOCONTAM Unit, underlined the importance of the monitoring and data collection processes as the basis for the risk assessment activity. One of the main objectives of the reorganisation is to gain in efficiency so as to offset a 10 % funding reduction over the next five years.

5. General Introduction

Pierre-Alexandre Belœil presented a general introduction on antimicrobial resistance (AMR) monitoring at the EU level. Further to the implementation of the technical specifications on AMR monitoring issued by EFSA in 2007 and 2008 by the Member States (MSs), incremental improvements have been recorded in AMR monitoring and reporting in the EU over the last five years, such as a change from diffusion to dilution methods for susceptibility testing, a switch from qualitative to quantitative and isolate-based data reporting and an enhancement of data analysis by addressing the multi-resistance phenomenon. These preparatory activities of the MSs and EFSA thus paved the way for proposing and adopting new EU legislation (Commission Implementing Decision 2013/652/EU) on harmonised monitoring and reporting of AMR in animals and food, more ambitious and more up-to-date. The main provisions of the new legislation, which applies from 1 January 2014, were also summarised.

The main aim of the 3rd Network meeting on AMR monitoring was therefore to present and discuss EFSA's plan to support MSs' implementation of the new monitoring and reporting regime in 2014 to enable this process to be as smooth as possible, in particular regarding randomised sampling and isolate-based data reporting. The MSs are strongly encouraged to become familiar with isolate-based data reporting and the use of the related reporting tool in 2014 so as to ensure compliance with the mandatory requirement for isolate-based data reporting in 2015.

6. The 2012 EU Summary Report on AMR: main findings

Pierre-Alexandre Belœil briefly presented the main findings on AMR from humans, food and animals from the 2012 EU Summary Report (EUSR) on AMR. AMR was commonly found in humans, animals and food with low levels of clinical resistance to critically important antimicrobials (CIAs) in humans. High to very high microbiological resistance to ciprofloxacin were observed in isolates from poultry. Microbiological co-resistance to CIAs was reported at low to very low levels in *Salmonella, Campylobacter* and *E. coli* isolates from animals and food. Some of the MSs which have had consistent AMR monitoring programmes over a number of years showed coherent increasing trends in ciprofloxacin resistance in *Campylobacter* and *E. coli* isolates from broilers. It is of note that some of the epidemiological cut-off values (ECOFFs) used to interpret 'microbiological resistance' in the 2012 EUSR on AMR were from the former provisions of the European Committee on Antimicrobial Susceptibility Testing (EUCAST). In addition, Christopher Teale presented the multi-drug resistance (MDR) results in food and animals reported in the 2012 EUSR on AMR for the first time. Multi-drug resistance and co-resistance results, such as the summary indicators of multi-/co-resistance and the multi-drug resistance patterns and ciprofloxacin resistance assessed at different thresholds, were presented and put into perspective by showing how these relate one to another.

7. Plan for 2013 EU Summary Report on AMR: the 2014 reporting season

7.1 Feedback from the 2013 reporting season on AMR reporting

Kenneth Mulligan presented a detailed update on the number of MSs and non-MSs that used the Data Collection Framework (DCF) to submit AMR data in the period 2011-2013. Isolate-based data reporting by DCF worked well and no major problems were encountered during the 2013 reporting season. Errors mostly related to duplicate values submitted in the same 'matrix'/'reporting context'[1].

7.2 Reporting manual on AMR for 2013 data reporting

Anca Stoicescu updated the SN's members on the Manual for Reporting on AMR within the framework of Directive 2003/99/EC and indicator bacteria for information derived from the year 2013. Manuals for reporting data on zoonoses and AMR have been separated this year for clearer readability, but no other major changes have been made in the manuals, which are planned to be sent for a short consultation during week 10 prior to publication. The main changes in the Web Application were also presented. It was strongly emphasised that the Web Application's function (button), which allows automatic importation of the values entered in the Antimicrobial Quantitative Tables into the Antimicrobial Qualitative Table, should not be used (clicked).

