

## Scientific Committee

### Draft minutes of the 27<sup>th</sup> meeting of the Working Group on Compendium

**Held from 17 to 19 January 2018, Parma (Italy)**

**(Agreed by written procedure on 8 June 2018)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Carlo Bicchi, Qasim Chaudhry and Eirini Kouloura

- **EFSA:**

SCER Unit: Bernard Bottex

#### **1. Welcome and apologies for absence**

The Secretariat 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<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 26<sup>th</sup> Working Group meeting held from 6 to 8 September 2017 in Athens**

The participants reviewed the draft minutes of the 26<sup>th</sup> working group meeting. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

#### **5. Scientific topic(s) for discussion**

##### **5.1. Chemical groups and substances of concern**

The working group reviewed the substances of concern with a cx-code, linking them to their hierarchical chemical group of concern when applicable. This work will facilitate the future screening of articles, as substances will be highlighted as of concern or as not of concern, directly in the abstracts.

#### **6. Next steps**

The priority for the future is to screen the literature retrieved by the Contractor for around 1000 remaining plants. Batches of plants will be allocated to each working group member. Once the literature screening has been finalised, one-to-one meetings will be organised with the Secretariat to agree with / ensure the correct coding of the information to be transferred to the EFSA database.

## Scientific Committee

### Minutes of the 26<sup>th</sup> meeting of the Working Group on Compendium

**Held from 6 to 8 September 2017, Athens (Greece)**

**(Agreed by written procedure on 22 January 2018)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Carlo Bicchi, Qasim Chaudhry, Eirini Kouloura, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

- **EFSA:**

AMU Unit: Andrea Bau

SCER Unit: Bernard Bottex

- **Procurement Compendium:**

Pavla Bartkova, Krystof Dibusz

#### **1. Welcome and apologies for absence**

The Chair, Vittorio Silano, welcomed the participants. Apologies were received from Secundino Lopez.

#### **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<sup>1</sup> and the Decision of the Executive Director on

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 25<sup>th</sup> Working Group meeting held from 30 May to 1 June 2017 in Barcelona**

The participants reviewed the draft minutes of the 25<sup>th</sup> working group meeting. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

#### **5. Scientific topic(s) for discussion**

##### **5.1. Chemical groups and substances of concern**

The working group reviewed the substances of concern with an RF-code, linking them to their hierarchical chemical group of concern, when applicable. The substances with a cx-code will be distributed among the working group members with expertise in chemistry to continue this task.

##### **5.2. Compendium – Yellow list**

The working group clarified remaining issues related to the plant species of batches 1 to 4 and started reviewing the work already done on the 5<sup>th</sup> batch. The working group members not working on the substances of concern will continue working on their 5<sup>th</sup> batch of plants, i.e. review the information collected by the Contractor and decide on the relevant data to be transferred to the compendium.

#### **6. Next meeting(s)**

Because of a reduced budget for end of 2017 and 2018, the working group members were informed that the next meeting planned from 29 November 2017 (starting at 9.00) to 1 December 2017 (ending at 12.30) in Parma is cancelled.

The next meeting of the working group will take place from 17-19 January 2018 and will only involve the “Chemists” of the working group to finalise the chemical group allocation to substances of concern.

One-to-one meetings will be organised between the experts dealing with plant screening and the Secretariat to review the work done. Experts

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

were invited to provide the Secretariat with their availability to meet in January or early February 2018

## Scientific Committee

### Minutes of the 25<sup>th</sup> meeting of the Working Group on Compendium

**Held from 30 May to 1 June 2017, Barcelona (Spain)**

**(Agreed on 6 September 2017)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Carlo Bicchi, Qasim Chaudhry, Eirini Kouloura, Secundino Lopez<sup>1</sup>, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

- **EFSA:**

AMU Unit: Andrea Bau<sup>1</sup>

SCER Unit: Bernard Bottex

#### **1. Welcome and apologies for absence**

The Chair Vittorio Silano 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<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declaration of

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<sup>1</sup> Absent on last day

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 24<sup>th</sup> Working Group meeting held from 15 to 17 March 2017 in Parma**

The participants reviewed the draft minutes of the 24<sup>th</sup> working group meeting held from 15 to 17 March 2017 in Parma. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

#### **5. Scientific topic(s) for discussion**

##### **5.1. Chemical groups and substances of concern**

The working group started reviewing the substances of concern, linking them to their hierarchical chemical group of concern when applicable. The working group started first with the substances already present in the EFSA catalogue (RF-code). The remaining substances will be distributed among the working group members with expertise in chemistry to continue this task.

##### **5.2. Compendium – Yellow list**

The working group clarified remaining issues related to the plant species of batches 1 to 4. The first four batches will be finalised as soon as possible. The working group members not working on the substances of concern will be allocated a 5<sup>th</sup> batch of plants to prepare for the next meeting, i.e. review the information collected by the Contractor and decide on the relevant data to be transferred to the compendium.

#### **6. Next meeting(s)**

The Working Group confirmed the following dates for 2017.

- 6 September 2017 (starting at 9.00) to 8 September 2017 (ending at 12.30) in Athens
- 29 November 2017 (starting at 9.00) to 1 December 2017 (ending at 12.30) in Parma

## Scientific Committee

### Minutes of the 24<sup>th</sup> meeting of the Working Group on Compendium

**Held from 15 to 17 March 2017, Parma (Italy)**

**(Agreed on 30 May 2017)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Carlo Bicchi, Qasim Chaudhry, Eirini Kouloura, Secundino Lopez<sup>1</sup>, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

- **EFSA:**

AMU Unit: Andrea Bau

SCER Unit: Bernard Bottex

#### **1. Welcome and apologies for absence**

The Chair, Vittorio Silano, 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<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working

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<sup>1</sup> Via conference call

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 23<sup>rd</sup> Working Group meeting held from 10 to 12 January 2017 in Parma**

The participants reviewed the draft minutes of the 23<sup>rd</sup> working group meeting held from 10 to 12 January 2017 in Parma. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

#### **5. Scientific topic(s) for discussion**

##### **5.1. Chemical groups and substances of concern**

The working group clarified further the chemical groups considered as of concern by default by introducing some hierarchical considerations. For example, carboline alkaloids belong to the group indole alkaloids, which belong to the group alkaloids.

During the next meeting, the working group will consider the substances of concern encountered so far and whether they can be linked with one of the chemical groups / subgroups of concern. The linkage should be done with the most specific subgroup possible.

In case a substance was considered as of concern but does not belong to one of the groups/subgroups of concern by default, the toxicology/adverse effect will have to be characterised; This will be done:

- by linking this substance to a plant and article retrieved by the Contractor describing the toxicity/adverse effect of that substance
- by linking this substance to a reference from the scientific literature, when the substance is known to be of concern by the working group but there is no article retrieved by the Contractor characterising this toxicity or adverse effect.

In preparation of this exercise, the list of substances of concern will be circulated in advance to the working group so that experts get a chance to identify the substances they created, and retrieve the group of concern to which the substance belongs, or the reason why they considered the substance as of concern.

The Contractor will also be contacted and asked whether it is possible to modify, on the platform, the form “not in list, add a new substance” so that when creating a new substance, the link to the group / subgroup of concern, or to the plant/article number, or to the reference of the article

characterising the toxicity of the substance, can be done directly in that form.

## **5.2. Compendium – Yellow list**

The working group was reminded that to code information coming from the abstract, the working group should have been unsuccessful in retrieving the full text, or the full text is written in a language that cannot be read by the working group. When coding information from the abstract, the information “[abstract only]” should be added next to the title of the paper, in the “opinion” section of the platform / article considered

The working group reviewed the various batches and possible difficulties. The objective is to finalise all 4 batches by the end of April so that a transfer to the EFSA database can be done, and the platform is upgraded to version 2 before starting with the plants of Batch 5.

## **6. Next meeting(s)**

The Working Group confirmed the following dates for 2017.

- 30 May 2017 (starting at 9.00) to 1 June 2017 (ending at 12.30) in Barcelona
- 6 September 2017 (starting at 9.00) to 8 September 2017 (ending at 12.30) in Athens
- 29 November 2017 (starting at 9.00) to 1 December 2017 (ending at 12.30) in Parma

## Scientific Committee

### Minutes of the 23rd meeting of the Working Group on Compendium

**Held from 10 to 12 January 2017, Parma (Italy)**

**(Agreed on 15 March 2017)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Carlo Bicchi, Qasim Chaudhry, Eirini Kouloura, Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

- **EFSA:**

AMU Unit: Andrea Bau

SCER Unit: Bernard Bottex

- **Procurement Compendium:**

Krystof Dibusz<sup>1</sup>

#### **1. Welcome and apologies for absence**

The Chair, Vittorio Silano, welcomed the participants.

#### **2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> Via conference call

### **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

### **4. Agreement of the minutes of the 22<sup>nd</sup> Working Group meeting held from 23 to 25 November 2016 in Madrid**

The participants reviewed the draft minutes of the 22<sup>nd</sup> working group meeting held from 23 to 25 November 2016 in Madrid. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

### **5. Scientific topic(s) for discussion**

#### **5.1. Chemical groups and substances of concern**

The working group clarified the rationale for considering certain groups of chemicals as of possible concern for human health by default. The working group also reviewed the list of substances of concern, as some of the substances listed were not problematic. The working group was reminded that, to be considered as of concern, a substance should:

- Belong to one of the chemical groups considered as of concern by default, or
- Be associated with human-health relevant toxicity or adverse effects in one of the scientific papers retrieved for the plant species considered, or
- Be known to be of concern by some member(s) of the working group.

The lists of chemical groups of concern and substances of concern will be updated directly in the COMBO Platform.

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

## 5.2. Compendium – Yellow list

With a couple of exceptions, batches 1 to 3 have now been screened by all working group members. The following needs were identified by the working group:

- The contractor will create a new status “no info” next to “approved”, “assigned”, “EFSA” etc.
- The weight of keywords with negative weight is too high, resulting in articles reporting both relevant and irrelevant effects being out of the top 50 list. The negative weights will be reduced by half.
- In case of an article reporting phototoxicity, the coding should be as follows:
  - Type of toxic test: case report
  - Route of exposure: oral
  - Critical effect: other toxicities
  - Effect or parameter linked to the endpoint: phototoxicity (the code has been created)
- Tannins, when reported in an article without any quantitative information, should be flagged for the compendium. In case quantitative information is provided, tannins will be flagged only if in concentration greater than 10% in the plant part considered.
- Carcinogenic effects should be coded in the “Add endpoint study” table, and not in the table “Add genotoxicity”. The codes “carcinogenic” and “co-carcinogenic” have been created for this purpose under the “Effect or parameter linked to the endpoint” field. The code “tumour promoting activity” should not be used because too vague.

