Scientific Network on Veterinary Medicinal Products Residues Data Collection Minutes of the 1st meeting

Held on 23-24 February 2016, Parma
(Agreed on 25 March 2016)

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name
Austria	Verena Spiteller
Belgium	Chantal Rettigner
Bulgaria	Yanko Ivanov
Cyprus	Constantinou Spyroula
Croatia	Bruno Calopek
Czech Republic	Jiří Drápal
Denmark	Jens Hinge Andersen
Estonia	Merle Suursaar
Finland	Kaija Leena Saraste
France	Isabelle Fournet
France	Isabelle Berta-Vanrullen
France	Brigitte Roudaut
Germany	Heideun Forchheim
Greece	Mary Pantelia
Hungary	Attila Tirián
Ireland	Eileen O'Dea
Ireland	Janice Whelan
Italy	Francesca Roberti
Italy	Michele De Martino
Latvia	Iveta Pugajeva
Lithuania	Snieguolė Trumpickaitė Džekčiorienė
Luxembourg	Jean Brasseur
Malta	Noel Demicoli
Netherlands	Olaf Stenvers
Poland	Kamila Mitrowska
Portugal	Patrícia Inácio
Romania	Constantin Iordache
Slovakia	Martina Ihnatova
Spain	Jesús Martín Ruíz
Spain	Ana Canals Caballero

Sweden	Frida Broman
United Kingdom	Carol Brailsford
Iceland	Ingibjorg Jonsdottir
Norway	Inger Halle Skagen
Norway	Marie Louise Wiborg
Norway	Per Bratterud

- **Hearing Experts**

Representatives of the European Reference Laboratories (EU-RLs) for residues of veterinary medicines and contaminants in food of animal origin: Joachim Polzer (Federal Office of Consumer Protection and Food Safety: BVL Germany), Leendert A. van Ginkel (Wageningen University and Research Centre: RIKILT, The Netherlands), Laura Ciaralli (Istituto Superiore di Sanità: ISS Italy), Eric Verdon (Laboratoire de Fougères: French Agency for Food, Environmental and Occupational Health and Safety: ANSES France).

- **European Commission:**

Frank Swartenbroux (Directorate-General for Health and Food Safety: DG Santé E2), Elzbieta Brulinska-Ostrowska, DG SANTE F5 (Health and Food Audits and Analysis).

- **EFSA:**

Risk Assessment and Scientific Assistance (RASA) department: Hans Verhagen (Head of Department) participated in agenda point 1.

Evidence Management (DATA) Unit: Doreen Dolores Russell (Chair), Enikő Varga (scientific secretary), Anca Stoicescu (scientific secretary), Simona Fusar Poli participated in agenda point 3.3, Sofia Ioannidou participated in agenda point 3.5, Alessandro Carletti participated in agenda point 5.4, Stefano Cappé and Francesco Vernazza attended part of the meeting.

Biological Hazards and Contaminants (BIOCONTAM) Unit: Karen Mackay and Ruth Roldan Torres first day.

Advisory Forum and Scientific Cooperation (AFSCO) Unit: Julia Finger attended part of the meeting.

Pesticides (PRAs) Unit: Daniella Brocca.

1. Welcome and apologies for absence

The Chair welcomed the participants to the meeting.

Apologies were received from Matthias Gehling/Germany, Vida Njoi/Slovenia Zuzana Birošová/Slovakia and Jose Luis Paramio Lucas/Spain.

Some opening remarks for this inaugural Network meeting were made by Hans Verhagen, EFSA's head of the RASA department.

2. Adoption of agenda

The agenda was adopted without changes.

3. Topics for discussion

3.1. An introduction to EFSA and the Evidence Management (DATA)

Doreen Dolores Russell (DATA Unit) gave a presentation on the background to the establishment of EFSA, its operating framework and organisational structure. She also explained that data collection and cooperation are enshrined in Regulation 178/2002/EC as well as outlining the role and activities of the DATA Unit. The purpose of other data collection scientific networks was briefly explained as well as the collaborative developments in standardising and improving data collection activities.

