Network on Veterinary Medicinal Product Residues
Minutes of the 4th meeting

Held on 30-31 October 2018, Parma

(Agreed on 20 November 2018)

Participants

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

Country	Name
Austria	Marina Mikula
Austria	Verena Spiteller
Belgium	Chantal Rettigner
Bulgaria	Tatyana Tihova
Bulgaria	Marina Zagorova
Cyprus	Militsa Hadjigeorgiou
Cyprus	Agathi Anastasi (via teleconference)
Czech Republic	Petr Hedbavny
Czech Republic	Veronika Vlasakova
Denmark	Pernille Bjorn Petersen
Estonia	Merle Laurimaa
Finland	Pirkko Tavast
Finland	Keija Leena Saraste (via teleconference)
France	Jean-Cedric Reminder
Germany	Katrin Konig
Germany	Nils Kuehl
Greece	Maria Alexandraki
Hungary	Kristian Varga
Ireland	Martina Stack
Italy	Michele De Martino
Italy	Francesca Roberti
Latvia	Daina Pule
Lithuania	Rimvydas Falkauskas
Luxembourg	Jean Brasseur
Netherlands	Rob Theelen
Netherlands	Sanne Van Der Voorde
Poland	Kamila Mitrowska

Portugal	Joana Leal
Romania	Constantin Iordache
Slovakia	Martina Ihnatova
Spain	Jesus Luis Capon Garcia Caro
Spain	Maria Rosa Hernandez Neves
Sweden	David Foster
United Kingdom	Eric Crutcher
Iceland	Sif Sigurdardottir
Norway	Waleed Ahmed
Norway	Per Bratterud

- **Hearing Experts**

Eric Verdon (EURL), Joachim Polzer (EURL)

- **EFSA:**

DATA (Evidence Management) Unit: Jane Richardson (Chair), Doreen Dolores Russell (Scientific Secretary), Eileen O'Dea, Mary Gilsenan, Stefano Cappè, Davide Gibin, Valentina Bocca, Luca Pasinato

- **Others:**

Pre-accession countries: Enkela Zani (Albania), Vedrana Jelusic (Bosnia and Herzegovina), Martin Josheski (FYR of Macedonia), Festim Rexhepi (Kosovo), Vladimir Zivkovic (Montenegro), Danka Spiric (Serbia), Elif Oktay (Turkey)

1. Welcome and apologies for absence

The Chair welcomed the participants in the meeting room and those joining by web-conference. Apologies were received from Croatia, Malta, Slovenia, Elzbieta Bruliska-Ostrowska (European Commission), Laura Ciaralli (EURL), Leen van Ginkel (EURL), Veerle Vanheusden (European Commission).

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 3rd meeting of the Network on Veterinary Medicinal Products Residues held on 10-11 October 2017, Parma

The minutes were agreed by written procedure on 10 November 2017 and published on the EFSA website 16 November 2017.

4. Topics for discussion

4.1. Joint Chemical Monitoring Network

Doreen Russell (DATA Unit) presented the background to the creation of a new network on chemical monitoring. In particular, the outcome of the consultation with the 3 existing networks - pesticide residues, chemical contaminants and VMPR (Veterinary Medicinal Product Residues) – the merger of which will form the new network was highlighted. She summarised the main points raised during

the consultation and how they would be addressed by EFSA. The next steps to finalising the creation of the new network were also shared with the meeting. Network Members were asked to contemplate new ways of working for the new network.

The network provided further feedback on the consultation. Some members commented on the timing of the merger, the necessity of the merger, the scheduling of the anticipated Network meeting in late March 2019 and the appropriate attendees. The final step to creation of the new network is approval by the EFSA Advisory Forum.

4.2. Update from the EURL meeting.

Joachim Polzer from the EURL (EU Reference Laboratory) provided feedback to the network from the last EURL meeting. He emphasised the importance of keeping ccA (cc Alpha) and ccB (cc Beta) as a modern statistical approach for decision making relating to both compliance and consumer protection.

The revision of CD 2002/657/ EC is on-going. The ccA and ccB concept will be maintained with some simplifications to facilitate reporting for example ccA for the main component in case of a summed marker definition. Further discussions are needed on the level of precision required for reporting sub-MRL (maximum residue level) results and the impact on the validation procedures required to support this. This is also being discussed at the EU Commission WG (working group) meetings.

