Scientific Panel on Plant Protection Products and their Residues

Minutes of the 6th meeting of the PPR Working Group on pesticides in foods for infants and young children

Held on 20-21 March 2018, Parma
(Agreed on 26 April 2018)

Participants

- **Working Group Members:**
  Colin Ockleford, Gerrit Wolterink (chair), Ine Waalkens-Berendsen, Mathilde Kersting, Susanne Hougaard, Thomas Kuhl (vice-chair), Ursula Gundert-Remy

- **Hearing Experts[1]:**

  Not applicable

- **European Commission and/or Member States representatives:**
  Not applicable

- **EFSA:**

  Pesticides Unit:

  Alexandre Nougadère, Arianna Chiusolo, Daniele Court Marques, Hermine Reich

  DATA Unit:

  Bruno Dujardin

- **Observers:**

  Not applicable

[1] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received by Mathilde Kersting and Ursula Gundert-Remy (21 March).

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the Working Group (WG) members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

Commission request for a scientific opinion on pesticides in foods for infants and young children (EFSA-Q-2016-00702)

4.1 Reporting from discussion group of the 92th PPR Panel Plenary meeting. Experts and staff involved in the discussion group informed the WG on the revised sections of the scientific opinion under development and all changes were agreed.

4.2 The WG was informed about the latest draft of the RPC model and updated exposure calculations for the selected active substances (case studies) were presented.

4.2 The scientific opinion was revised by the WG in order to prepare the draft document that will be presented to the PPR Plenary in May for possible adoption. Meanwhile a member of the PPR Panel will be asked to peer review the draft document. Moreover, the Scientific Committee will be consulted for commenting to the draft opinion.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

5. Any other business

Not applicable.

6. Next Meeting

Not applicable.

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 5th meeting of the PPR Working Group on pesticides in foods for infants and young children

Held on 6 - 7 February 2018, Parma
(Agreed on 20 March 2018)

Participants

- **Working Group Members:**
  Colin Ockleford, Gerrit Wolterink (chair), Ine Waalkens-Berendsen, Mathilde Kersting, Susanne Hougaard, Thomas Kuhl (vice-chair), Ursula Gundert-Remy

- **Hearing Experts[1]:**

  Not applicable

- **European Commission and/or Member States representatives:**
  Almut Bitterhof, Fruzsina Nyemecz, Volker Wachtler

- **EFSA:**

  Pesticides Unit:

  Alexandre Nougadère, Arianna Chiusolo, Daniele Court Marques

  DATA Unit:

  Bruno Dujardin

- **Observers:**

  Not Applicable

[1] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the Working Group (WG) members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

Commission request for a scientific opinion on pesticides in foods for infants and young children (EFSA-Q-2016-00702)

4.1 Refinements for the Raw Primary Commodities (RPC) model were presented. The WG was updated on exposure calculations for the 5 active substances (case studies), based on RPC refinements.

4.2 The methodology to calculate dietary exposure in infants below 16 weeks of age, based on the application of the SC guidance, was presented and agreed by the WG. The contribution to pesticides residues exposure from drinking water (to reconstitute infant formula) was considered negligible, based on EU Water Directive. It was also agreed that metabolites in groundwater should not be considered because evaluated at active substance approval/authorisation and considered 'not relevant'.

4.3 The WG was informed on the outcomes from the assessment of the appropriateness of the toxicological reference values for the 5 active substances based on summary toxicity endpoints reported in the EFSA conclusions and EC Review Reports and applying the SC guidance for infants below 16 weeks of age.

4.4 A proposal for the evaluation of uncertainties affecting the different components of the assessment in the opinion was presented and agreed by the WG.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

4.5 The structure of the scientific opinion to be developed was defined by the WG.

5. Any other business

Not applicable.

7. Next Meeting

20 (full day) - 21 (morning) March 2018 in Parma.