7.3 DCF: Data Collection Framework

Kenneth Mulligan gave a short demonstration of the use of DCF transmission: format validation, data insert, staging points of area validation, data acceptance, rejected transmission. It was underlined that EFSA will only maintain the DCF system for data transmission in the near future, as two reporting systems cannot be sustained in parallel under current budgetary circumstances. In 2014, the Web Application can still be used.

Nevertheless, as isolate based AMR data, which can only be transmitted to EFSA through the DCF, are to be reported mandatorily in 2015, a question may arise as to whether the reporting of AMR data through the Web Application will be maintained in 2015. Therefore, MSs are strongly encouraged to use the DCF in 2014 and for this purpose, to use the different instruments developed by EFSA, such as grants (see section 11.3), training

[1] As defined in the Data dictionaries/guidelines for reporting data on zoonoses, AMR and food-borne outbreaks

programmes and supporting tools (see section 11.4). The final decision regarding maintaining the Web Application for reporting AMR data in 2015 will be taken later on in 2014, notably in the light of the 2014 reporting season results.

7.4 DCF data models and data dictionaries/guidelines for 2013 AMR data

Verena Spiteller presented data models for submission of 2013 AMR data, whether qualitative, quantitative or isolate based-data, including a brief summary of the models' fields and pick-lists. No major changes have been made compared with the previous year, although two additional fields (*Total number of samples tested positive for the bacteria* and *Total number of epidemiological units tested positive for the bacteri*a) have been added. The reason for adding the two fields in the data models and their definitions were presented.

7.5 Isolate-based data reporting: the experience of Austria

Peter Much presented Austria's experience in reporting AMR isolate-based data over the last three years. Issues were typically related to very few 'confusing' fields; however, EFSA's support desk was very efficient and problems were quickly solved. As improvements in EFSA's data models were made in 2011 and 2012, less work was needed to submit data year after year. Overall, no major problems occurred. In addition, collaborative attitudes of national data reporters are considered crucial, as they are key driving forces behind the achievement of the common goal of reporting appropriate data. Coding is also an important step, as, once data are coded, errors are more difficult to detect. It would be advisable that soon after isolate-based data submission, EFSA provides feedback on aggregated data at relatively short notice so that data providers can double check data consistency.

7.6 Plan for data validation and consultation (updated presentation)

Stefano Cappè presented the plan for 2013 data validation and consultation. Notably, it has been agreed that the opening of DCF for 2013 data reporting will occur on 24 March 2014 and that of the Web Application on 2 April 2014, while the deadline for data submission is in practice on 28 May 2014. The reporting systems for data submission should in principle remain operative from 29 May to 31 May, although, as EFSA is closed on these days, the zoonoses support and IT support helpdesks will not be operative. MSs were therefore kindly requested to submit data by 28 May 2014.

The data submitted through DCF will be migrated to the Web Application to generate aggregated data reports so that the transmitted data can be seen and double checked easily. Data migration will be functional as soon as the period of reporting through the Web Application has started, i.e. from 3 April onwards. In the case of migration problems, the data managers will generate equivalent tables via SAS on demand through *ad hoc* requests to the EFSA support desk. In any case, since last year's reporting season, DCF validation has been enhanced to detect errors which were identified during the phase of data migration last year and which hampered successful data migration for a number of MSs.

In addition, it is planned that data validation will be performed between 28 May and 23 June 2014. EFSA will check the submitted data against a number of criteria and provide feedback to MSs by sending letters requesting clarifications and/or amendments and tables on 'occurrence of resistance' (aggregated data), if all MSs/reporting countries respect the deadline of the end of May. This important improvement should be made possible thanks to the internalisation of AMR analysis in EFSA, successfully performed last year. It is foreseen that MSs will have two weeks to amend data, between 23 June and 4 July 2014, and subsequently, EFSA will carry out a second validation. Validation results will be communicated to the MSs which will have from 22 July to 8 September to provide their final feedbacks. This extends the previous deadline of 1st September to account for the summer break. After this latter date, it has been agreed that data cannot be changed, as the database will be frozen and the data reported used to draft the report.

7.7 Tour de Table on MSs' intentions regarding isolate-based data reporting in 2014

A tour de table was organised on the MSs'/reporting countries' intentions regarding both AMR data intended to be reported (combinations of zoonotic and indicator bacteria, animal populations, food categories and sampling stage) and the format of submission either isolate-based or aggregated AMR data. The answers gave a clear overview of the data expected to be submitted. In particular, three countries are already planning to report data on ESBL-producing *E. coli* in 2014.