Belgium asked about the relevance of requesting validation of methods at 10% of the MRL for exposure assessments. The MRLs were set by EMA (European Medicines Agency) at a level safe for the consumer and most of the methods are currently validated at 50% of the MRL. The data should be first assessed before asking MSs to invest time and money: if EFSA identifies a real need for more accurate data regarding some substances, methods could then be validated at a lower level. The EURL answered that laboratories already have accredited methods in place thus only minor work would be required for the extension of the methods to a lower concentration level. In EFSA's view, there is a need for greater transparency on results that are below the MRL and the Commission also supports this. The possibility to include some presentations from the EFSA CONTAM team to support the reporting of results below the MRL was welcomed by the network.

4.3. Issues from the first official reporting season

A number of Member States (France, Germany, Italy and the Netherlands) provided an overview of the main issues encountered during the first official reporting of VMPR data to EFSA (2017 data).

France – There were many challenges in implementing SSD2 for this new domain. Timelines from receiving data in April to transmission were tight but manageable and 91% of 800k data records were transmitted. The availability of risk managers during the summer holiday period was a particular challenge.

About 9% of the required data was missing including some mandatory fields e.g. ccA and ccB. Other elements such as country of origin and action taken were not in the database and their addition to the data was time consuming. MRLs and Result Units were also added manually by ANSES which was a resource intensive activity. Other issues raised were:

- Feedback on data transmission
- DCF error messages are not always clear
- SSD2 format and different documents were difficult to find
- National report – there were communication issues regarding responsibilities within France and there is a need for a word version rather than pdf.

JIVE is considered a good collaboration tool and convenient to find all the meeting documents in one place. It has some drawbacks: classification of posts in a relevant folder; the need for a login; the interface is not user-friendly making it difficult to find things and further it is difficult to customise communication classifications in the platform.

Germany: Data preparation and transmission was time consuming, especially the transformation from national to EFSA coding with additional information having to be generated at the national authority (BVL) level. The timeliness of providing all the documents by EFSA could be improved as they are needed well in advance, ideally two years before the data submission.

The main issues were with Business Rules regarding:

- GBR22 (Fat Weight) because the laboratories do not record % fat weight if the food is fat
- GBR48 (Evaluation of result) there is a need for a code to report 'detected but compliant'; there are additional complications when, for one sample, one result is compliant and another is not
- GBR48 and VMPR17 (Sum Parameters)

JIVE collaboration was a very positive experience during the reporting period.

The Netherlands – Reported to the network that the data required a great deal of preparation over the past year and thanks were given to the EFSA team who provided support through this process.

Foodex2 classification was difficult due to missing information and this required considerable work.

The reporting of natural occurrence and natural contamination needs further clarification. There were some difficulties in determining how to report the results, and the presenter gave some examples of this.

Italy – There was substantial work required to bring together all the sources of data from the Italian organisations involved in VMPR activities. Special thanks were given to Jane Richardson for her work in supporting the Italian team.

There were some issues in finding documents thus a single repository is recommended. Revisions to documents should be avoided until the following reporting period. The availability of IT support during the summer was an internal issue for Italy. In respect of Dioxins and PCBs - catalogues were missing some codes and there were some difficulties related to MRLs including congeners.

4.4. Proposed changes and enhancements –

Catalogues and business rules

EFSA introduced the proposed enhancements and changes to the catalogues and BRs (Business Rules) for the next reporting period and for the move towards harmonisation in reporting. Davide Gibin (DATA Unit) presented an analysis hierarchy for VMPR Matrix. Further detail on explicit/implicit facets and how to report wild game/feed was described to the network.

Austria asked for an improvement to the link between the animal sample and the substance: EFSA replied that it is working on developing this link as well as the MRLs. Denmark suggested that the group of 'others' could be flagged by a BR to capture and address this issue before it goes to the national report. EFSA requested that new term requests and changes are provided to EFSA before the end of the 2018 for inclusion in the major release of the catalogues.