The working group will proceed further with the screening of batch 4 for the next meeting.

## 6. Next meeting(s)

The Working Group confirmed the following dates for 2017.

- 15 March 2017 (starting at 9.00) to 17 March 2017 (ending at 12.30) in Parma
- 30 May 2017 (starting at 9.00) to 1 June 2017 (ending at 12.30) – place to be determined
- 6 September 2017 (starting at 9.00) to 8 September 2017 (ending at 12.30) in Athens
- 29 November 2017 (starting at 9.00) to 1 December 2017 (ending at 12.30) in Parma

## Scientific Committee

### Draft minutes of the 22<sup>nd</sup> meeting of the Working Group on Compendium

**Held from 23 to 25 November 2016, Madrid (Spain)**

**(Agreed on 10 January 2017)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Carlo Bicchi, Qasim Chaudhry, Eirini Kouloura, Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

- **EFSA:**

AMU Unit: Andrea Bau

SCER Unit: Bernard Bottex, Stefania Infantone

- **Procurement Compendium:**

Krystof Dibusz, Tomas Novotny, Khush Sandhu

#### **1. Welcome and apologies for absence**

The Chair Vittorio Silano 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<sup>1</sup> and the Decision of the Executive Director on

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 21<sup>st</sup> Working Group meeting held from 31 August to 2 September 2016 in Parma**

The participants reviewed the draft minutes of the 21<sup>st</sup> working group meeting held from 31 August to 2 September 2016 in Parma. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

#### **5. Scientific topic(s) for discussion**

##### **5.1. Interim report of the procurement OC/EFSA/SCER/2014/05**

The working group discussed the interim report prepared by the Contractor. The report summarises everything that has been done up to now and lists what is still to be done. A total of 3350 plant names were initially submitted by EFSA to the Contractor. After removing the duplicates and taxonomy mistakes, this number has been reduced to 2645 plant species. 916 of them have been transferred as such to the EFSA data warehouse and are accessible on the EFSA website. 1729 have been inserted in the “yellow” list and are subject to the extensive literature review. 1.2 million articles have been loaded on the COMBO Platform as a result of this literature search.

The Working Group reviewed the interim report and provided some suggestions to the Contractor to improve the document. Recommendation was made to clarify in the report which databases from “Web of Science” were used to check the literature, and to delete steps 3 and 4 on page 18 referring to a search in general text books in case the search in the scientific literature is unsuccessful.

Concerning next steps, the participants were informed that EFSA has extended the duration of the contract by 18 months; the contractor will be asked, during this period, to check again the taxonomy of the 2645 plant species against the database that EFSA will choose as source for all its activities. The Contractor is also asked to perform the extensive literature search on the 916 plants that were directly transferred to the EFSA database. All the 2645 plant species will therefore have been subject to taxonomy check, update of information following extensive

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

literature search, validation by the working group and transfer to the EFSA database by mid-2018.

In view of the increased workload for the working group, caused by the validation of the information retrieved by the contractor, the Chair recommended EFSA considers increasing the composition of the Working Group.

The Contractor then presented the second version of the COMBO Platform to the participants. A couple of modifications have been made to make the platform more user-friendly. The participants agreed to switch to the new version of the platform after Batch 4 has been completed.

The participants discussed possible improvements to be considered by the Contractor, either on the COMBO platform or to facilitate the validation of the information retrieved by the working group:

- Information on the language of the full texts should be provided so that the working group or EFSA do not waste time trying to retrieve the full text if unable to read it in the end.
- The rating from the Contractor should be differentiated from the rating of the Working Group as, at the end of the day, the rating of the working group will prevail.
- The sorting by criterion A can be hidden as it is applied by default to all papers
- In the Tab "proposed compounds", the rule of "true/false" whether a newly created substance has been linked to a plant will be expanded to make sure that a substance created under "endpoint study" and not "composition" is marked as "true".
- True duplicates of articles should be automatically removed from the list of articles for a given plant species.
- Some working group members reported back that environment-articles reporting ecological studies get too high scores when applying the keywords criteria and therefore keep away what could be relevant papers from the Top50 articles. The working group recommended allocating negative weight to the following keywords: soil, ground, surface, sea, aquatic, lake, terrestrial, woodland, geo\*, eco\*, river, fate, sediment, persistence, stream, biota. The size of the weight is to be decided by the Contractor. A test should be done on *Berula erecta*.
- In order to avoid confusion with the old platform, when it comes to sorting articles, the display of the Top 50 by criterion A and year should be put as default. Then if someone needs to look at the next 50 articles (articles 51 to 100), he/she should get a button to click and get the top 100 articles sorted by criterion A but only articles N°51 to 100 should be displayed



- The Contractor was invited to pay attention to possible spelling mistakes of chemical names, as this complicates a lot the task of the working group when searching cid and CAS numbers.

The contractor invited the working group members to report back mistakes when they find any so that his team can improve.

## **5.2. Compendium – Yellow list**

### **5.2.1. Guidance on the methodology to be applied**

It was clarified to the participants that, for a given plant species, at least 7 papers providing information on composition should be considered. By composition, it is meant both relevant and irrelevant information for the compendium. In case it is not possible to retrieve the composition information from “relevant” papers, i.e. dealing with adverse effects that are human health-relevant, papers reporting irrelevant effects, e.g. insecticidal/pesticidal activity or therapeutic effect, will be considered. In case it is not possible to find the 7 papers in the first 50 articles, or if the expert in charge of the plant does not feel confident that relevant composition information has been captured with the first 50 articles, then the next 50 articles (i.e. articles N°51 to 100) will be considered.

In case of a paper reporting an adverse effect or some toxicity linked to a specific substance, but the paper does not provide any quantitative information on that substance, the information on the substance and the toxicity/adverse effect will be coded in “endpoint study” only. The substance will not be coded under “composition”.

Working Group members were reminded that to search a given substance or its synonym in “proposed compounds”, they need to press “Ctrl+F”

These considerations will be further clarified in the guidance document.

### **5.2.2. Screening of Batches 1-2-3**

The following issues were identified when reviewing the plants from the first three batches:

- Diuretic effect, when reported as a therapeutic effect, is irrelevant for the Compendium.
- Electrochemical extraction will not be coded;
- For botanicals where only the genus is reported (.spp), i.e. no specific species has been identified, the Contractor will do the literature search with the genus name. If some of the articles provide relevant information for the compendium, and this information is associated with an accepted species of the genus considered, then the .spp will be replaced by the species for which relevant information has been transferred to the EFSA database.

- A code for phototoxicity is needed. Colleagues from Data and AMU will be consulted regarding whether such a code already exists somewhere
- A code for co-carcinogenic effect is needed. It should be added to the genotoxic/mutagenic codes
- Endocrine active effects, even if demonstrated in vitro are relevant for the EFSA database and will be coded under “endpoint study” (the code “endocrine” already exists under “critical effect”)
- Effects such as “lowering of blood sugar, triglyceride, cholesterol” are only of concern for specific subgroups of the population and not the general population. They will be considered as irrelevant for the EFSA database (positive effect)

### **5.2.3. Transfer to the EFSA database**

For more than 100 plant species, it was not possible to retrieve any relevant information from the literature. These plants will still be loaded in the EFSA database, with some information on the number of articles retrieved, how many abstracts were considered as potentially interesting, and led to a further consideration of the full text. This information will be inserted in the Fact Table/Remark for the time being.

### **5.3. Follow-up activities – chemical characterisation**

The chemical groups considered as of concern by default will be split between the working group members so they can to provide, in a few words, the rationale why they were considered as of concern. A couple of examples of the toxic effects for these groups will be provided.

The working group underlined the need for chemical characterisation (chemical groups + toxicity) of the substances inserted in the database; it was explained that the EFSA Chemical Hazard Database should first be considered as the information for substances already assessed by EFSA can be retrieved from this database. Once it has been clarified how many substances need further chemical characterisation, a call for an outsourced activity will be prepared.

It will be further underlined in the preamble that hazard is not the same as risk; therefore the fact that a plant contains a substance from a group of concern does not imply that this plant is not suitable for food use.

## 6. Any Other Business

The Chair thanked Stefania Infantone for the support provided for one year to the working group as a trainee in the SCER Unit, and wished her good luck for the future.

## 7. Next meeting(s)

The following meeting dates were agreed:

- 10 January 2017 (starting at 9.00) to 12 January 2017 (ending at 12.30); Parma – New dates agreed during the working group
- 1 March 2017 (starting at 9.00) to 3 March 2017 (ending at 12.30)  
*[These dates will have to be modified]*
- 30 May 2017 (starting at 9.00) to 1 June 2017 (ending at 12.30)
- 6 September 2017 (starting at 9.00) to 8 September 2017 (ending at 12.30)
- 29 November 2017 (starting at 9.00) to 1 December 2017 (ending at 12.30)

## Scientific Committee

### Minutes of the 21<sup>st</sup> meeting of the Working Group on Compendium

**Held from 31 August to 2 September 2016, Parma (Italy)**

**(Agreed on 25 November 2016)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Carlo Bicchi, Qasim Chaudhry, Eirini Kouloura, Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

- **EFSA:**

AMU Unit: Andrea Bau

SCER Unit: Bernard Bottex, Stefania Infantone

- **Procurement Compendium:**

Krystof Dibusz (via conference call)

#### **1. Welcome and apologies for absence**

The Chair, Vittorio Silano, 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<sup>1</sup> and the Decision of the Executive Director on

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 20<sup>th</sup> Working Group meeting held on 29 June to 1 July 2016 in Parma**

The participants reviewed the draft minutes of the 20<sup>th</sup> working group meeting held from 29 June to 1 July 2016 in Parma. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

#### **5. Scientific topic(s) for discussion**

##### **5.1. Compendium – substances and chemical groups of concern**

The working group discussed a contribution explaining why the chemical group “sesquiterpene lactones” was considered as of concern by default. The working group agreed that such rationale should be provided for all chemical groups identified as of concern, but should be much shorter (1 or two paragraphs per chemical group).

The working group also clarified the status (of concern / of no concern) of a number of substances encountered in the articles retrieved by the contractor. The lists of substances/chemical groups of (no) concern on the platform were updated accordingly.

##### **5.2. Compendium – Yellow list**

The working group reviewed the work done for the first three batches of plants allocated to each Expert. It was clarified that for plants with more than 50 articles, the first 50 articles, scored according to their matching with pre-agreed keywords, should be considered in anti-chronological order, i.e. from the most recent to the oldest. A sorting function was created by the contractor on the platform to do so.

The working group and the contractor identified a number of plant species for which no (relevant) article is available. This is still useful information that should be reported in the database for these plant species. EFSA colleagues dealing with the Database will be contacted to discuss how to do this in practice.