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 4th meeting of the PPR Working Group on pesticides in foods for infants and young children

Held on 23 - 24 November 2017, Parma
(Agreed on 5 February 2018)

Participants

- **Working Group Members:**
  Gerrit Wolterink (chair), Thomas Kuhl (vice-chair) (day 1), Colin Ockleford, Ine Waalkens-Berendsen, Mathilde Kersting, Susanne Hougaard, Ursula Gundert-Remy.

- **Hearing Experts[1]:**

  Not applicable

- **European Commission and/or Member States representatives:**
  Not applicable

- **EFSA:**

  Pesticides Unit:

  Alexandre Nougadère, Arianna Chiusolo, Daniele Court Marques

  DATA Unit:

  Bruno Dujardin

- **Observers:**

  Not Applicable

[1] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Thomas Kuhl (day 2).

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the Working Group (WG) members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topic(s) for discussion

Commission request for a scientific opinion on pesticides in foods for infants and young children (EFSA-Q-2016-00702)

4.1 The strategy to address the request from the Commission regarding the appropriateness of residue definition (ToR4) was presented with the assessment and agreed by the WG.

4.2 The WG was updated on the progress regarding the RAC (individual-based) model, and data from the application of the RAC model to the consumption data of the Comprehensive Database were presented.

4.3 Preliminary results on individual-based exposure (RAC-converted) data as well as PRIMo exposure estimates were presented, including input data on occurrence of 5 active substances (case studies) used for exposure calculations.

4.4 Outcomes from the critical review of literature on developing nervous system were presented. The WG agreed the strategy to report in the opinion the available evidences.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

4.5 The structure of the scientific opinion to be developed was defined by the WG.

5. Next Meeting

6 (full day) - 7 (morning) February 2018 in Parma.

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 3rd meeting of the PPR Working Group on pesticides in foods for infants and young children

Held on 5 - 6 September 2017, Parma
(Agreed on 23 November 2017)

Participants

- **Working Group Members:**
  Gerrit Wolterink (chair), Ine Waalkens-Berendsen (day 1), Mathilde Kersting, Susanne Hougaard, Thomas Kuhl (vice-chair), Ursula Gundert-Remy.

- **Hearing Experts[1]:**

  Not applicable

- **European Commission and/or Member States representatives:**
  Not applicable

- **EFSA:**

  Pesticides Unit:

  Alexandre Nougadère, Arianna Chiusolo

  DATA Unit:

  Bruno Dujardin

- **Observers:**

  Not Applicable

[1] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Colin Ockleford and Ine Waalkens-Berendsen (day 2).

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the Working Group (WG) members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topic(s) for discussion

Commission request for a scientific opinion on pesticides in foods for infants and young children (EFSA-Q-2016-00702)

4.1 The WG was informed about the letter sent by the Specialised Nutrition Europe (SNE) to the PPR Panel. SNE asked to be invited for a technical hearing in order to provide further information/data to the WG on the mandate and on two specific substances (mercury and chlorate). Based on the clarifications[4] received from the Commission on the interpretation of ToR (environmental contaminants, persistent pesticides and substances added as mineral will not be addressed in the opinion) the request was considered out of the scope of the mandate.

4.2 The WG was updated on the progress regarding the verification of the RAC (individual-based) model to be applied together with the current method (summary statistics) for exposure calculations. The criteria for selection of active substances to be tested for exposure assessment (case studies) were agreed by the WG.

4.3 The methodology applied for the literature review on physiology of developing systems (nervous, immune, reproductive, endocrine, ADME)

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[4] Captured in the minutes of the 1st WG meeting

was presented with the outcomes. Preliminary information obtained from the relevant references for ADME/gut/microbiome was also presented.

4.5 The structure of the scientific opinion to be developed was defined by the WG.

5. Next Meeting

23 (afternoon) - 24 (morning) November in Parma.

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 2nd meeting of the PPR Working Group on pesticides in foods for infants and young children

Held on 14 - 15 June 2017, Parma
(Agreed on 5 September 2017)

Participants

- **Working Group Members:**
  Colin Ockleford , Gerrit Wolterink (chair), Ine Waalkens-Berendsen, Mathilde Kersting, Susanne Hougaard (day 2), Thomas Kuhl (vice-chair), Ursula Gundert-Remy (by TC on day 2).