Business Rules

Jane Richardson (DATA Unit) presented the harmonised BRs which is work in progress. Some proposals were made but feedback is needed from the network on this topic. The next steps are to create a harmonised set of business rules and make these available for testing. Feedback on business rules can be shared on JIVE

France thanked EFSA for opening a test data collection and asked for further clarity on the 'resUnit' issues. EFSA replied that reporting should be in accordance with the legislation but the creation of a limits file would assist with reporting the correct unit. Austria asked if a style sheet can be provided for the xml which EFSA confirmed would be posted on JIVE.

Validation reports

Luca Pasinato (DATA Unit) sought feedback from the network on the validation reports. Portugal commented that it would be useful to have the table in excel in a dynamic format. EFSA advised and demonstrated that it's possible to download in excel. Norway asked about the acceptance procedure – can data be changed once accepted in the DWH. EFSA replied that changing the data at this point can be very problematic and that it's better to accept only when have fully checked the data. Denmark advised that they like the VMPR validation report and would like to send it to a third party thus a reproducible and printable format is requested while Greece asked that the report should allow the export of not only the sub-groups for non-compliant results but all sub-groups of substances. Austria would like a time stamp on the reports to see which datasets are included in the table and EFSA suggested to include also the original file names of the listed datasets.

VMPR National reports

EFSA advised that the national reports are only available as a pdf. file and asked the network if this format meets their needs. France asked if the EC (European Commission) accept the format and EFSA advised the EC were consulted during its development. France also made the point that it is difficult to modify the pdf, consequently a Word file would be preferable. It was agreed to run a trial using the Word plugin for Microstrategy. EFSA agreed to the suggestion from Denmark to improve the format on the national report. EFSA will explore the suggestion from Austria to produce species level reports for sharing with third countries.

Annual report

EFSA advised that the 2017 annual report would not deviate from previous formats due to timelines. Issues raised concerned publishing sensitive information such as indicating the detection capacity of the laboratories. The EURL advised that they share the concerns expressed but are obliged to publish methods on the EURL website.

EFSA will identify what the best approach is. There is a need to consider public access to document requests and the move towards greater transparency.

The network discussed the substances quantified but below the MRL and how this information can be presented. EFSA advised that in the future there could be different levels of showing information: not only compliant and non-compliant results but also quantifiable results. Norway highlighted that it would be costly to report the amount of substance detected while the Netherlands report only according to the legislation, although the sub-MRL results could still be used in Risk Assessment. Further discussion is needed on the topic of reporting, analysing and publishing information of compliant but quantifiable results.

31 October 2018

5. Welcome and apologies for absence

The Chair welcomed the participants to the second day of the meeting.

6. Topics for discussion

6.1 Reporting system stability and ServiceNow

Stefano Cappè (DATA Unit) described how data issues are addressed through assistance requests and incident reporting. In the former instance, this can be a standardised service while in the latter it would often require an IT system fix. Evolving from relationship between the users of the systems – essentially data providers and EFSA was the absence of a system to quantify service management matrices – leading to the introduction of ServiceNow, an automated system that generates tickets in response to emails sent to the EFSA functional mailboxes. EFSA also informed the network that in the future will be moving to cloud based systems.

Norway asked about the overlap between JIVE and France asked if in ServiceNow the history of an email discussion can be captured. Last minute unavailability of the DCF due to maintenance was a concern for Austria. EFSA agreed to improve communication on systems affected by maintenance, the impact on other systems and to share predicted closure timeframes.

6.2 Harmonised chemical reporting – status update and next steps

Jane Richardson provided an update on the input received from the contaminants, VMPR and pesticides networks. She explained that all data will enter in one data collection (SSD2) emphasising that 'progLegalRef' reporting becomes important and consequently the need to link with a legal limits file. In relation to legal limits the Netherlands made the point that this is checked in monitoring programmes. EFSA agreed adding that it is important to have the EC involvement in maintenance of the limits file.

The Chair advised that the new data collection will open on 15 May 2019 for contaminants and VMPR only. Denmark remarked the data collection is opening late for VMPR and EFSA advised that for 2017 VMPR reporting very little VMPR data was sent before May 2018. Austria asked if 'progLegalRef' refers to the legislation for which the sample was taken or to the legislation according to which the result was evaluated. EFSA clarified within one sample different values for 'progLegalRef' can be reported as appropriate for a result's assessment. Austria expressed concerns that this proposal violates the general business rules that ensure constant values for the descriptors of a sample and could impact on the ability to provide this mandatory information in the next data collection. France asked about the deadline for the respective domains (end June 2019 for VMPR and 1 October 2019 for contaminants). The FYR Macedonia requested an earlier reporting period (April) and also an update of the mapping tool including the codes missing for feed. On the latter point EFSA agreed but also stressed that the tool for contaminants and VMPR should be recognised as an interim solution for reporting data.