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

As the work is progressing, new substances are identified as of concern. The preamble will be updated to explain that all substances of concern were not identified at the same moment, therefore the list of substances of concern reported for a given plant species may not be complete.

Members of the working group were confronted with articles providing essential oils composition, i.e. listing hundreds of substances. The working group decided that only substances with a concentration greater than 1% will be reported, unless they show non-thresholded toxicity, or they are highly toxic.

Following discussion during the last meeting, the platform has been modified to code enzyme inhibition activity as an effect. When it comes to digestive enzyme inhibition activity, the working group decided to code amylase inhibitors but to consider glycosidase inhibitors as not of concern.

### **5.3. Follow-up activities**

The Working Group members, with the help of the Secretariat, will finalise the three batches of plants they have been assigned by the end of September. Working Group members will then receive a new batch of plants to screen for the November meeting. The objective is to identify relevant articles and information to be transferred to the EFSA database. The coding of the information itself is not a priority for the next meeting, as it can be handled by the Secretariat at a later stage.

## **6. Any Other Business**

None.

## **7. Next meeting(s)**

The following meeting dates were agreed:

- **23 November** (starting at 9.00) - **25 November 2016** (ending at 12.30); **Madrid**

The Working Group identified the following dates for 2017, pending confirmation of the budget available. The meeting places will be identified at a later stage.

- 10 January 2017 (starting at 9.00) to 12 January 2017 (ending at 13.00)
- 1 March 2017 (starting at 9.00) to 3 March 2017 (ending at 12.30)

- 30 May 2017 (starting at 9.00) to 1 June 2017 (ending at 12.30)
- 6 September 2017 (starting at 9.00) to 8 September 2017 (ending at 12.30)

## Scientific Committee

### Minutes of the 20<sup>th</sup> meeting of the Working Group on Compendium

**Held from 29 June to 1 July 2016, Parma (Italy)**

**(Agreed on 31 August 2016)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Carlo Bicchi, Qasim Chaudhry, Eirini Kouloura, Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

Ulla Beckman-Sundh participated via teleconference

- **EFSA:**

SCER Unit: Bernard Bottex, Stefania Infantone

- **Procurement Compendium:**

Krystof Dibusz (via conference call)

#### **1. Welcome and apologies for absence**

The Chair, Vittorio Silano, 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<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### **4. Agreement of the minutes of the 19<sup>th</sup> Working Group meeting held on 27-29 April 2016, Prague**

The participants reviewed the draft minutes of the 19<sup>th</sup> working group meeting held from 27 to 29 April 2016 in Prague. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

#### **5. Scientific topic(s) for discussion**

##### **5.1. Compendium – White list**

The summary report of the Compendium, to be released on 5 July 2016, was presented to the participants. The report enables searching the Compendium by family names, species name and substances of concern. This report, which is still in progress, will be accessible to all via the EFSA website. The final version of the report will be released in early 2017, after the information on the yellow species has been added to the database; the final version will also allow for searching the Compendium by adverse effect / toxicity endpoint.

##### **5.2. Compendium – Yellow list**

The working group reviewed the plants species provided by the contractor and clarified pending issues. The working group discussed more specifically how to address plant species with a lot (more than 50) articles. In order to speed up the work, the first 50 articles, i.e. scoring the highest according to the keywords, will be considered. These articles will then be considered from the most recent to the oldest for relevant information. In case an article repeats the same information as a previously considered more recent paper, with no new information, that article will be considered as a duplicate.

In case a genus (instead of specific species) has been listed in the Compendium, the literature search will be done with the genus. In order to be considered as relevant, an article needs to be about an accepted species of the genus considered, and to contain relevant information on composition and/or adverse effect. In such a case, the species will be created in the database.

Enzyme inhibition activity will be considered as an effect. Specific codes will be created for transferring this information to the database.

The working group identified the need to characterise the toxicological properties behind the chemical groups considered as “of concern by default”. Experts who are unsure whether a substance is of possible concern or not can use Pubchem Search, ChemID plus or the CRC Natural Compound Database to try and determine whether the substance belongs to one of the chemical groups of concern or has reported oral toxicity.

### 5.3. Botanical Novel Foods

The contribution from the Working Group to the public consultation of the NDA guidance documents on novel foods was discussed on 25-27 May by the NDA WG on Novel Foods. The contribution was much appreciated and will be used to improve both guidance documents of the NDA Panel.

### 5.4. Follow-up activities

The working group discussed follow-up activities for the years 2017-2018. At the end of the current mandate (December 2016), around 600 “yellow” species will be pending extraction/validation of the data from the articles retrieved by the contractor. The 900 “white” species that were transferred directly to the EFSA database should also be the subject of an extensive literature review. Finally the characterisation of the toxicity for all the substances considered to be of possible concern for human health and transferred to the EFSA database should be done in a systematic way. The Working Group suggested outsourcing these activities in two separate calls: the first one will address the data extraction and validation for the 600+900 above-mentioned botanical species. The second call will concern the toxicity characterisation of the substances of possible concern.

## 6. Any Other Business

None.

## 7. Next meeting(s)

The following meeting dates were agreed:

- **31 August** (starting at 9.00) - **2 September 2016** (ending at 12.30); **Parma**
- **23 November** (starting at 9.00) - **25 November 2016** (ending at 12.30); **Madrid**

## Scientific Committee

### Minutes of the 19<sup>th</sup> meeting of the Working Group on Compendium

**Held on 27 to 29 April 2016, Prague (Czech Republic)**

**(Agreed on 29 June 2016)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Eirini Kouloura, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)

Secundino Lopez participated via teleconference

- **EFSA:**

SCER Unit: Bernard Bottex, Stefania Infantone

AMU Unit: Andrea Bau via teleconference

- **Procurement Compendium:**

Krystof Dibusz, Tomas Novotny.

#### **1. Welcome and apologies for absence**

The Chair Vittorio Silano welcomed the participants. Apologies were received from Carlo Bicchi and Qasim Chaudhry.

#### **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<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

### **4. Agreement of the minutes of the 18<sup>th</sup> Working Group meeting held on 24-26 February 2016, Parma**

The participants reviewed the draft minutes of the 18<sup>th</sup> working group meeting held from 24 to 26 February 2016 in Parma. The adopted minutes will be published on the EFSA website:

<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>

### **5. Scientific topic(s) for discussion**

#### **5.1. Compendium – White list**

The summary report of the Compendium that will be released later this month was presented to the participants. The report enables searching the Compendium by family names, species name and substances of concern. This report, which is still in progress, will be accessible to all via the EFSA website. The final version of the report will be released in early 2017, after the information on the yellow species has been added to the database; the final version will also enable searching the Compendium by adverse effect / toxicity endpoint.

#### **5.2. Compendium – Yellow list**

The working group reviewed the first plants' species provided by the contractor and clarified pending issues. Very few articles could be retrieved for these plants and for several species, all retrieved information was considered as irrelevant for the Compendium. The working group agreed that plant species for which no information could be identified

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

after the literature search will remain in the database and the absence of information will be flagged.

The working group discussed possible solutions to deal with plant species for which the literature search retrieved a high number of articles. A combination of solutions was identified and is further described in the guidance document circulated together with these Secretary notes. It was agreed that the contractor would screen plant species by increasing number of hits, i.e. will start with plant species with less articles and keep plants with the highest number of articles for the end.

As a general rule, the working group considered that 25 “accepted” papers”, i.e. from which relevant information was extracted to transfer to the Compendium, are needed to be confident that the relevant information for a given plant species has been captured. This number will be reconsidered based on the experience gained and the level of redundancy observed between the various papers. From these 25 papers, at least 7 papers should provide information on composition.

The keywords to score articles in terms of relevance were reviewed, in order to give more weight to papers dealing with adverse effect / toxicity information or composition and adverse effect / toxicity information, and less weight to papers dealing with composition information only. Keywords with negative weights have also been inserted to lower down the score of papers dealing with effects that are not relevant for the compendium (e.g. insecticide properties of a plant preparation).

The working group agreed that an article cannot be rejected on the basis of the analytical methodology applied, or because it reports traditional use information.

The working group agreed that substances cannot be excluded based on their level in a given plant preparation. When quantitative information is available, the range of concentration, rather than single average concentration, should be reported.

The contractor alerted the working group on the number of new substances resulting from the yellow species literature search and that do not exist yet in the EFSA catalogue. In order to speed-up the process for registering them, the working group will be given the possibility to add new substances (with information on the Pubchem cid and CAS numbers) on the platform, without the need to refer to the contractor. In case a working group member has a doubt about whether a new substance should be transferred to the EFSA database, he will consult the “Chemists” of the working group. A list of substances and chemical groups considered as of no concern will be created and uploaded on the platform. Each time a working group member decides that a substance or a chemical group is not of concern, he/she will add the name to the list.

Specific issues discussed during the meeting:

- In case an article is about a synonym of the plant of interest, and some information relevant for the compendium has been extracted from that article, and this synonym does not exist in the database, then the synonym will be added to the Compendium. The MTX code for the accepted name will then be used also for the synonym. There will not be any new search of the literature using the synonym.
- Plant properties to bioaccumulate contaminants from the soil or heavy metals are considered as irrelevant for the Compendium.
- Articles related to patent should be systematically rejected.
- Keywords in article titles will not have their weight multiplied by 2 anymore
- The list of substances and chemical groups of concern (combo\_substance\_18\_March) will be reviewed by Eirini and Robert. Proposals for changes will be implemented only early 2017, with the release of the final version of the database. The working group discussed in particular the issue of sesquiterpenes and decided that the alkaloids are of concern, the hydrocarbons are of no concern, and the alcohols and esters should be considered on a case by case basis.
- Data extracted from the full text of an article and data extracted from the abstract (when the full text cannot be retrieved) should be clearly differentiated in the database. One proposed solution is to indicate after the reference “[abstract only]”.

### **5.3. Botanical Novel Foods**

The contribution from the Working Group to the public consultation of the NDA guidance documents on novel foods will be discussed on 25-27 May by the NDA WG on Novel Foods. The Secretariat was invited to attend to clarify possible questions.

## **6. Any Other Business**

The Danish QSAR database (<http://qsar.food.dtu.dk>) was presented to the participants. The use of QSAR tools was suggested in the opinion on the QPS approach for the assessment of botanicals, to characterise substances whose structure is known but for which there is no information on safety. The working group took note of this database and recommended further exploring its usefulness for EFSA's needs.