3.2. Role of Network on Veterinary Medicinal Products Residues (VMPR)

Anca Stoicescu (DATA Unit) presented the terms of reference of the Scientific Network on VMPR Data Collection. The scope of the VMPR network was described namely to provide advice and assistance to EFSA on the specific matters indicated in the terms of reference such as updating the data model, catalogues and reporting specifications; defining optimal data analyses; exchange of information and sample based data on residues of veterinary medicinal products; review the annual summary report. She advised that this would be realised through communication between EFSA and the VMPR network via meetings, teleconferences, information sharing and emails while trainings are also envisaged. She also highlighted that it is the role the Member States' (MSs) representatives to liaise at national level to ensure information sharing.

3.3. Administrative procedures

Simona Fusar Poli (DATA Unit) explained how to correctly complete the EFSA form for obtaining the financial reimbursement and the associated travel and financial information.

3.4. European Commission (EC) activities in the field of VMPR data collection

Frank Swartenbroux (DG Santé E2) explained the EC involvement in collecting data on VMPR. At present, data is reported to an EC online residue application which contains the current year's monitoring plans as well as the results from the previous year and is used for producing the annual VMPR report - allocated to EFSA in 2009 - and for data extraction. He indicated that recommendations have been made in various EFSA annual reports regarding the limitations of use of the aggregated VMPR data available from the database which was subsequently illuminated by the horse-meat scandal in 2013 where the short-comings of the data extracted on phenylbutazone were brought into focus in the scientific risk assessment. Consequently in 2013 the EC mandated EFSA to collect information on all residue samples (sample-based data), to collect information related to follow up actions linked to non-compliant results and to enable differentiated access for the EC and MSs.

Spain pointed out that Directive 96/23 states that MSs have to send their results to the EC so no obligation to send results to EFSA. The EC representative replied

that legally this was not believed to be an issue as EFSA is already required to collect data under general food law (Regulation 178/2012/EC) but he added that this requirement could be specifically included in the new food and feed regulation. The United Kingdom asked if national plans would still be sent to the EC, which was confirmed, and also asked for clarification on the reporting of animal identification details. EFSA advised that it introduced this requirement in the 'Guidelines for reporting data on residues of veterinary medicinal products' (available at: http://www.efsa.europa.eu/en/supporting/pub/783e) to allow the reporting of the numbers of samples tested from a single animal but that the guidelines can be revised so that the samples from the same animal or farm can be reported using a unique reference which does not compromise confidentiality.

Spain asked about the reporting of mandatory and optional data elements and the challenges of providing the different information needed. Spain was also concerned about the resource issue due to the fact that the national plans will be submitted to the EC and the results to EFSA. Elzbieta Brulinska-Ostrowska, the Directorate F, Health and Food Audits and Analysis representative, indicated that when the new database is ready it will negate the need to use the old database for providing residue testing results, and thus eliminate the double work, as the extraction of the results from the new database will demonstrate whether the plan has been implemented or not. The EC also acknowledged the concerns raised but responded that in any event the national residues plan and the results are reported separately in the EC residue platform and with the food and feed law review a sample based reporting system is now needed.

3.5. Scientific evaluation of VMPR data in EFSA and the steps to perform an exposure assessment

For the scientific evaluation of VMPR data the legal requirements were outlined by Karen Mackay (BIOCONTAM Unit) including National Residue Control Plans (NRCP); sampling levels and frequency, groups of substances, the annual data submission requirements (current year's plans and previous year's monitoring results; details of the products sampled and production volume details). EFSA produces an annual report which summarises the monitoring results in a defined format: including animal/animal products for each main substance group, assessment of samples analysed for each substance group, assessment of sample analysed and results.

Sofia Ioannidou (DATA Unit) outlined the EFSA scientific opinions where data from the NRCP were extracted: namely chloramphenicol in food and feed, nitrofurans and their metabolites in food and malachite green in food. She explained the importance of having detailed data for exposure assessments and the constraints of using aggregated data; specifically these are: no indication of the sample matrix (blood, muscle, fat etc.), concentrations are not reported and the lack of information on sampling numbers.

The meeting discussed the presentations and also the relevance of using the data for exposure assessments. The United Kingdom raised a question about the necessity to report the animal identification in the VMPR data model and highlighted its difficulties. EFSA explained that it doesn't need the animal ID, but would need to know the total number of samples tested from the animal, as requested by the Commission. EFSA indicated that the main goal of the current

on-going pilot project is to test the usability/feasibility of the data model and guidance document. Based on the outcome of the pilot project the guidance will be revised and it is expected that other solutions will be found for counting the samples tested from the animal.

