Network on Veterinary Medicinal Product Residues
Minutes of the 3rd meeting

Held on 10-11 October 2017, Parma

(Agreed on 10 November 2017)

Participants

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

Country	Name
Austria	Verena Spiteller
Belgium	Chantal Rettigner
Bulgaria	Lazura Simeonova Doncheva
Cyprus	Militsa Hadjigeorgiou
Croatia	Bruno Calopek
Czech Republic	Jiri Drapal
Czech Republic	Oldrich Valcl
Denmark	Pernille Bjorn Petersen
Estonia	Merle Suursarr
Finland	Pirkko Tavast
France	Stephanie Prevost
France	Jean-Cedric Rettigner
Germany	Katrin Konig
Germany	Ina More
Greece	Maria Alexandraki
Hungary	Attial Tiran
Ireland	Eileen O'Dea
Ireland	Janice Whelan
Italy	Silvia Ciardullo
Italy	Michele de Martino
Italy	Francesca Roberti
Latvia	Elina Ciekure
Lithuania	Snieguole Trumpickaite Dzekcioriene
Luxembourg	Jean Brasseru
Malta	Noel Demicoli
Netherlands	Henk van der Schee
Poland	Kamila Mitrowska

Portugal	Joana Leal
Romania	Cristina Teodora Ionescu
Romania	Constantin Iordache
Slovakia	Martina Ihnatova
Slovenia	Vida Znoj
Spain	Inmaculada Mendez Martinez
Sweden	Frida Broman
Sweden	David Foster
United Kingdom	Myles Munro
United Kingdom	Carol Siwicka
Iceland	Sif Sigurdardottir
Norway	Waleed Ahmed
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), Eric Verdon (Laboratoire de Fougères: French Agency for Food, Environmental and Occupational Health and Safety: ANSES France)

- **European Commission:**

Veerle Vanheusden (DG SANTE, Unit E2), Judith Manhardt-Welbers (DG SANTE – Directorate F)

- **EFSA:**

Evidence Management (DATA) Unit: Jane Richardson (Chair), Doreen Dolores Russell (Scientific Secretary), Mary Gilsenan, Stefano Cappe, Valentina Bocca (for agenda item 4.3), Davide Gibin (for agenda item 4.3), Valentino Avon (for agenda item 4.3) Luca Pasinato (for agenda item 5.1), Alessandro Carletti (for agenda item 5.2)

Biological Hazards and Contaminant Unit: Karen Mackay

Pesticides Unit: Daniela Brocca

- **Others:**

EU candidate countries: Elmira Mehmeti (Albania), Daniela Ristoska (FYR of Macedonia), Vladamir Zivkovic (Montenegro), Srdjan Stefanovic (Serbia), Ilknur Gonenc (Turkey), Dinaida Tahirovic (Bosnia and Herzegovina)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from the Netherlands (first day only).

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 2nd meeting of the Network on Veterinary Medicinal Products Residues held on 14-15 February 2017, Parma.

The minutes were agreed by written procedure on 21 March 2017 and published on the EFSA website 23 March 2017.

EFSA informed the network that it is endeavouring to have the minutes available as soon as possible after the meeting for the network to review prior to publication. After the meeting the presentations from the meeting will be provided and participants are also invited to complete a short online survey.

4. Topics for discussion

4.1 VMPR update including the timelines for the reporting VMPR results from 2017 to EFSA

Veerle Vanheusden (DG SANTE) provided an update from the EC (European Commission) concerning 2018 data submission for VMPR (Veterinary Medicinal Products Residues)-2017 data- in SSD2 (Standard Sample Description version 2) format. She emphasised that the level of detail provided using SSD2 (information on the substances analysed and in which food matrices, the percentage of non-compliances, the results for samples with residues below the MRL (maximum residue limit) and the follow up actions taken on non-compliances) supports risk management actions. EFSA agreed to develop harmonised and automated national reports based on data received for completion and finalisation by the MSs (member states) and EFSA will be the contact point for assistance.

In relation to timelines, the data collection will open in January 2018 and valid data should be in the EFSA data collection system by 1 June 2018. To meet this timeframe MSs are encouraged to start data submissions early. The meeting was informed that the Commission residues' application will not be available for VMPR data submissions next year – but will remain open only for reporting national plans. Some information on the new official control regulation (Regulation (EU) 2017/625), was shared with the meeting and that the replacement of Council Directive 96/23/EC will need to be considered both internally by the EC in conjunction with external consultations: for VMPR it will be important to consider which MRLs will apply and the reference points for action.

In the discussion that followed Belgium indicated that the proposed deadline for reporting is very challenging not only because the new reporting system will entail a large amount of work but also because their database is closed until March: a deadline at the end of August was suggested to align with pesticides. The EC replied that the EU requires the MSs to draft their own national monitoring report by the end of August. Given that EFSA will prepare the VMPR national reports, an earlier data submission is needed to give EFSA sufficient time to generate the reports. EFSA added that national reports produced from the data would include tables but that MSs would need further time to add their text to the tables produced from the data before sending the reports to the EC.