## 7. Next meeting(s)

The following meeting dates were agreed:

- **29 June** (starting at 9.00) - **1 July 2016** (ending at 12.30h); **Parma**
- **31 August** (starting at 9.00) - **2 September 2016** (ending at 12.30h); **Parma**
- **23 November** (starting at 9.00) - **25 November 2016** (ending at 12.30h); **Madrid**

## Scientific Committee

### Minutes of the 18<sup>th</sup> meeting of the Working Group on Compendium

**Held on 24-26 February 2016, Parma (Italy)**

**(Agreed on 27 April 2016)**

#### **Participants**

- **Working Group Members:**

Robert Anton, Ulla Beckman-Sundh, Carlo Bicchi, Qasim Chaudhry (Chair 25/2/16 PM and 26/2/16), Eirini Kouloura, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair 24/2/16 and 25/2/16 AM)

Secundino Lopez participated via teleconference

- **EFSA:**

SCER Unit: Bernard Bottex, Stefania Infantone

- **Procurement Compendium:**

Krystof Dibusz participated via teleconference

#### **1. Welcome and apologies for absence**

The Chair Vittorio Silano welcomed the participants and invited the new experts, Carlo Bicchi and Eirini Kouloura, to introduce themselves to the Working Group.

#### **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<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

### **4. Agreement of the minutes of the 17<sup>th</sup> Working Group meeting held on 15-17 December 2015, Rome**

The minutes of the 17<sup>th</sup> Working Group meeting held on 15-17 December 2015 were agreed. The adopted minutes will be published on the EFSA website:

<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>.

### **5. Scientific topic(s) for discussion**

#### **5.1. Compendium – White list**

Since the last meeting, EFSA has been working with the Contractor and some experts of the working group at coding clarifications for the transfer of the white list plant species to the EFSA data warehouse. In order to ensure compatibility of the Compendium with the other EFSA databases, all substances and chemical groups in the compendium have to be allocated a single identifier code.

The Working Group spent the first part of the meeting in searching identifiers (Pubchem identifier and/or CAS Number) for the substances of concern still pending. The working group also reviewed all chemical groups mentioned in the compendium. Finally, references that were duplicated in the database were corrected.

The corrected data will be sent to the Contractor in order to finalise transfer of the Compendium and publish the database for external user access as soon as possible.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

## **5.2. Compendium – Yellow list**

The Contractor presented the platform that will be used for the validation of the data retrieved during the extensive literature review. Around 1500 plants will be subject to such literature review. Relevant papers are selected on the basis of their abstracts and a list of keywords agreed by the working group during previous meetings. If the abstract passes the inclusion/exclusion criteria, information deemed relevant by the contractor to be inserted in the compendium is extracted from the full scientific paper. The working group is then requested to review this information before it is transferred to the EFSA data warehouse.

A guidance describing step-by-step the use of the COMBO platform and how to validate the data is annexed to these Secretary notes.

From a rapid check on a limited number of plant species, the working group identified that the automatic engine developed by the Contractor to screen the scientific literature databases overlooked some relevant papers. The contractor was requested to solve this problem and re-screen the literature before the working group can start validating the information proposed for inclusion in the compendium. Once the automated search engine has been fixed, the working group will do again a new test on several plant species to ensure that the engine captures all relevant scientific articles.

## **5.3. Botanical Novel Foods**

The working group reviewed the “Note on the information to be requested for the assessment of Botanical Novel Foods” and further discussed how to scientifically use the “History of safe use” for the assessment of botanical traditional food from a third country. It is not possible to translate the concept of “History of safe use” in science-based requirements because of its limitation regarding the lack of information about potential long-term effects and chronic toxicity, as well as the absence of information of possible allergenicity of the traditional product for the European population. The working group also further discussed the concept of “appropriate” characterisation of the composition of a plant preparation: the working group concluded that it is not possible to set thresholds such as “80% of the composition to be characterised”, or “top 10 substances to be identified”. The working group recommended instead to report analytical data (including LOD and LOQ of the method) and to go for a search of the literature using a pre-determined list of keywords to maximise the chance of identifying substances of possible concern in the plant preparation.

The updated note on the information to be requested for the assessment of Botanical Novel Foods will be used as a contribution from the SC Working Group Compendium to the ongoing public consultation of the

NDA guidance document on traditional foods from third countries. Suggestions for improvements will be inserted in track changes mode in the guidance document by the Secretariat and then circulated to the working group for review. After approval from the working group, the contribution will be sent for consideration of the NDA Panel.

The Secretariat informed the working group about a stakeholder meeting that will be organised on 16 April 2016 in Brussels to discuss the draft guidance documents for novel foods and traditional foods from third countries. The deadline for registration is 14 March 2016.

## 6. Any Other Business

The working group was informed about a new database from Kew called "Medical Plant Name Services". The working group reviewed the possible added value of this new database compared to the databases "theplantlist.org" and "ars-grin" that are used to verify the taxonomy of the plant species in the Compendium. The working group noted that the new database does not solve the inconsistencies in taxonomy sometimes encountered for plant species and therefore recommended to stick to the sources of information used previously.

## 7. Next meeting(s)

The following meeting dates were agreed:

- **27 April** (starting at 9.00) - **29 April 2016** (ending at 12.30); **Prague**
- **29 June** (starting at 9.00) - **1 July 2016** (ending at 12.30); **Parma**
- **31 August** (starting at 9.00) - **2 September 2016** (ending at 12.30); **Parma**
- **23 November** (starting at 9.00) - **25 November 2016** (ending at 12.30); **Madrid**

Parma, 10 February 2016

EFSA/SC/2065

## SCIENTIFIC COMMITTEE

### Minutes of the 17<sup>th</sup> meeting of the Working Group on Compendium

Rome, 15 to 17 December 2015

(Agreed on 24 February 2016)

#### Participants

- **WG Experts:**  
Robert Anton, Ulla Beckman-Sundh, Qasim Chaudhry, Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)
- **EFSA:**  
AMU Unit: Andrea Baù<sup>1</sup> and Jane Richardson<sup>1</sup>  
SCER Unit: Bernard Bottex, Stefania Infantone

#### 1. Welcome and apologies

The Chair welcomed the participants and explained that the first day of the meeting would be dedicated to review the progress of the procurement for the preparation of version 3 of the compendium. The minutes of this first part of the meeting will be drafted by the Contractor and circulated together with these Secretary notes. The remaining 1.5 days would be used to address possible tasks identified during the first day and requiring the input of the working group, and to address EFSA related issues.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

#### 4. Adoption of the minutes of the 16<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 16<sup>th</sup> working group meeting held from 30 September to 2 October 2015 in Parma. The adopted minutes will be published on the EFSA website (<http://www.efsa.europa.eu/sites/default/files/assets/wgCompendium.pdf>).

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<sup>1</sup> Present on 15/12/2015 only

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## 5. Compendium – White list

916 plants have been uploaded in the EFSA data warehouse. EFSA and the contractor are still busy correcting coding inconsistencies (e.g. all farmed animals such as goats, chickens etc. should be coded as “target species”) and creating specific identification codes for the substances of concern identified so that the new version of the compendium can also retrieve the information from the EFSA Chemical Hazards Database. This on-going exercise has delayed the release of the Compendium for external user access, which is now foreseen for February 2016.

No particular action was required from the working group at this stage

## 6. Compendium – Yellow list

The botanical species highlighted in yellow in the Compendium version 10, as well as the botanicals in the “insufficient info” list, and the botanicals in the “no tox” list will be subject to extensive literature review.

### *a) Protocol for the extensive literature review.*

The working group reviewed the protocol for the extensive literature review that has been described in the interim report N°1. A number of issues were further clarified:

- If no relevant data can be extracted from the extensive literature review, the contractor should consult the books and monograph references previously sent.
- Only one set of keywords will be used for the search. Criteria A and B in the interim report N°1 will therefore be pooled. It is not a problem if some keywords like “gentox” and “tox” are counted twice as a result of this decision. Each keyword has been allocated a weight and relevant papers are organised according to the total weight resulting from the matching keywords found in the titles or the abstracts.
- Weighing factors should ensure that scientific papers providing relevant quantitative information get a higher weight than papers providing only qualitative information;
- For papers referencing another paper as the source of the (quantitative) information relevant for the compendium, the rule is to go back to the primary source of the information when possible.
- Biocidal data are out of the inclusion criteria
- An additional inclusion/exclusion criteria for the quality of the data to be coded needs to be created
- In terms of approach to be taken, the working group recommended the contractor to start with the plant species for which there is limited information, i.e. limited number of hits when doing the literature search.
- For plant species leading to over 50 articles after the inclusion/exclusion criteria have been applied, the participants agreed on the following approach: screen the top 50 articles. If no relevant information for the Compendium, look at the next 50 articles. If still no relevant information, look into the books and monograph references previously provided. If still nothing, then stop the search.
- In order to optimise the resources and ensure that the project is finalised by the end of 2016, only 10% of the abstracts will be double checked.

The working group spent most of the second day of the meeting on reviewing and finalising the allocation of the substances of concern from the white list to their chemical groups of concern. These substances and chemical groups of concern will be used as keywords for the extensive literature search.

The contractor noted that the list of substances (and therefore the list of keywords) will increase as the yellow list literature review is ongoing. The list of substances of concern, related chemical groups and Param-Code will therefore have to be updated regularly.

When discussing the review by the Working Group of the data extracted by the contractor, it was clarified that almost all the WG Members have access to bibliographic databases. The list of the scientific journals to which EFSA has access will be circulated to the working group.

**Actions:** - ***Secretariat to circulate the list of journal subscriptions to which EFSA has access.***

## **7. Botanical Novel Foods**

Members of the working group were informed that the EFSA NDA Panel has launched a consultation on its draft guidance on data requirements for novel food applications. A second specific guidance will be developed for foods that are novel for Europe but have a history of safe use in third (non-European) Countries.

It was noted that the circulated draft briefly addresses the data needed for botanical novel foods and documents history of safe use.

In view of the specificity and complexity (in terms of chemical composition variation) of botanical products, the working group agreed to prepare a note describing the data that would be needed to assess the safety of a botanical novel food. This note will be discussed with the Scientific Committee before it is submitted as a contribution for the NDA consultation

The working group identified that three main sections are needed for the note:

- Identification of the novel food (botanical identity, composition of the preparation, manufacturing, process, stability)
- Evidence on long term use (extent of use, number of persons exposed)
- Evidence for safety

The note will make the link with the tools that have been developed by EFSA for that purpose: the Compendium, the Chemical Hazard database, the list of substances and chemical groups of concern, strategy for literature review.