Austria raised a question about the necessity of reporting 'Limit of detection' (LOD) and 'Limit of qualification' (LOQ). EFSA clarified that for VMPR data reporting the limits of $cc\alpha$ and $cc\beta$ are sufficient. In relation to Austria's point Eric Verdon (ANSES, Laboratoire de Fougères) explained that moving from a strict regulatory control of residues to an exposure surveillance of these same residues requires changing some of the screening method especially for antibiotic residue controls. As a consequence the laboratories might have to change some of their routine procedures in the future. He added that this will be a long process that could be divided into different steps and in this respect the new data model is a significant step forward. He highlighted that the current reporting system based on strict compliancy/non-compliancy status does not include enough data on the identification and the concentration of a residue that is needed for the assessment of compliance and non-compliance.

Belgium added that in some cases only immunological methods are employed for screening. The more detailed, quantitative analyses are only performed for the non-compliant results and thus the change to the methods used would require more resources.

Joachim Polzer (BVL) made the point that there are a solid number of quantified data already available in MSs' laboratories and in the first instance the MSs are requested to submit those data. For reporting sample based data, the data already available from the laboratories derived from the methods currently available can be reported, a point that was endorsed by Denmark.

Frank Swartenbroux reminded the participants that the current data reporting on VMPR does not provide detailed quantitative information about the non-compliance data either, however those results are also available in the laboratories.

Spain raised a question about the possibility of additional EFSA procurements. EFSA replied that there could be a new procurement for implementing the VMPR data model in 2016, but currently this is under discussion.

3.6. Introducing the new approach for collecting VMPR data

Anca Stoicescu introduced the new approach for collecting VMPR data based on the increased demand for risk assessments and the concomitant restrictions on using aggregated data as the background to EFSA receiving the mandate from the EC to collect sample based data. The main components of the VMPR data model were explained to the participants and examples of the checks built into the data model were presented. The 'Guidelines for reporting data on residues of veterinary medicinal products' are complimentary to the data model and financial assistance for pilot project for this data collection was offered and awarded to ten MSs. It is within the remit of this pilot project for the participating MSs to identify shortcomings and to make suggestions for the improvement of the data model, data catalogues, business rules and guidance document.

The next steps in the process were outlined including the development of a reporting tool to assist with the reporting of sample-based data as well as training. All network representatives were encouraged to collect a limited dataset in 2016 and to transmit to EFSA in 2017 thus providing an opportunity to work with the data model and to test it in preparation for the sample-based VMPR collection that will commence in 2017 for transmission to EFSA before 31 March 2018.

In relation to reporting deadliness, the United Kingdom asked if additional time would be available to report or would the 31 March 2018 deadline (for reporting 2017 data) be rigidly adhered to. A concern is that a non-compliant sample identified in late December 2017 could feasibly not meet the reporting deadline. The EC agreed that given such a scenario it would be very difficult to meet the deadline.

24 February 2016

4. Welcome and apologies for absence

All participants were welcomed to the second day of the meeting.

5. Topics for discussion

5.1 Cooperation between EFSA and MSs

Julia Finger (AFSCO Unit) gave an overview of how EFSA collaborates with MSs. She explained that the Network Members (or their alternate members) are nominated by the Advisory Forum and the AFSCO Unit acts as an interface between the Advisory Forum and the EFSA Scientific Units who manage the Networks. She also explained that the national Focal Points facilitate the information flow and assist Advisory Forum members and Network representatives.

5.2 The activities and work of the European Union Reference Laboratories (EURL) in relation to VMPR data

Representative from each of the 4 EURLs for residues of veterinary medicines and contaminants in food of animal origin provided details about their functions, scope of activities and analytical methods employed. They explained that the EURLs are the intermediate links between the EC and the National Reference Laboratories (NRLs) of the 28 EU MSs. Each Reference Laboratory is responsible for certain substances. Among others, the tasks of the EURLs are to develop and validate test methods, to carry out arbitral analyses, to provide advice to the EC and to support the NRLs. Moreover they promote harmonisation in the proficiency of the laboratories, thus helping to avoid market distortions in the Single European Market.