Norway asked if the DCF (data collection framework) could open from November 2017 to test data submissions. EFSA informed the meeting that the DCF is still open for additional testing and support is available: any support requests should

be sent to EFSA as soon as possible. However the DCF will need to be closed prior to the opening of the data collection for configuration changes. Italy advised that it cannot send the data owing to changes in their own data warehouse. EFSA advised that a partial submission is possible and if the other data is available in SSD1 format a data transformation is a feasible solution. Portugal explained that it will have problems reporting positive results within the proposed timeframe and France added that the analyses of their laboratory results would only be ready in March 2018 so the end of June 2018 would be a more realistic deadline. France asked about reporting maximum limits as it is difficult to have this information in the database and EFSA agreed that an electronic file with the MRLs related to food and residue would be a useful tool to support data providers.

Austria asked if the requirements for the national reports are the same as validation reports. EFSA's objective is to develop using the validation reports as a starting point with text boxes to allow MSs to provide conclusions resulting in a national report. EFSA suggested the creation of a small task force to review the national reports. Slovakia asked if all substance groups need to be reported and how to address double reporting. EFSA confirmed all groups would need to be reported and in relation to double reporting EFSA will look at how it can align the VMPR data collection with pesticides and contaminants. The ultimate objective for EFSA would be to integrate all data collections, while respecting legislative requirements.

In light of the discussion and the comments from participants the 2017 VMPR data collection will open as soon as possible and the deadline for submissions to the EFSA DCF is 30 June 2018.

4.2 Update from the EURL meeting: ccAlpha, ccBeta and summed residue definitions

Joahim Polzer (EURL) presented the requirements for methods validation. He explained that LOD (limit of detection) and LOQ (limit of quantification) do not consider measurement uncertainty. He explained how, when using screening methods, ccβ (ccbeta) indicates the method performance. He also explained how to calculate the decision limit based on the summing of MRLs.

Following the presentation Austria asked what to report when reporting parts of a sum. It was agreed to report the lowest ccβ when multiple methods have been used to test for a substance and ccα (ccAlpha) when the result is above the level of interest.

Eric Verdon (EURL) explained how to calculate ccα and ccβ when applied to quantitative methods for VMPRs using examples for residues with legal limits and for banned substances.

Romania indicated that if ccβ will not be required in the future for confirmatory tests but will only be required for screening if a screening test is negative, then it will be necessary to include this in the national control plan. The UK wishes to report ccα and ccβ independently of the test type, EFSA agreed to review the business rule which compares ccα and ccβ.

Serbia specified the differences between VMPR and Contaminants concerning uncertainty of measurement. EFSA clarified that if ccα and ccβ are reported there is no need to report the measurement uncertainty and that for the sum of

residues there will be a new business rule (ccα is not required for part of sum). Norway asked if the MRPL (minimum required performance limits) - analytical methods to detect substances without a maximum limit - will be taken out of the decision and the EURL confirmed that for non-food related matrices such as urine it will still be relevant as the RPA (reference point for action) is in place. The need for an electronic limits file pesticides (in the format used by pesticides) was raised by Austria. The EC agreed but commented that such a tool would be challenging to create and to maintain considering the ongoing work in cascade MRLs.

4.3 Reporting of 2016 VMPR data to EFSA (test phase): lessons learned and data collection configuration updates Part 1 (Residues within the scope of VMPR reporting, new and deprecated terms, FoodEx base terms vs. facets)

The Chair Jane Richardson (DATA Unit) recapped that the 'VMPR_SS2_WF2' test data collection has been open since 28/04/2017. To date, 24 countries have submitted data to the system with 19 countries achieving a valid submission. The data collection is still open and additional support can be provided, upon request, to those countries that have not achieved a valid submission. Based on the experience gained and feedback received from data providers EFSA presented the following proposed configuration changes and advice to facilitate VMPR data reporting upon which the network's input was sought.

- Amended and deleted BR (Business Rules)
- Assessment of overlap of substances between VPMR, Pesticides and Contaminant Occurrence
- New codes added to the PARAM, ANYLMD and SAMPMD catalogues
- Guidance on the use of FOODEX2 codes
- FOODEX2 code mappings to the SANTE reporting categories
- A proposal to use EUROSTAT data for production volumes
- Harmonisation of reporting quantitative screening tests with other data collections

Valentina Bocca (DATA Unit) presented an analysis of common BR failures and outlined proposals for converting BR with warnings into errors. The BR assessment was augmented by an analysis performed by Denmark. The network discussed the proposal.

The UK asked if it necessary to report the sampling event ID – which EFSA confirmed it is not - while Portugal asked why some fields are not indicated as mandatory. On this latter point EFSA advised that some fields are dependant mandatory this is indicated in the documentation. Cyprus asked about the BR concerning accreditation procedures and the differences between validated but not accredited and EFSA said it would check this issue with pesticides.