- **Hearing Experts[1]:**
  Not applicable

- **European Commission and/or Member States representatives:**
  Not applicable

- **EFSA:**

  Pesticides Unit:

  Alexandre Nougadère, Arianna Chiusolo, Daniele Court Marques, Federica Crivellente (day 2), Hermine Reich (day 1), Luc Mohimont (day 1)

  DATA Unit:

  Bruno Dujardin (day 1)

- **Observers:**
  Not Applicable

[1] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Susanne Hougaard (day 1).

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the Working Group (WG) members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topic(s) for discussion

Commission request for a scientific opinion on pesticides in foods for infants and young children (EFSA-Q-2016-00702)

4.1 Food consumption data for baby food and conventional food available in the EFSA Comprehensive Database were presented and age classes were defined for exposure calculation. The selection of active substances and the methodology to be used for exposure calculations will be proposed and agreed during the next WG meeting.

4.2 The status of the on-going development for RAC model (tool to match occurrence and food consumption data) was also presented as well as the next steps (i.e. finalise the verification of conversion factors).

4.3 The WG was updated on the on-going EFSA work for the Cumulative Risk Assessment (CRA) of pesticides and in particular the methodology for cumulative assessment groups (CAGs) and establishment of CAGs for nervous system and thyroid was presented. The Scientific Reports on CAGs for effects on nervous system and thyroid will be finalised by the end of the year, after the public consultation.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

4.4 The methodology for the literature review on physiology of developing systems (nervous, immune, reproductive, endocrine, ADME) was presented and agreed by the WG. Moreover, preliminary information on the developing functions in brain and brain barriers were presented, including data gaps and future research needs.

4.5 The WG was informed about the outcome from public consultation of the draft Scientific Committee guidance on the 'risk assessment of substances present in food intended for infants below 16 weeks'.

5. Next Meeting

5 (afternoon) - 6 (morning) September in Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 1st meeting of the PPR Working Group on pesticides in foods for infants and young children

Held on 29 (afternoon) - 30 (morning) March 2017, Parma (Agreed on 26 June 2017)[1]

Participants

- **Working Group Members:**
  Gerrit Wolterink (chair), Mathilde Kersting, Susanne Hougaard (by TC), Thomas Kuhl (vice-chair) (by TC), Ursula Gundert-Remy

- **Hearing Experts**[2]**:**

  Not applicable

- **European Commission and/or Member States representatives:**

  DG SANCO: Almut Bitterhof, Francesco Carlucci, Marina Marini

- **EFSA:**

  Pesticides Unit: Alexandre Nougadere, Arianna Chiusolo, Daniele Court Marques, Hermine Reich (day 2), Luc Mohimont

  DATA Unit: Bruno Dujardin, Davide Arcella

- **Observers:**
  Not Applicable

[1] The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

[2] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Colin Ockleford and Ine Waalkens-Berendsen.

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director on Declarations of Interest[4], EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the Working Group (WG) members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topic(s) for discussion

Commission request for a scientific opinion on pesticides in foods for infants and young children (EFSA-Q-2016-00702)

4.1 The WG was informed on the EFSA Pesticide Unit roles and responsibilities, DOI's policy and use of Open Text.

4.2 The WG was informed on the term of reference (ToR) for the Commission (EC) mandate on the development of the scientific opinion on the pesticides in foods for infants and young children. The WG was also informed that a document with requests for clarifications on the ToR (and the specific tasks to be carried out) was submitted (after the discussion during the PPR Plenary in January). The WG agreed on submitted requests.