## **8. Next meeting dates**

The following meeting dates were agreed:

- **24 February** (starting at 9.00) - **26 February 2016** (ending at 12.30); **Parma**
- **27 April** (starting at 9.00) - **29 April 2016** (ending at 12.30); **Prague**
- **29 June** (starting at 9.00) - **1 July 2016** (ending at 12.30); **Copenhagen – to be confirmed**
- **31 August** (starting at 9.00) - **2 September 2016** (ending at 12.30); **Parma**
- **23 November** (starting at 9.00) - **25 November 2016** (ending at 12.30); **Madrid – to be confirmed**

Parma, 4 December 2015

EFSA/SC/2021

## SCIENTIFIC COMMITTEE

### Minutes of the 16<sup>th</sup> meeting of the Working Group on Compendium

Parma, 30 September to 2 October 2015

(Agreed on 16 December 2015)

#### Participants

- **WG Experts:**  
Robert Anton, Ulla Beckman-Sundh, Qasim Chaudhry, Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)
- **EFSA:**  
AMU Unit: Andrea Baù<sup>1</sup> and Jane Richardson<sup>1</sup>  
SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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.

Qasim Chaudhry informed the participants that he left FERA and is now employed by University of Chester. This professional change does not impact on the assessment of his annual DOI and his eligibility level.

#### 4. Adoption of the minutes of the 15<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 15<sup>th</sup> working group meeting held on 1&2 July 2015 in Brussels. The adopted minutes will be published on the EFSA website.

#### 5. Compendium – White list

The working group was informed about the end of the transfer of the botanical species from the white list to the EFSA DATA warehouse. 916 out of 921 botanical species have been

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<sup>1</sup> Present on 1/10/2015 AM only

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

migrated. The 5 last ones have been transferred to the yellow list because they lack the minimum amount of information required for the transfer.

#### *a) Preamble of the compendium*

The working group reviewed the content of the preamble to be read by the users of the Compendium before accessing the database. The working group decided to reduce the document to the disclaimer and the sections describing the purpose of the compendium and its structure. The section describing the history of the Compendium and the work done by the Scientific Committee on this activity since 2006 will be described in a separate document, accessible with a hyperlink if the reader wants further information on the development of the compendium.

#### *b) Access to the white list information*

EFSA provided the working group with examples of summary reports that can be built to retrieve the compendium information from the EFSA Data Warehouse. The database can be searched by species but also family, compound, target organ/adverse effect or a combination of these criteria. For substances that have already been assessed by EFSA, it will also be possible to retrieve the toxicity summary from the EFSA chemical hazard database.

EFSA is now working at finalising and testing the reports. A number of consistency corrections (e.g. use furanocoumarins instead of furocoumarins) are being done to the database. Both the EFSA Chemical Hazard Database and the Compendium should be released for external use early 2016.

### **6. Compendium – Yellow list**

The botanical species highlighted in yellow in the Compendium version 10, as well as the botanicals in the “insufficient info” list, and the botanicals in the “no tox” list will be subject to extensive literature review.

#### *a) Protocol for the extensive literature review.*

The working group reviewed the protocol for the extensive literature review that has been described in the interim report N°1 and suggested a number of additional selection criteria to reduce the number of abstracts to be considered by the contractor:

- Ignore all abstracts related to patent registration of description (e.g. *Acacia concinna*)
- Ignore abstracts with scientific botanical names other than the “official ones”. It was noted that the author name is very important, as a different author name may refer to a completely different species. For example, the Author name for *Acacia concinna* is (Willd.) DC. There is also an *Acacia concinna* Phil. but this species is a synonym of *Senegalia visco* (Lorentz ex Griseb.) Seigler & Ebinger, which is different from *Acacia concinna* (Willd.) DC. The contractor is invited to refer to the database [www.theplantlist.org](http://www.theplantlist.org) to differentiate between relevant and different species.
- Only the abstracts fulfilling the following criteria should be considered:
  - Contains the keywords “a” listed on p21 of the interim report N°1, or
  - Contains keywords from “a” and “b” listed on p21 of the interim report N°1
- *In vitro* studies related to mutagenicity/genotoxicity should be considered. Other *in vitro* studies are included
- Effects related to specific groups that are not representative of the general population (e.g. diseased people, e.g. diabetes, hypertension) are out of the scope of this extensive literature search. Studies related to children, elderly or pregnant women should be considered.



- In case of scientific papers where the abstract is in English but the full text is in another language, and the contractor does not have the expertise to understand the latter language, he will refer to EFSA who will try and find a solution.

*b) Insertion of substances in the compendium.*

- When a paper reports a substance present in a plant preparation, and describes some toxicity associated with this substance, the substance will be inserted in the compendium, regardless of whether it belongs to a red or black chemical group
- For substances listed in a scientific paper without any information about possible toxicity, the contractor will refer to the updated list of chemical groups prepared by the working group. If the substance belongs to a red group, it will be inserted in the compendium. If it belongs to an orange group, the contractor will refer to EFSA for further instructions. If the substance does not belong to a red or an orange group, it will be kept out of the compendium. The working group could not identify any tool to find out the chemical group to which a substance belongs. The contractor will have to make sure that some of their staff have expertise in organic chemistry and can identify the chemical group of a substance based on its structure.

*c) Update of COMBO WEB.*

The platform will be updated for the specific needs of the yellow species and the extensive literature search outcome.

The genotoxicity table is still to be developed. The place where to put information regarding carcinogenicity should be clarified.

The current COMBO WEB only allows for indicating the number of animals per dose group. The working group underlined the need to record as well the number of doses tested, the dosages, and at which dose(s) the effect is seen (should the dose-response be non-monotonic). The working group was reminded that the purpose of the compendium is hazard identification, not to perform a full risk assessment on a particular substance. There is therefore a need to find the right balance between the completeness of the information reported, and the need to address over 2000 botanical species by the end of 2016.

The solvent types used for botanical extraction should be better characterised. There is a field that could allow doing so but it is currently shared for further "plant/substance description". In case the substance has not been assessed by EFSA, this field will already be used for naming the substance.

Following discussion with the contractor, it was clarified that the type of extract should be mentioned, when the information is available, in the field "additional plant/substance description", after a semicolon if this field has been temporarily used to indicate the name of a substance that has not been yet coded by EFSA.

*d) Validation of the yellow list.*

The working group was introduced to the COMBO WEB Platform used for the transfer of the white list botanical species. The platform will be updated to meet the requirements of the yellow list but it is expected that the structure of the platform will be close to the existing one.

In order to be able to validate the information gathered by the contractor, the working group will need not only the COMBO WEB information, but also the list of abstracts and full papers from which the information was extracted, and the full bibliographic database (papers included/excluded with abstracts) for the botanical species considered.

The working group will validate on a systematic basis the information filled in the COMBO WEB system, but acknowledged that it cannot review the literature search for all the botanical species of the yellow list. A decision was made to randomly check for 10% of the botanicals species whether the literature search is complete and if no relevant information has been missed.

The working group reiterated the importance of looking not only at the scientific literature but also at general text books (e.g. Bruneton), google scholar etc.

## **7. Working group composition**

The working group discussed the need to increase its composition and expertise to compensate at least for the members who left the group over the past years and were never replaced. The following areas of expertise were identified for the possible candidates: botany, toxicology, (etno)pharmacology, phytochemistry.

The Secretariat will use the Advisory Forum and the Member States' Focal points to look for possible candidates.

The working group also recommended EFSA to consider setting up a network on botanicals, should the need for assessing botanical preparations increase in the near future.

## **8. Next meeting dates**

The following meeting dates were agreed:

- **15 December** (9.00-18.00) – **17 December 2015** (9.00-13.00); **Rome**
- **24 February** (starting at 9.00) - **26 February 2016** (ending at 12.30); **Parma**
- **27 April** (starting at 9.00) - **29 April 2016** (ending at 12.30); **Uppsala – to be confirmed**
- **29 June** (starting at 9.00) - **1 July 2016** (ending at 12.30); **Copenhagen – to be confirmed**
- **31 August** (starting at 9.00) - **2 September 2016** (ending at 12.30); **Parma**
- **23 November** (starting at 9.00) - **25 November 2016** (ending at 12.30); **Madrid – to be confirmed**

Parma, 25 September 2015

EFSA/SC/1982

## **SCIENTIFIC COMMITTEE**

### **Minutes of the 15<sup>th</sup> meeting of the Working Group on Compendium**

**Brussels, 1 & 2 July 2015**

**(Agreed on 30 September 2015)**

#### **Participants**

- **WG Experts:**  
Ulla Beckman-Sundh, Qasim Chaudhry, Secundino Lopez<sup>1</sup>, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano (Chair)
- **EFSA:**  
SCER Unit: Bernard Bottex

#### **1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Robert Anton.

#### **2. Adoption of agenda**

The agenda was adopted without changes.

#### **3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the experts invited for the present meeting. No conflicts of interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

Participants were informed that Qasim Chaudhry can no longer chair the working group because EFSA changed the classification of his organisation (from Food Safety Organisation (FSO) to non-FSO), a decision which is still to be confirmed by the EFSA Management Board. Vittorio Silano, on request of the Secretariat, accepted to chair this meeting on an ad-hoc basis.

#### **4. Adoption of the minutes of the 14<sup>th</sup> working group meeting**

The participants reviewed the draft minutes of the 14<sup>th</sup> working group meeting held on 19 and 20 May 2015 in Prague. The adopted minutes will be published on the EFSA website.

#### **5. SC activities on botanicals – note for discussion**

The working group was informed that the deadline of the current mandate has been extended by EFSA in order to coincide with the end date of the procurement procedure

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<sup>1</sup> Via conference call

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

aimed at transforming the Compendium into a web-searchable database and expanding its content.

The working group prepared a draft note for the Scientific Committee, summarising the main achievements of the working group, ongoing activities and areas where additional work is needed. This note was to facilitate discussion by the new Scientific Committee, during its meeting on 23 July 2015, on its work programme for the next years.

The resulting note for discussion will be circulated to the working group for review before it is sent to the Scientific Committee.

## **6. Preamble of the compendium**

As a new (web-searchable) version of the Compendium will be published this autumn on the EFSA website, the working group reviewed the preamble that describes the purpose of this hazard database and explains its structure.

The update of the preamble will be circulated to the working group for review, together with these notes. It was agreed that further consideration of the preamble may be appropriate when the third version is ready for publication.

## **7. Version 3 of the Compendium – Migration to the EFSA Data Warehouse**

The working group went through the lists of plant species identified by the contractor in charge of the transformation of the compendium as requiring further correction/clarification.

The corrections were sent to the contractor directly during the meeting.