It was also highlighted that EURLs make use of advanced apparatus and possess very well trained staff for the performance of analytical services on VMP residue analysis. The EURLs provide assistance and/or training to laboratories that do

not have access to the specified methods required by specific tests. The EURLs have the expertise and facilities to carry out confirmatory analyses when unexpected or even conflicting results require the intervention of an independent party. It was also explained that all methods developed by the EURLs are available to official laboratories of EU MSs and to the EU candidate countries.

With reference to the 'Guidelines for reporting data on residues of veterinary medicinal products' Spain initiated a discussion around an example presented in the document for a reported sampling result. Spain indicated that if this example was followed when reporting data it would lead to an unrepresentative number of non-compliant results being reported. Following a full discussion and exchange of views on this example with contributions from Denmark, France, Frank Swartenbroux and Leendert A. van Ginkel EFSA agreed to improve this example in order to provide clarity and also to include further examples when revising the guidance document.

5.3 An introduction to harmonised data collection in EFSA

Enikő Varga (DATA Unit) explained why EFSA collects data and who the main data providers are, what data is collected by EFSA and how data collection is undertaken. She defined some of the standard terms used to describe the components of an EFSA data collection and she presented the evolution from an un-standardised data format to a standardised data collection format.

Spain asked whether an additional pilot project is envisaged in 2016 and asked whether it will be a grant or procurement. EFSA replied that it's under discussion currently but if it is agreed it will be procurement.

The Netherlands asked how the MSs will be notified about future procurements. EFSA replied that information is posted on the EFSA website but that if a call is published the information will be circulated to the Network.

5.4 The Standard Sample Description Version 2 (SSD2) pilot project for VMPR data collection

Alessandro Carletti (DATA Unit) presented the scientific cooperation activities with the MSs regarding the testing and implementation of the SSD2 the aim of which is to have one common data model for submitting data electronically to EFSA. He presented the tasks and the deadlines of the 2015 procurement which was awarded to ten MSs He also asked what kind of support the reporting countries would need for the implementation of SSD2 including training and mentoring as examples.

5.5 The VMPR Reporting Template

Enikő Varga gave a brief introduction to the meeting of the main aims behind the development of the VMPR reporting template. She explained that the tool, the reporting template, is a simple and useable platform for MSs to use to map their country specific standard terminology to those published by EFSA. The template can be used to generate an XML (EXtensible Markup Language) file, for submission to the DCF Data Collection Framework, - the EFSA web interface for

data submission. The template also helps improve the quality of data submitted to EFSA, as it provides an immediate, basic data validation.

Spain asked if the reporting tool would be used to generate the XML to submit the data to the EFSA DCF. EFSA clarified that all the MSs' terms must first be mapped to the EFSA terms and once this is ready the tool provides an XML file; however the created XML file must be uploaded manually into the DCF. Norway asked if it would be possible to share the embedded macros in the Excel tool in order to re-use the coding in their own systems. EFSA replied that the tool at present is protected to prevent manipulation of the codes to protect the quality and integrity of the data reported using the tool.

5.6 Sharing activities and experiences in VMPR data collection: outcomes of the discussion

Enikő Varga provided an overview of the analysis performed on the returned completed questionnaires that had been sent to the Network representatives by EFSA prior to the meeting. The intention was to gather information on the currently existing arrangements in MSs for VMPR data collection.

According to the answers received from 25 countries, half of the MSs receive the data from the laboratories at individual level and 90% of the organisations in charge of reporting VMPR data are also responsible for reporting other data to EFSA (mainly pesticides and chemical contaminants). One third of the respondents do not have any experience of EFSA's SSD (Standard Sample Description) while approximately one third of respondents report that not all organisations/laboratories involved in the VMPR data collection are aware of the existence of the new sample-based VMPR data model and its related guidance published on the EFSA website. Based on the responses from the questionnaires 40% of the MSs are interested in a customised Excel table which transforms the data into the required SSD format as described under point 5.5 above.

6. Date for next meeting

Based on feedback provided by the Network members after the meeting the preferred date for the next network meeting is scheduled to take place on 14-15 February 2017.

7. Conclusions

The Chair thanked all the participants and contributors to the meeting. All presentations will be available and be accessible via the EFSA document management system; minutes of the meeting would be drafted and circulated to the Network for their comments prior to publication on the EFSA website. The meeting were asked to consider their needs for training upon which EFSA will make some proposals.

8. Closure of the meeting

The meeting was closed at 13:00 as anticipated.