4.3 ToR and the specific tasks to be carried out by the WG in the development of the opinion were discussed with the EC (by TC) as follows:

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

General considerations:

- EC clarified that the opinion should address the appropriateness of the currently established health based guidance values (ARfD and ADI) for the age groups of infants and young children given that in 1997/1998 the Scientific Committee for Food (SCF) had raised doubts about their applicability for these age groups. It was also reminded that the specific tasks were proposed by EFSA in the reply letter to the first EC mandate received in October 2014[5].
- EC is aware that different terminologies are used in the legislation[6] and by EFSA[7] to define the 2 subgroups of the population under consideration. The WG will clearly define the ages of the subgroups of the population in the opinion.
- EC specified that all "exceptional cases" should not be considered under this request, such as substances intentionally added to dietetic food and f as mineral (e.g. copper compounds), substances already present in the environment or in the food chain (e.g. CS2, bromide ion, etc.), persistent pesticides such as persistent organic pollutants from Stockholm Convention, but also pesticides with DT90 (soil) >100 days (e.g. boscalide, penthiopyrad, etc.). EC mentioned that analysis of soil is recommended before producing crops intended to food for infant and young children.

MRLs based on ADI

In the first bullet point of the ToRs, EC requests to assess the appropriateness of the approach to base the MRLs for pesticides for food for infant and young children on the ADI (and ARfD) values. How should this be interpreted? While it is understood that these toxicological values are currently used to assess the safety of MRLs, they are not the actual basis for deriving the MRLs as such. Does the EC foresee the use of a different approach for MRLs for infant food? Or did the EC refer to the appropriateness of the ADI (and ARfD) for assessing the safety of the MRLs? Does the EC envisage the setting of MRLs in such a way that the exposure at the MRL level would correspond to 100% of the ADI (or ARfD), considering that this would lead to MRLs lower or higher than 0.01 mg/kg (see also next paragraph)?

- EC wants EFSA to state on the appropriateness for infants and young children of the existing health-based guidance values

[5] http://raw-app.efsa.eu.int:8080/raw-war/wicket/page?2
[6] Directive 2006/141/EC.
[7] In the EFSA Comprehensive Food Consumption database: "infants" are also children up to 1 years old, "toddlers" are children from 1 to 3 years old ("young children" in Directive 2006/141/EC). In the EFSA Scientific Committee guidance on 'substances present in food intended for infants below 16 weeks of age', infants are children between 0-16 weeks.

(HBGVs) set for the general population, and to assess if specific HBGVs and/or additional Uncertainty Factors (UF) should be necessary.

- The setting of MRL at the HBGV threshold is neither asked for nor recommended. This principle is not followed generally in pesticides legislation as MRLs are set on the basis of Good Agricultural Practices (GAP). For foods for infants and young children the EC is clearly in favour to use MRLs "as low as reasonably achievable" (ALARA principle) particularly for infants and young children (see next point).
- No risk management proposals are asked by EC to EFSA, but risk assessment considerations only.

MRL >0.01 mg/kg

Currently the default MRL for pesticides in food for infants and young children is 0.01 mg/kg, with lower MRLs or a ban for some specific pesticides (Directive 2006/125/EC and Directive 2006/141/EC). Regulation (EC) 609/2013 requires that the EC has to make provisions (in the future) on the use/banning of pesticides according to those of Directive 2006/125/EC and 2006/141/EC. According to recital 2 of Regulation (EU) 609/2013: "The maximum residue levels in infant food should be set at the lowest achievable level to protect vulnerable population groups, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination." This, and the request from the first bullet point of the ToRs (to address the approach to base the MRLs for pesticides in food for infants and young children on the ADI values) might open up the possibility for setting MRLs >0.01 mg/kg. The only difference with the MRL setting for pesticides in food for the general population would be that a specific risk assessment for infants and children would be required, possibly using an infant/child specific ADI/ARfD.

Is the EC considering the possibility of permitting increased levels of pesticides in food for infants and young children (MRLs>0.01 mg/kg), provided it is scientifically justified to conclude that this would not pose an unacceptable health risk to infants or young children?

- EC does not expect the possibility to set MRL at higher values than current default MRL value of 0.01 mg/kg defined for the majority of the pesticides according to Directives 2006/125 and 2006/141.
- EC confirms the need to set "MRL as low as reasonably achievable" (ALARA principle should not be reconsidered), i.e. if necessary and possible lower than 0.01 mg/kg.
- EC lets EFSA chose the methodology to check if:

- Current MRLs are safe (particularly default MRL on foods for infants and young children);
- New MRLs should be derived, and in which case(s);
- Real levels in food (from monitoring programmes) do not present a risk for the infants and young children.