The working group clarified that:

- Species currently under annex B (no reported adverse effect or substances of concern identified) should be considered as “yellow species” and therefore be subject to an extensive literature search
- Algae, fungi and cyanobacteria are put on hold and will not be inserted in version 3 of the compendium
- Lichens will be included in version 3 of the Compendium
- When transferring the data to the EFSA data warehouse, the date indicated for the species in the white list should be the date of transfer; while for the yellow species, it will be the date of the literature search. As a consequence, when someone searches the database, the date of the latest literature search will be displayed for yellow species, while for the white species, a message such as “extensive literature search pending” should appear
- The working group reviewed the codes for toxicity and concluded that 9 codes are needed:
  - Acute toxicity (up to 24 hours)
  - Subacute toxicity (from 24 hours to 30 days)
  - Subchronic toxicity (from 30 days to 90 days)
  - Chronic toxicity (from 90 days to lifetime)
  - Carcinogenicity
  - Reproduction toxicity
  - Developmental toxicity
  - Epidemiological studies (delete “with volunteers”)

- Case reports / field observations
- The working group reviewed the list of chemical groups of concern and, more particularly, the contribution received from Robert Anton for the classification of fatty acids. The working group concluded that for such “common” groups, it is not possible to set groups or subgroups as “of concern” and decided instead to build a negative list of compounds. This decision concerns other broad groups such as proteins/peptides/amino acids, carbohydrates/polysaccharides/sugars, and minerals.

## **8. Next meeting dates**

The following meeting dates were confirmed for 2015:

- **30 September** (9.00-18.00h) – **2 October 2015** (9.00-13.00h); **Parma**
- **15 December** (9.00-18.00h) – **17 December 2015** (9.00-13.00h); **Rome**

Parma, 24 June 2015

EFSA/SC/1944

## SCIENTIFIC COMMITTEE

### Minutes of the 14<sup>th</sup> meeting of the Working Group on Compendium

Prague, 19 & 20 May 2015

(Agreed on 1 July 2015)

#### Participants

- **WG Experts:**  
Robert Anton, Ulla Beckman-Sundh (Chair), Qasim Chaudhry, Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano
- **EFSA:**  
AMU Unit: Andrea Bau<sup>1</sup> and Jane Richardson<sup>1</sup>  
SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants. The first day of the meeting was dedicated to the interim review with the contractor of the results of the procurement for the transformation and further development of the compendium of botanicals. The first day of the meeting is subject to minutes written by the Contractor and that will be circulated together with these notes.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declarations of interest and the Specific Declarations of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

Participants were informed that, because of a change of classification of his organisation by EFSA (from Food Safety Organisation (FSO) to non-FSO) to be further confirmed by the EFSA Management Board, Qasim Chaudhry cannot chair the working group anymore. Ulla Beckman-Sundh was invited by the Secretariat to chair this meeting on an ad-hoc basis.

#### 4. Adoption of the minutes of the 13<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 13<sup>th</sup> working group meeting held on 10 and 11 March 2015 in Parma. The minutes will be published on the EFSA website.

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<sup>1</sup> Participated during Day 1 only

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## **5. Procurement for the transformation and further development of the compendium**

The contractor presented the work done so far and summarised in part 1 of the external scientific report.

Out of 2850 plants in the compendium, around 900 have been kept in the white list, i.e. can be transferred with the information already gathered by the working group.

The Contractor reported that all EFSA catalogues have now been uploaded. A 6-step wizard was developed to help with the transformation of the existing information in the white list into the new data models. A number of examples were discussed with the working group to clarify identified issues and difficulties.

A web conference will be organised following this meeting between the Contractor and the Secretariat to learn more about the ComboWeb interface and to be able to provide further guidance to the working group members who will have to validate the transformation of the data to version 3 of the compendium. It was agreed that the working group would check the first 100 botanicals of the white list to ensure common understanding of how transformation to the new data model should be done. After that, the working group will be requested to review 10% of the botanicals on a random basis, before the species in the white list are moved to version 3 of the compendium.

A number of specific issues were clarified between the participants:

- The application should show the scientific name only and not the common name, even if most of the MTX codes are primarily associated to common plant names
- The field “registration date” will be modified to “date of entry” and dates will always be expressed with the same format: YYYYMMDD
- Even if some of the codes are still missing, internal codes will be created while the official codes are being generated by EFSA in order not to delay the work
- A file defining most of the toxicity terms (e.g. acute, sub-chronic, chronic) will be sent by EFSA to the contractor to ensure common understanding of how a given study should be coded.

Concerning the yellow list, i.e. list of plant species that will be subject to an extensive literature search, the Contractor presented the literature search protocol and a number of examples. The Secretariat asked for these examples to be annexed to the External Scientific Report – Part 1.

To decide on substances of concern to be inserted in the database, the participants agreed on the following methodological steps:

- 1) transform the white list according to the new data model;
- 2) check all the substances of concern listed in the white list versus the red chemical groups;
- 3) screen the yellow list: check the substances identified versus the substances of concern kept in the white list versus the red chemical groups.

If a substance considered as of concern does not belong to a red chemical group, it will be brought to the attention of the working group who will then decide whether to update the list of chemical groups and add this substance or not.

The participants clarified a couple of issues related to the literature search:

- A couple of keywords such as AMES or micronucleus will be added to the search keywords to capture genotoxicity studies.

- A case study for botanical species leading to >100 papers will be developed to decide on criteria to reduce the number of hits. One solution is to go directly to the primary papers instead of considering review papers, although review papers dealing specifically with the botanical species of interest should be considered.

For the yellow list, the working group will be asked to verify all new data to be added to the Compendium. The above-mentioned ComboWeb interface will be used for that purpose.

## **6. Request for a safety assessment of alkenylbenzenes**

The working group members were updated about the outcome of the discussion during the last plenary meeting of the Scientific Committee where the request for a risk assessment of alkenylbenzenes was discussed. The Scientific Committee commented that the received request was too broad and that no new information would change the conclusion of the assessments previously done. A letter will be drafted in that sense to the three members of the Advisory Forum who sent this request.

## **7. Renewal of the mandate of the Working Group**

The mandate of the working group will end with the release of an updated version of the compendium (white list) (August 2015). The procurement for the transformation and further expansion of the compendium is running until end of 2016 and will require an SC group of experts to review the new data collected by the contractor. A proposal will therefore be made at the 1<sup>st</sup> plenary meeting of the new Scientific Committee (23 July 2015) to renew the mandate of this working group.

In order to facilitate the discussion during the SC plenary meeting, the working group listed the tasks and issues that can be anticipated for the working group for the coming years:

- In the short term, the working group should collaborate with the NDA Panel in developing the draft guidance for novel food applications, focussing on the sections related to the assessment of botanicals and botanical preparations. The purpose is to ensure that this new guidance is in line with the SC guidance (2009).
- Follow up of the procurement until end of 2016, verifying the data extracted from the extensive literature search (yellow list).
- Contribution of the working group to the user-friendliness of the new version of the compendium, and more particularly on the way data can be extracted and should be presented.
- Launch of a new procurement as from 2017, aimed at performing an extensive literature search for the botanical species of the white list, i.e. those that have not been subject to the literature search in 2016 + characterisation of the toxicity for the substances of concern listed in the compendium.
- The working group noted that the current compendium could be improved by providing information on the likelihood of a substance of concern being present in a given type of extract, based on solubility and polarity.
- Chinese plants: most of the time, only the abstracts are available in English but there could be a need to access the full text if at some point EFSA is notified about Chinese plant(s) preparations (e.g. under the future novel food regulations). If tools such as Google Translate<sup>®</sup> do not provide an adequate solution, other means (e.g. cooperation with Chinese food safety authorities) could be explored.
- So far, the Scientific Committee has mostly worked on developing tools for the identification of hazards linked to botanical preparations. The implementation of the new novel food regulation, as well as the plants to be assessed by the FEEDAP Panel, require the Scientific Committee to now develop further guidance for the risk



assessment of botanical preparations. One key issue is to clarify the concept of history of use and how to consider it in risk assessment in a weight of evidence approach. This question is particularly important when the plant preparation contains non-thresholded substances. Another point that may require further guidance is what should be an “appropriate” composition characterisation, i.e. what percentage of a preparation should be characterised to allow for a risk assessment. The working group should also consider how to deal with mixture effects. Some botanical food supplements can contain up to 20 different plants as well as additional chemical substances. It was noted that a Horizon 2020 project called EUROMIX is already looking at chemical mixtures.

- A suggestion was made to get EMA HMPC represented in relevant activities (e.g. in case of assessment of specific botanicals).

A discussion paper will be drafted during the next working group meeting, to be brought to the attention of the new Scientific Committee.

## **8. Next steps**

The next working group meeting will be dedicated to:

- Clarifying possible issues identified by the Contractor
- Drafting a note for discussion for the new Scientific Committee about the importance of renewing this working group and the issues that could be addressed under the new mandate
- Reviewing and finalising the disclaimer to be attached to the new version of the Compendium.

## **9. Next meeting dates**

The following dates for the meetings in 2015 were confirmed:

- **1 July** (10.00-18.00) – **2 July 2015** (9.00-16.00); **Brussels**;
- **30 September** (9.00-18.00) – **2 October 2015** (9.00-13.00); **Parma**;
- **15 December** (9.00-18.00) – **17 December 2015** (9.00-13.00); **Rome**.

Parma, 12 May 2015

EFSA/SC/1914

## SCIENTIFIC COMMITTEE

### Minutes of the 13<sup>th</sup> meeting of the Working Group on Compendium

Parma, 10 & 11 March 2015

(Agreed on 19 May 2015)

#### Participants

- **WG Experts:**  
Robert Anton, Ulla Beckman-Sundh, Qasim Chaudhry (Chair), Kirsten Pilegaard, Mauro Serafini and Vittorio Silano
- **EFSA:**  
SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Secundino Lopez.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

#### 4. Adoption of the minutes of the 12<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 12<sup>th</sup> working group meeting held on 20 and 21 January 2015 in Parma. The minutes will be published on the EFSA website.

#### 5. Request for a safety assessment of alkenylbenzenes

Members of the Working Group were informed about a joint request made by some members of the Advisory Forum for EFSA to assess the risk of exposure to alkenylbenzenes (methyleugenol, estragole, safrole) via food of plant origin. The request asks for considering possible mixture and matrix effects. A note will be prepared for the next meeting of the Scientific Committee to discuss the problem formulation and the terms of reference for a possible mandate.

The discussion paper will be shared with the working group before it goes to the Scientific Committee.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## **6. Transformation of version 2 of the Compendium into version 3 by the contractor**

The working group reviewed the plant parts to be used by the contractor when transforming the compendium. The broadest terminology will be used to facilitate the search of the database (e.g. berries = fruit); the specific plant parts listed in a generic term will be listed in the preamble.

The working group started addressing the requests for clarification received from the contractor. They mostly relate to the appropriate linking of the references to the information presented for a given species. The remaining species will be distributed to the responsible persons for further completion.