The network discussed the BR addressing the evaluation and assessment of the result and whether both are considered important to retain or if the evaluation code should be kept but not the assessment.

Comments on the different proposals were raised. Italy agreed with the first option proposed by EFSA as it is line with pesticides while Ireland said reporting

the assessment is difficult. Denmark suggested restricting the evaluation to either complaint or non-compliant. In Austria's opinion only the assessment should be retained while Romania asked whether a non-compliant result would render the whole sample non-compliant. The EC agreed with this latter point as it is possible to have a result above the MRL but the sample is compliant due to measurement uncertainty. EFSA agreed to investigate an option where the assessment would only be required in cases where the competent authority wishes to indicate and assessment which differs from the evaluation. The network also considered if reporting the action taken whether this would affect the whole sample not just the result.

Sweden suggested keeping the total number of BRs as low as possible to enable management at MS level. Specifically on the evaluation assessment as this is required for the national reports as well as the annual report a solution could be to implement a warning rather than an error. Austria requested clarity on the reportable terms 'above level of interest' and 'below level of interest'. In the feedback provided by Denmark there was also a comment concerning the long data string for reporting the action taken assessment.

Denmark raised a point in relation to sample survey design to identify all samples taken under the specific activity. On this point, EFSA asked the network whether samples are grouped according to a specific survey/study design can be identified by the 'progId' (programme ID). Ireland said that they issue a code for samplers depending on the sampling process but it is necessary to do this at an early stage while Hungary informed the network that they use a sampling programme. Sweden advised that it strives to group the sampling but is quite challenging while Norway advised that it could be possible to do it. Concluding this part of the discussion EFSA said that it can see the benefit of Denmark's point but it may be difficult so EFSA would need to examine the relevant business rule accordingly.

David Gibin and Valentino Avon (DATA Unit) presented the new terms that have been added to the catalogues on request from data providers. The new catalogue browser developed by EFSA to assist in navigating the EFSA catalogues was demonstrated to the meeting.

Regarding catalogues, Austria noted that feed is included in an animal category. EFSA will correct this. Hungary made the point that as data providers are required to report for the previous year, changes to catalogues will have an impact on the data providers. EFSA agreed but the catalogue browser can help with this aspect.

The Chair presented some common substances used in pesticides, VMPR and contaminant occurrence data collections and the possibilities for alignment in the reporting of this data. The issue of dual use substances was discussed and EFSA was asked to see if the param catalogue could be used to support reporting in these cases, ideally linked to an electronic file of legal limits. Latvia indicated that reporting substances in the B3 group (Other substances and environmental contaminants) was problematic. However in the current national plans B3 substances are included and would therefore need to be reported. The EC advised that for third countries this data on B3 substances is requested so they would need to consider any possible impact.

Prior to the meeting, population data from EUROSTAT was sent to the network to see if this information could be used for reporting production volumes in the report. The consensus of the network was not to use this data as the figures are compiled by a different body in each MSs and at different times thus potentially leading to inconsistencies.

EFSA also made a note of the countries that have used/will use the EFSA Excel mapping tool to report VMPR data. The intention is to arrange a teleconference with the countries to obtain feedback to improve the tool with the tool's developer.

Second Day

5. Topics for discussion

5.1 Hands-on demonstration of VMPR Microstrategy Reports – validation reports derived from the 2016 VMPR data collection

Luca Pasinato (DATA Unit) gave a hands-on demonstration of how to view the data validation reports for VMPR data in Microstrategy. He also presented dashboards examples annual report charts and tables. The national report will to be developed will need to include follow-up actions and conclusions.

The network commented positively particularly on the design and layout of the proposed annual and validation reports. Five MSs indicated that they would be willing to be part of a task force to look at the structure of the national reports.

5.2 Data Quality key performance indicators

Alessandro Carletti (DATA Unit) informed the network meeting of the ongoing pilot Framework Partnership Agreement on data quality with five Member States. He advised the meeting that the data quality assessment is a measure of the fitness of data for a specific purpose. Establishing a data quality framework requires the definition of domain stakeholders for the use of data together with their requirements for the data, and is underpinned by a data statistical analysis. In the context of the pilot framework partnership agreement EFSA described a data quality virtuous cycle based on four main steps: define, measure, analyse and improve. The aim is to create a system to ensure a continuous improvement in the quality of collected data for use in scientific outputs. The process of data quality improvement has an impact in terms of effort and resources required both at EFSA level and at data provider level. The scope and further steps of this project was presented in relation to the VMPR data domain.

The network will be sent an invitation to join the next scheduled teleconference in November 2017.

6. Conclusions

The Chair summarised the main points from the meeting; the follow up actions will be communicated by email to the network along with all the presentations from the meeting.

7. Closure of the meeting

This part of the meeting ended at 13:00 as anticipated. The network reconvened in the afternoon with representatives from the pesticides residues network – see separate minutes.