Contribution of other foods

In the second bullet point of the ToRs, the EC requests to assess the contribution of other foods consumed by infants and young children that are not covered by Regulation (EU) No 609/2013.

Does this request refer to the contribution of other foods to the total dietary exposure or to the contribution to the total diet (consumption) of the infants and young children? If the question is about exposure, which substances should be evaluated/ screened? Has the EC already a priority list of substances to be evaluated? Or EFSA would define its own priority list of pesticides according to criteria to be defined? EFSA notes that no dietary risk characterisation is asked by the EC for the second and third bullet points of the ToRs.

- EC clarified that the request is about the contribution of each food category (food for infants and young children and other food, i.e. conventional food) to the total dietary exposure (chronic and acute), for infants and young children.
- EC specified that approaches/methodologies should be developed for both pre- and post- marketing assessments, i.e. both to check if MRLs are sufficiently protective for the consumers but also what is the real contribution to the exposure considering monitoring results.
- EFSA highlighted the fact that changing the exposure model for toddlers could also bring about different results than those currently obtained with PRIMo v2.
- EC confirmed that EFSA can decide which method(s) is (are) the best to address this task. The safety of current MRL of 0.01 mg/kg and specific MRLs from specific legislation on infants and young children should be checked by estimating total dietary exposure. Lowest MRL could be proposed by EFSA. Monitoring data should be also used to estimate actual exposure at post-marketing level.

Impact of cumulative exposure

In the third bullet point of the ToRs, the EC requests to address the impact of a cumulative exposure to pesticides which share a common toxicological effect. The acceptance letter of 7 November 2016 indicated that the PPR Panel would provide its views on whether the opinions and

methodologies it delivered from 2008 to 2013 to support the cumulative risk assessment of pesticides apply to the toxicological effects which may affect populations of infants and children. Is this approach agreeable for the EC?

- EC remarked that this task was proposed by EFSA (reply letter to the first EC mandate). EC wants to know the consequences of the application of cumulative exposure, such as the need for additional UF.
- EFSA asked if the Cumulative Assessment Groups (CAGs) under development/finalization should be used for this task. EC is aware that EFSA is still developing the methodology for cumulative risk assessment, thus it will not be completely addressed for the specific mandate, but indications for the future applicability of the methodology should be provided in the opinion.

Appropriateness of residue definitions (RD)

In the fourth bullet point of the ToRs, the EC requests EFSA to address the appropriateness of the residue definitions established under Regulation (EC) No 396/2005 for foods for infants and young children. As indicated in the acceptance letter of 7 November 2016, the exact scope of this question needs to be clarified. Factually, Regulation (EC) No 396/2005 establishes residue definition for monitoring and these definitions are appropriate for risk assessment only when they are identical to the respective residue definition for risk assessment. Does the EC want EFSA to review the appropriateness of using conversion factors from monitoring to risk assessment to perform assessments on the safety of MRLs? The EC is invited to clarify if and what type of additional input in this matter is needed.

- EC clarified that currently diverging residue definitions have been established for MRLs under Regulation No (EC) 396/2005 and for MRLs in food for infants and young children due to the fact that the legislation for infants and young children was not updated in parallel to Regulation (EC) No 396/2005. EC agreed that considering the limited timeline and the complexity of the subject, it would not be possible to address those residue definitions one by one. Hence EC expects EFSA to describe whether and in which cases a difference in residue definitions between both legislations would be justified. These approaches and general considerations could then be applied for substance-specific assessment in the future, but specific examples such as PTU (propylene thiourea) may be incorporated in this opinion for illustration. EC also explained that a Refit exercise of pesticides legislation is currently ongoing which will result in a report to Council and Parliament in 2018. Once this review is finalised steps are foreseen to align the legislation on infants and young children to

Regulation (EC) No 396/2005, in particular to address the issue of diverging residue definitions.