Norway asked for better term definitions in the catalogue for types of sampling and sought clarity on the difference between legal level and legal limits. Greece asked if data providers and the validator from one domain will have access to data from the other domains EFSA clarified that each data provider and validator will have access only to their domain's data, France asked if SSD2 can be used in all EFSA reporting domains to which EFSA replied that is only appropriate for laboratory results. Bulgaria asked about pesticides reporting in VMPR – EFSA replied that they should continue to report pesticides in the VMPR as they did for 2017.

6.3 Open data activities

Jane Richardson provided the progress on access to data and current open data maturity. The EFSA working group looked at proactive open data publication process. The outcome is that there will be proactive open data –timely and comprehensive (as part of annual reports publication). The recommendations of the WG and next steps were outlined and will use the approach described in the technical report to publish the VMPR data with the annual report for 2017, subject to the approval of the Advisory Forum. The Netherlands asked what can be done about publishing old data. EFSA advised that it will address new data first and deal with the historical data on a case-by case basis as the data providers would need to be informed. The Netherlands also agreed to share with EFSA the approach they are using which EFSA welcomed adding that it will contribute to data interoperability.

Cyprus was concerned about metadata as the variables are coded. EFSA advised that descriptive metadata prepared on behalf of the countries would link to the terminology.

6.4 Collaboration and task forces

Eileen O'Dea (DATA Unit) presented an introduction to the collaboration task forces and invited interest from the network. In the scope of this objective she outlined the FPA (Framework Partnership Agreement) and its objective of improving quality via coordination and which has seen improvements primarily in systems and coordination. The lessons learned from the FPA were highlighted.

New ways of working such as JIVE, Skype, Knowledge Junction and the work in progress to create themed task forces were presented to the meeting.

France asked about the future of the FPA and that if the initiative is not continued it would affect continuous improvement. On this point EFSA advised the future of the FPA was under discussion.

During a tour de table meeting participants indicated their areas of interest in the themed task forces which was duly noted. Other Member States informed the meeting that they would need to consult internally before stating a preference.

7. Any Other Business

No further matters were raised.

8. Date for next meeting

The next meeting (merged network) will take place week commencing 25 March 2019. Some members expressed concern that the date coincides with the deadline of national plan submission. EFSA checked for available suitable rooms for the first weeks of April 2019 but there is no availability.

9. Closure of the meeting

The meeting ended at 13:00 as anticipated in the agenda.

Actions from meeting

Action owner	What needs to be done	Deadline	Meeting minutes reference
Network	Check list of substances in VMPR catalogue and inform EFSA before major release of catalogues	By end of 12/2018	4.4
Portugal	Send EFSA document containing Matrix issues encountered (e.g. Piglets)		4.4
EFSA	EFSA to ascertain if a BR can be implemented for the group 'other' before it enters the national report	End 12/2018	4.4
EFSA	XML style sheet to be put on JIVE.	Done	4.4
Romania	To send EFSA the scope of methods report they have in mind	End 12/2018	4.4

EFSA	Implement a time stamp on the validation reports	End 12/2018	4.4
France	To test the office plugin (for national report)	By end 1/2019	4.4
EFSA	EFSA to contact NL about 2 non-compliant results in one sample.	ASAP	4.4
EFSA	Discuss reporting sub-MRLs	Nest network meeting	4.4
EFSA	EFSA to see if the history of an email exchange can be captured in ServiceNow in different tickets can be captured	By end 12/2018	6.1
FYI Macedonia	Send suggestions to EFSA as to how to divide milk by species	By end 12/2018	6.2
Network	To check the analysis hierarchy and to see if anything missing by the end of 2018.	By end 12/2018	6.2
EFSA	Check the BR for 'progLegalRef'	By end 12/2018	6.2
EFSA	Collaborate with Network members regarding the priority Task Force themes and volunteers	As input to discussion at the 1st Network on chemical monitoring meeting	6.4