## **7. Next meeting dates**

The following dates for the meetings in 2015 were confirmed:

- **19 May** (9.00-18.00) – **20 May 2015** (9.00-13.00); **Prague**. This meeting will coincide with the interim meeting of the Procurement on Compendium. The objective of the meeting is to review the database version of the compendium (version 3) as well as the protocols for the extensive literature search;
- **1 July** (10.00-18.00) – **2 July 2015** (9.00-16.00); **Brussels**.

Parma, 10 March 2015

EFSA/SC/1874

## SCIENTIFIC COMMITTEE

### Minutes of the 12<sup>th</sup> meeting of the Working Group on Compendium

Parma, 20 & 21 January 2015

(Agreed on 10 March 2015)

#### Participants

- **WG Experts:**  
Robert Anton, Ulla Beckman-Sundh<sup>1</sup>, Qasim Chaudhry (Chair), Secundino Lopez, Kirsten Pilegaard, Mauro Serafini and Vittorio Silano
- **EFSA:**  
SCER Unit: Bernard Bottex, Caroline Merten<sup>2</sup>

#### 1. Welcome and apologies

The Chair welcomed the participants, explaining that the first day would be dedicated to the kick-off meeting of the procurement OC/EFSA/SCER/2014/05 aiming at transforming and further developing the Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. The outcome of this meeting is summarised in separate meeting minutes prepared by the Contractor.

The Chair invited the participants to introduce themselves during a “tour de table”.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>4</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

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<sup>1</sup> Present on day 1 only

<sup>2</sup> Present for the risk-ranking discussion (see point 6)

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

#### 4. Adoption of the minutes of the 11<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 11<sup>th</sup> working group meeting held from 16 to 18 December 2014 in Parma. The minutes will be published on the EFSA website.

#### 5. Kick-off meeting of the procurement for the transformation and further development of the compendium

The report regarding the kick-off meeting is subject to specific minutes to be provided by the Contractor; as soon as received, it will be shared with the working group for comments.

The transformation of the Excel-based compendium into version 3 is foreseen by end of May 2015 for release on the EFSA website in summer 2015.

The protocols for the extensive literature review are expected around mid-March 2015. The protocols will be tested with a number of plant species, eventually revised and re-tested prior to the interim meeting of the project planned in May 2015.

The following 20 species will be used when testing the protocols for the literature search:

<i>Aloe barbadensis</i>	<i>Dracunculus vulgaris</i>
<i>Artemisia herba-alba</i>	<i>Embelia angustifolia</i>
<i>Cupressus sempervirens</i>	<i>Erythroxylum laurifolium</i>
<i>Curcuma longa</i>	<i>Ipomoea dumosa</i>
<i>Cyathea glabra</i>	<i>Phoradendron leucarpum</i>
<i>Cyperus esculentus</i>	<i>Phyllanthus niruri</i>
<i>Decalepis hamiltonii</i>	<i>Viscum album</i>
<i>Dracocephalum thymiflorum</i>	<i>Zingiber officinale</i>
+ 4 species selected randomly from the no-info list	

The working group reviewed the list of chemical groups and highlighted those that are of higher concern (in red). When doing the literature search:

- in case substances are identified with associated relevant toxicity data, they will be added to the compendium, regardless of whether they belong to a black or red chemical group, together with the characterisation of the toxicity (toxicological endpoint, tested species, dose etc.) retrieved from the previously-mentioned literature search
- in case composition data linked to a specific plant preparation is found, but there is no information on possible toxicity linked to these substances, then the contractor should refer to the list of chemical groups and flag the substances belonging to the red ones. It was clarified that the characterisation of possible toxicity of these substances will be done as a second step. Substances belonging to the black groups will be kept in a separate database pending future checks for possible toxicity (but after the red ones have been done).

The list of chemical groups will be annexed to the preamble. The red groups will be illustrated with examples of substances taken from the Compendium. The black groups will be listed as such, without any example. The preamble for the compendium was updated to reflect this decision.

The sources of information considered to build the list of chemical groups will be added.

The EFSA catalogues (e.g. for plant parts or adverse effects) to be used by the contractor will be finalised by EFSA and sent to the working group as well for information.

## **6. Critical review of methodology and application of risk ranking for prioritisation of food and feed related issues, on the basis of the size of anticipated health impact - Applicability to Botanicals**

The contractor of the above-mentioned procurement presented the outcome of their project to the working group. In view of the complexity of botanicals in terms of variability in the amount and quality of information available, depending on the species considered, the contractor suggests an expert judgement approach for the priority ranking. Two approaches were explored, the Carnegie-Mellon and the Delphi approaches. Both of them suggest a scoring of the botanicals on the basis of pre-defined criteria, either by gathering experts in a workshop, or using electronic tools like an online consultation.

The working group stressed that this approach could be done for well-known plants but would be more difficult for plants where only limited data is available. The approach does not seem applicable for big lists of plant species. One possibility could be to regroup plants (e.g. containing the same chemical groups).

The Scientific Committee underlined that ranking of the botanicals in the current compendium is not relevant. Prioritisation should be considered if at some point EFSA is notified with a list of plant preparations for assessment. Once we have the information in the Compendium, the composition data of the plant preparation and the information on traditional use and anticipated use in Europe, then a ranking exercise would become possible.

The Working Group suggested spending some time to identify critical criteria for priority setting, taking into account the various pieces of information available.

The Working Group was informed that the outcome of this discussion will be reported at the next meeting of the Scientific Committee, during which possible follow-up of this risk-ranking project will be further discussed.

## **7. Next meeting dates**

The following dates for the meetings in 2015 were agreed:

- **10 March** (9.00-18.00) – **11 March 2015** (9.00-13.00); **Parma**;
- **19 May** (9.00-18.00) – **20 May 2015** (9.00-13.00); **Prague**; This meeting will coincide with the interim meeting of the Procurement on Compendium. The objective of the meeting is to review the database version of the compendium (version 3) as well as the protocols for the extensive literature search;
- **30 June** (9.00-18.00) – **2 July 2015** (9.00-13.00); **Parma**;
- **30 September** (9.00-18.00) – **2 October 2015** (9.00-13.00); **Parma**;
- **15 December** (9.00-18.00) – **17 December 2015** (9.00-13.00); **Rome**.

## **8. Any Other Business**

The working group was informed about an ongoing consultation from the European Medicines Agency (EMA) on the use of herbal medicinal products containing estragole and pulegone/menthofuran. The working group identified a number of issues to bring to the attention of EMA. The submission of comments will be coordinated with the other EFSA Panels/Units who worked on these substances. Members of the working group were invited to send their possible comments to the Secretariat.

Parma, 16 January 2015

EFSA/SC/1843

## SCIENTIFIC COMMITTEE

### Minutes of the 11<sup>th</sup> meeting of the Working Group on Compendium

Parma, 16 to 18 December 2014

(Agreed on 20 January 2015)

#### Participants

- **WG Experts:**  
Robert Anton, Qasim Chaudhry (Chair), Secundino Lopez, Kirsten Pilegaard, Mauro Serafini
- **EFSA:**  
SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Ulla Beckman-Sundh and Vittorio Silano.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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. Adoption of the minutes of the 10<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 10<sup>th</sup> working group meeting held from 25 to 27 August 2014 in Paris. The minutes will be published on the EFSA website.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## **5. Preparation of the kick-off meeting with the contractor in charge of transforming and further expanding the Compendium**

Participants were informed that the call for outsourcing the transformation of the MS Excel-based Compendium into a web searchable database and its further expansion has been successful and that the kick-off meeting will take place in January 2015

The working group identified/clarified the following issues for the discussion with the contractor:

### ***Prioritisation:***

The contractor should start filling in data gaps for plant species that are currently “empty” and for the ones that have been listed in the “no info” list

### ***Data search strategy:***

The contractor will have a first search using only the scientific accepted name and the synonyms identified in the current version of the Compendium. The search will be done using the genus and species but excluding the Author(s) name. This first search will reveal whether data are available for the plant species considered, in which case the contractor will proceed with the second step of the data search, or whether indeed there is no info for this plant species.

For plant species for which data could be identified, two searches will be conducted in parallel.

The first one aims at finding evidence of adverse effects linked to the consumption of the plant.

*Keywords: poison\*, tox\*, intox\*, adverse, safe\*, side effect\*, harm\*, hazard\*, risk, bioactiv\*.*

The second search aims at identifying naturally occurring substances present in the plant or in a plant preparation that could be of concern for human health.

*Keywords: composition, pharmacol\*, analy\*, qualitative, quantitative, chemical, compound\*, substance\*, constituent\*, component\*, agent, profile.*

If the substances identified belong to the red list of chemical groups identified by the working group, they will be inserted in the compendium. If the substance does not belong to these chemical groups, it will be kept out of the Compendium. In case of doubt, the contractor will consult the working group.

The working group agreed that the priority is to fill in the information gaps in the Compendium. The characterisation of the toxicity of the substances of possible concern will be done in a second (later) step.

### ***Inclusion / exclusion criteria for the literature search:***

- In vitro data are excluded from consideration, unless they relate to genotoxicity (mutagenicity). For example, in vitro data showing cytotoxicity will not be considered
- Pesticidal activity (e.g. on insects) considerations are excluded
- Allergy data are excluded
- Data resulting from dermal / inhalation route of exposure will not be considered



- Biocidal data, data on cattle, farmed animals, and pets, data resulting from animal and human studies will be considered for the compendium
- Ecotoxicology data are excluded

### **Tools for the data search:**

In addition to the scientific literature searching tools such as Web-of-Science and SciFinder, the contractor is invited to consider the following text books / sources of information:

- Frohne D, Pfänder HJ and Anton R. 2009. *Plantes à risques*, Ed. Tec et Doc-Lavoisier, ISBN: 978-2-7430-0907-1
- Bruneton J. 2009. *Pharmacognosie, (Phytochimie, Plantes médicinales)*, Ed. Tec & Doc, Lavoisier, Paris, 4ème édition, ISBN: 978-2-7430-1188-8
- Bruneton J. 2005. *Plantes toxiques (Végétaux dangereux pour l'homme et les animaux)*, Ed. Tec & Doc, Lavoisier, Paris, 3ème édition, ISBN : 2-7430-0806-7
- Evans WC. (2009) *Trease and Evans Pharmacognosy*. Elsevier. ISBN: 978-0-7020-2933-2
- American Herbal Products Association. 1997. *Botanical Safety Handbook*. Mc Guffin M (Ed). ISBN: 0-8493-1675-8
- PDR for Herbal Medicines. 2004 Thomson ed. ISBN: 1-56363-5125
- EMEA, ESCOP and Kommission E monographs
- Council of Europe natural sources of flavourings reports (Council of Europe Publishing)
- Hagers Handbuch der Pharmazeutischen Praxis, Springer Verlag, 1998. ISBN: 3-540-52688-9
- Tisserand R and Young R. 2014. *Essential oil safety - a guide for health professionals*. 2nd Edition. Churchill Livingstone Elsevier. ISBN: 978-0-443-06241-4
- Chapman & Hall / CRC Dictionary of Natural Products (DNP). See <http://dnp.chemnetbase.com/tour/>

### **Database specificities:**

- Need for a “status” scrolling list with the following options: no info, to compendium, no alert for tox or adverse effects, pending
- Need for registering the date of the latest modification for the various plant species
- Need to be able to trace back where each plant species comes from (e.g. AESGP list, health claims list, exotic country name.)
- The section “preparation” of the database should indicate the preparation mode as well as the conditions of preparation (heated or not). The following options are available: extract (solvent) as reported in the scientific publication, essential oil, supercritical extract, plant material (fresh/dried/powdered), unknown.
- Data model: botanical name (accepted + synonym), family, plant part, chemotype<sup>3</sup>, preparation type, reported adverse effect, chemical group + substance of concern, remark, reference.