- EC highlighted the fact that the need for addressing the appropriateness of the residue definitions established under Regulation (EC) No 396/2005 for foods for infants and young children was evidenced by EFSA (reply letter to the first EC mandate). However, the EC remarked that the issue is not limited to foods for infants and young children, since the Regulation (EC) No. 396/2005 also does not foresee specific residue definitions for processed food in general.
- EC specified that if relevant metabolites are evidenced for processed food for infants and young children, the complete assessment is not necessary but EFSA should present in the opinion the potential issue and recommendations should be provided (e.g. for a next mandate).
- EFSA already indicated that substances being hydrolysed during processing would be likely to result in diverging residue definitions between both legislations because MRLs under Regulation 396/2005 are mainly established for raw agricultural commodities (RAC) while MRLs in food for infants and young children actually refer to processed commodities**.**

Experience gained under Regulation (EU) No 1107/2009

With respect to the request of the EC that EFSA should take into consideration the experience gained in the assessment of toxicological studies in the framework of the peer review under Regulation (EU) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (including specific guidelines developed in that context), EFSA has no specific experience with respect to the adequacy for infants and children of the hazard identification and characterisation process for pesticides active substances, but will invite Member States to share their experience at national level through the Pesticides Steering Network.

- EFSA informed EC on the outcome from the PSN consultation (Feb 2017) and the fact that no data are available.
- EC proposed to consult also the PAFF Committee, however EFSA remarked that both PAFF Committee and PSN have representatives from the same Organisations, thus it was agreed that this consultation is not needed. EFSA will consider PAFF Committee consultation in case of further needs.

4.4 Dietary risk assessment of pesticide residues in EU was presented to cover: EFSA role for pre- and post-marketing assessments; the MRL setting and dietary risk assessment process; the monitoring programs (including food for infant and young children in EU 2015 monitoring); EU report on pesticide residues; and ANSES study on infants and young

children chronic dietary exposure/risk ('The infant Total Diet Study' (TDS), 2016).

4.5 An overview on food consumption data in infants and young children (toddlers) available in the EFSA Comprehensive database on European food consumption was presented. In addition, the status of development for the RAC model (tool to match occurrence and food consumption data) was provided.

It was agreed to complement consumption data for infants available in the EFSA comprehensive database with the data available in the Scientific Committee guidance on 'substances present in food intended for infants below 16 weeks of age' (draft guidance currently under public consultation). The WG also agreed on the need to include in the opinion a developed methodology for exposure assessment.

4.6 The WG was informed on the ongoing EFSA initiatives on cumulative risk assessment to pesticides, including developing methodology for hazard assessment (Cumulative Assessment Groups (CAGs) of pesticides), exposure assessment (probabilistic modelling of the dietary exposure to pesticide residues) and risk assessment (tiered methodology for cumulative risk assessment).

4.7 A summary of the opinions of the Scientific Committee for Food (SCF) issued in 1997 and 1998 was presented.

The WG agreed that almost all identified issues by the SCF for health implications to infants and young children (susceptibility, adequacy of toxicological testing protocols, data availability) have been already addressed in the draft SC guidance on infants up to 16 weeks of age, taking into consideration latest scientific developments.

4.8 The content of the draft SC guidance on 'substances present in food intended for infants below 16 weeks of age' (currently under public consultation) was presented to cover: consumption data for infants used to estimate exposure; the physiology of developing systems (nervous, immune, reproductive and endocrine systems); testing strategies considerations and a decision tree approach to support the risk assessment.

The WG agreed that the SC document provides a conservative guidance to protect the most sensitive sub-population (neonates) and it should be used as reference in the development of the scientific opinion, unless consumption pattern for the investigated sub-populations (infants and young children) would be different. It was also agreed that a literature search should be conducted for young children, to complete the physiology/biochemical evaluation of developing systems in this sub-population and highlight further susceptibility.

4.9 A proposal of the outline of the scientific opinion to be developed by the WG was presented and agreed by the WG.