7.8 Plan for 2013 AMR data analyses

Pierre-Alexandre Belœil presented the plan for 2013 data analysis. Regarding 2013 data, the most recent EUCAST ECOFFs will be used in accordance with the new EU legislation and consequently, historical AMR datasets will be also reinterpreted using new ECOFF values for the sake of epidemiological continuity. A consultation of the MSs on resistance results in historical data analysed by using the new ECOFFs is planned to be launched either in spring or in connection with the consultation on 2013 data on occurrence of resistance foreseen in the summer. In addition, the format of the 2013 EUSR on AMR will change as the narrative text is intended to be much more reduced while expanding the section on main findings. The summary indicators of MDR will be included in the report, while results on the association of resistance traits in 2012 data will be included in the Joint ECDC-EFSA-EMA report on consumption of antimicrobials and antimicrobial resistance in animals, food and humans (JIACRA) report to be published by the end of 2014 (see section 13). The analyses of co-resistance and multi-resistance patterns in 2013 AMR data will be insourced in EFSA in 2014, although it is currently foreseen to publish the corresponding results in the 2014 EUSR on AMR in 2015. Finally, a tracing analysis of the diffusion of the multi-resistance (cluster analyses) will be performed on historical data and 2013 data by an external contractor through procurement. A corresponding external Scientific Report of EFSA is foreseen to be published after consultation in 2015.

8. The NARMS programme in the USA: achievements and challenges faced

Heather Tate from the US Food and Drug Administration (FDA) presented the National Antimicrobial Resistance Monitoring System for enteric bacteria (NARMS), which involves eight different agencies in the USA. The presentation addressed exhaustively all the infrastructural issues related to AMR monitoring; the sampling programme, the zoonotic agents addressed, the laboratory methods, the panel of antimicrobial substances tested and the interpretative criteria were presented in detail. The outcomes of this monitoring include individual agencies' NARMS reports and an interagency NARMS report. The presentation was very well received and allowed fruitful exchange of views.

9. Implementation of 'new' harmonised AMR monitoring in animals and food

9.1 Update on the mandate on randomised sampling for AMR monitoring

Pierre-Alexandre Belœil presented the mandate received from the EC and the approach of EFSA to address this request. The simple and robust randomised sampling procedure proposed is a compromise between 'good statistical practices' and practical issues, mostly relying on a 'modified' two-step stratified sampling approach with proportional allocation of the sample numbers per strata. The draft report is foreseen to be sent for consultation in April 2014.

9.2 Tour de table on the on-going implementation of the new legislation and MSs' intentions regarding 2014 data reporting (in 2015)

Due to the fact that MSs should evaluate carefully the impact of the new legislation (reporting of isolate-based data) and the EFSA's support in data reporting through the DCF to be provided in 2014, it was agreed that this consultation will be done later on via e-mail.

11. Plan for the future EU Summary Reports on AMR

11.1 Draft multi-annual plan on EUSRs

Frank Boelaert presented a draft multi-annual plan for production of the EUSRs for the period 2014–2020, which has been discussed already a first time with EC and ECDC. The plan is scheduled to be presented to the Standing Committee on the Food Chain and Animal Health (SCoFCAH).

Background – after 10 years, the EUSRs have grown considerably underpinned by accumulating data submitted each year. Consequently, analyses have become more complex. Currently, two reports of around 300 pages are produced yearly, including data submitted for legislative purposes (target verification, AMR monitoring).

EFSA proposed this plan for the EUSRs after internal consultation of the relevant units considering harmonisation across other domains like pesticides and contaminants (aggregated *vs*. sample level data). The data validation timelines are in revision with the aim to meet the legal annual publication deadline (end of November). As regards data, once the data validation period is closed and the data locked/frozen, EFSA will logically not accept newly submitted data any more or data not captured by the zoonoses database, such as data submitted via email.

It is envisaged that the annual EUSRs will remain *Descriptive Reports*, including factual summary tables and a summary of main findings. Additional, *ad hoc (joint) Scientific Reports* can be initiated as needed (*e.g.* EC's request, EFSA self mandate) including thematic data analyses addressing specific questions (*e.g.* farm to fork analysis, in-depth analysis of MDR, serovar trend analyses).

11.2 The Sample Standard Description 2: an introduction

Stefano Cappè informed the Network about the Standard Sample Description (SSD2): a model harmonising the collection of a wide range of analytical results in several domains of EFSA activity. It lists data elements that are standardised and can be conveniently used by both data providers and data receivers to fully describe samples and analytical parameters for assessment purposes. The SSD2 includes agreed terminologies and validation rules to guarantee data quality (in data export, transmission and storage). In order to support MSs/reporting countries in reporting isolate-based AMR data coded with SSD2 codes through the DCF in 2015, two training sessions are foreseen at EFSA in the second semester of 2014 (see section 14.2 below).

11.3 Move to DCF reporting: supporting grants and contracts

Francesca Riolo updated the Network on the grants to support both the building of a system to export data from the national repositories in compliance with the EFSA data model and controlled terminologies (including isolate-based AMR data) and the update of historical data, via DCF. A new call will be launched in the coming weeks to provide support and the deadline for application is on 30 April 2014. MSs were strongly encouraged to apply to the call. The rules were agreed as for the previous calls – granted by data collection area and not by bacteria. The Netherlands, Romania and the United Kingdom showed interest in applying.

11.4 EFSA supporting tools for isolate-based data reporting

Kenneth Mulligan briefly presented the tools developed by EFSA to support MSs' isolate-based data reporting by transmitting XML files to DCF. Two types of models were developed in Excel and are available to MSs to produce XML files. A *'Manual model'*, where MSs could select directly in the antimicrobial model worksheet the EFSA pick list terms which are needed, and a '*Dynamic model'*, where MSs create a mapping of all the pick list terms used in national data, to their corresponding EFSA pick list codes. The use of the '*Dynamic model*' requires a more detailed training which is planned to be organised on demand prior to, and at the beginning, of the 2014 reporting season for interested MSs. Discussion with the Scientific Network members was related to the applicability of this model to collect data in the laboratory.

12. Update on ECDC guidelines for AMR monitoring and reporting

Pierre-Alexandre Belœil briefly presented the protocol for harmonised surveillance of AMR in human isolates of *Salmonella* and *Campylobacter* produced by ECDC. One of the aims of this protocol is to have a better comparability of data between humans and animal/food. The objectives of the EU surveillance, the panel of antimicrobials tested, the methods, interpretative criteria and reporting format represent the main content of these guidelines. The document should be published on the ECDC website in March.

13. Update on the Joint ECDC/EFSA/EMA Working Group on the analyses of the relationship between antimicrobial resistance and consumption in humans, animals and food

Pierre-Alexandre Belœil briefly presented progress of the joint ECDC/EFSA/EMA working group (WG) on the analyses of the relationship between antimicrobial use and resistance in humans, animals and food. Specific combinations of antimicrobials/bacteria were proposed to explore possible approaches for analysis. The draft approach was presented, including how current scientific limitations will be addressed in the report. The report is scheduled to be issued by the end of 2014.

14. Any Other Business

14.1 Date for next meetings

No preliminary date for the next antimicrobial resistance meeting was agreed.

14.2 Dates for trainings

In order to support MSs/reporting countries to report through DCF with SSD2 codes, two dates for training are proposed on the:

- 23 October 2014: 1-day after the Scientific Network: training for scientists;
- 1 December – 2 December 2014: 1.5-day training for IT experts.

Member States are requested to send a nomination for training attendees to **zoonoses_support@efsa.europa.eu** by the end of April.

14.3 Validation of historical data-timelines

Regarding the validation of the historical AMR data, MSs and other reporting countries will be asked by e-mail to validate the historical data after re-interpretation using the new ECOFFs and the timelines for this will be agreed.

15. Conclusion(s)

The Chair briefly summarised the main decisions and outcomes of the meeting.

16. Closure of the meeting

The meeting was closed and the Chair thanked the Scientific Network members for a fruitful meeting.