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<sup>3</sup> See example of *Artemisia absinthum* in the compendium

### **Quality check:**

To ensure that the data search meets the Working Group's needs for the completion of the compendium, the data retrieved and inserted in the database for the first 100 plants will be double-checked by the working group. After that, a random check and validation of the outcome of the data search (the method for the random pick of plant species will be clarified with EFSA statisticians) will be performed during the whole project.

## **6. Update of the compendium**

The working group reviewed the preamble to keep track of the new working strategy to develop version 3 of the Compendium.

The working group reviewed the contributions received. The resulting version of the compendium will be circulated to the working group for further review of the toxicological information related to the plant species

## **7. Next meeting dates**

Participants agreed on the dates for the meetings in 2015:

- **20 January** (9.00-18.00) – **21 January 2015** (9.00-13.00); **Parma**; the first day of the meeting will be held jointly with the contractors of the procurement for the transformation and further expansion of the Compendium.
- **10 March** (9.00-18.00) – **12 March 2015** (9.00-13.00); **Parma**;
- **19 May** (9.00-18.00) – **21 May 2015** (9.00-13.00); **Copenhagen**;
- **30 June** (9.00-18.00) – **2 July 2015** (9.00-13.00); **to be determined**;
- **30 September** (9.00-18.00) – **2 October 2015** (9.00-13.00); **Rome**;
- **15 December** (9.00-18.00) – **17 December 2015** (9.00-13.00); **Parma**;

## **8. Any Other Business**

The participants were informed on the outcome of the joint Italian Presidency/Herbal Medicinal Product Committee of the European Medicines Agency on scientific issues in evaluating safety and efficacy of herbal medicinal products of well-established use and traditional use and botanical food supplements held in Rome on 4-5 November 2014. The work made by EFSA on the Compendium was most appreciated but several participants questioned the work of EFSA related to health claims and why certain botanical preparations are considered as food supplements. It was clarified that it is not EFSA's role to decide whether a botanical or botanical preparation should be considered as food or as a medicine.

The participants were also summarised the outcome of the Conference on Botanicals in Food organised by the Technical University of Denmark (DTU), the French Agency for Food, Environmental and Occupational Health & Safety (Anses) and the Federal Institute of Risk Assessment (BfR) last 19-20 November in Copenhagen. The conference reviewed the state of the art of the risk assessment and the regulation. All the documentation related to this meeting is available at: <http://www.conferencemanager.dk/Botanicalsinfood/about.html>.

## SCIENTIFIC COMMITTEE

### Minutes of the 10<sup>th</sup> meeting of the Working Group on Compendium

Paris, 25 to 27 August 2014

(Agreed on 16 December 2014)

#### Participants

- **WG Experts:**

Robert Anton, Ulla Beckman-Sundh, Qasim Chaudhry (Chair), Secundino Lopez, Kirsten Pilegaard, Mauro Serafini, Vittorio Silano

- **EFSA:**

SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Maria Teresa Nogueira.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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. Adoption of the minutes of the 9<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 9<sup>th</sup> working group meeting held from 11 to 13 June 2014 in Parma. The minutes will be published on the EFSA website.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## **5. Scientific topics for discussion ([EFSA-Q-2012-00486](#))**

### **5.1 Conversion of the Excel Compendium into a web-searchable database**

The participants were updated about the procurement that will be launched early July 2014 to outsource (i) the transformation of the MS Excel-based Compendium into a web-searchable database hosted in the EFSA data warehouse, and (ii) the extensive literature search for data to complete and further expand the Compendium.

The working group discussed in further details the work to be undertaken by the contractor regarding the expansion of the compendium. In view of the Summer 2015 deadline to publish version 3 of the compendium, and considering the upcoming implementation of the new Novel Food Regulation, the working group expressed the view that the priority is to perform a literature search for possible adverse effects or substances of concern for the plant species for which the information is still lacking. This comprises newly introduced species that are absent from European national lists but that are listed in non-European countries, European species listed in the “no-info” list of the compendium or in the compendium itself but that have not been addressed yet by the working group. In view of the short deadline for publishing version 3 of the compendium, the objective is to flag reported adverse effects or substances of concern in the plants listed.

After the publication of version 3 of the compendium, the contractor will be requested to characterise the toxicity of the identified substances or chemical groups of concern that are not already in the EFSA Chemical Hazard Database.

The working group confirmed that algae and fungi are still kept on hold for possible future insertion in the compendium.

### **5.2 Update of the compendium**

The working group reviewed the contributions received; the ones that could not be addressed will be added also to the Compendium and highlighted as pending for review. The resulting version of the compendium will be circulated to the working group for further review of the toxicological information related to the plant species.

The Preamble of the compendium will flag the importance of looking at related species for possible additional information when looking at a particular plant or plant preparation.

The preamble will explain that when no specific species was mentioned in the lists considered by the working group, the spp. was kept in the compendium

The preamble will specify that possible interactions with other plants or pharmaceutical products are not addressed in the Compendium

## **6. Next meeting dates**

Participants were informed about the cancellation of the meeting initially planned from 22 to 24 October 2014. The following December meeting was re-confirmed:

- **16 December – 18 December 2014; Parma** (time to be determined)

As soon as the outcome of the call for tender is known, a survey will be circulated among the working group members to agree on the meeting dates for the first half of 2015.

## SCIENTIFIC COMMITTEE

### Minutes of the 9<sup>th</sup> meeting of the Working Group on Compendium

Parma, 11 to 13 June 2014

(Agreed on 25 August 2014)

#### Participants

- **WG Experts:**

Robert Anton, Qasim Chaudhry<sup>1</sup>, Secundino Lopez, Maria Teresa Nogueira, Kirsten Pilegaard<sup>2</sup>, Mauro Serafini, Vittorio Silano

- **EFSA:**

SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Ulla Beckman-Sundh.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>4</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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. Adoption of the minutes of the 8<sup>th</sup> working group meeting

The participants reviewed the draft minutes of the 8<sup>th</sup> working group meeting held from 28 to 30 April 2014 in Madrid. The minutes will be published on the EFSA website.

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<sup>1</sup> Chair on 11/06/14 pm, 12/06/14 pm and 13/06/14 am

<sup>2</sup> Chair on 11/06/14 am and 12/06/14 am

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## **5. Scientific topics for discussion ([EFSA-Q-2012-00486](#))**

### **5.1 Conversion of the Excel Compendium into a web-searchable database**

The participants were updated about the procurement that will be launched early July 2014 to outsource (i) the transformation of the MS Excel-based Compendium into a web-searchable database hosted in the EFSA data warehouse, and (ii) the extensive literature search for data to complete and further expand the Compendium. Participants were invited to advertise as broadly as possible the call for tender.

### **5.2 Update of the compendium**

The working group reviewed the contributions received. The resulting updated version of the compendium will be circulated to the working group for further review of the toxicological information related to the plant species.

The working group suggested inserting in the preamble of the compendium the importance of looking at related species for possible additional information when looking at a particular plant or plant preparation.

## **6. Next meeting dates**

The following dates were agreed by the Working Group for the next meetings.

- **25 August** (14.00 – 18.00) – **27 August 2014** (9.00 – 16.00), Paris
- **22 October** (9.00 – 18.00) – **24 October 2014** (9.00 – 13.00), Parma
- **16 December – 18 December 2014** (time and location to be determined)

## **7. Any Other Business**

- **PlantLIBRA Project**  
The participants were informed about the final meeting of the DG RTD-funded FP7 PlantLIBRA project held Vienna from 12 to 14 May 2014. The Secretariat will contact the coordinators and ask for access to the various outcomes of the project.
- **BELFRIT Project**  
The Secretariat will send a letter to the coordinators of the project, asking for the possibility to access the BELFRIT list and ensure that the Compendium and the BELFRIT list are aligned.

## SCIENTIFIC COMMITTEE

### Minutes of the 8<sup>th</sup> meeting of the Working Group on Compendium Madrid, 28 to 30 April 2014

#### Participants

- **WG Experts:**

Robert Anton, Ulla Beckman Sundh, Qasim Chaudhry (Chair), Secundino Lopez, Maria Teresa Nogueira, Kirsten Pilegaard, Mauro Serafini, Vittorio Silano

- **EFSA:**

SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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. Agreement of the minutes of the 7<sup>th</sup> working group meeting held on 5 and 7 February, Parma

The participants reviewed the draft minutes of the 7<sup>th</sup> working group meeting held from 5 to 7 February 2014 in Parma. The minutes will be published on the EFSA website.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

## 5. Scientific topics for discussions ( [EFSA-Q-2012-00486](#) )

### 5.1 Conversion of the Excel Compendium into a web-searchable database

The participants were informed about the procurement that will be launched by mid-June 2014 to outsource (i) the transformation of the MS Excel-based Compendium into a web-searchable database hosted in the EFSA data warehouse, and (ii) the extensive literature search for data to complete and further expand the Compendium.

It was clarified that in the end, the Compendium should describe the toxic effect(s) associated with the identified substances of possible concern, but also the reported adverse effects associated with the human consumption of a given plant preparation. When looking for possible adverse effects, as a first step, no distinction will be made whether they result from food or feed consumption; in a second step, it will be decided whether the identified adverse effect(s) are human relevant.

Regarding substances of concern, when a specific substance is identified, the contractor will be requested to characterise the related toxicity. When no specific substance of concern is identified, the contractor will be asked to characterise the toxicity related to the chemical group(s) or subgroup(s) identified.

In order to address these data needs, an extensive literature search will be conducted for the various plant species, looking first for their chemical profile, then for toxicity data for the substances identified (to be decided whether they should be related to a specific substance of concern or to a chemical group) and for adverse effects associated with the plant. The toxic effects associated with a plant preparation will be clearly separated from the toxic effects related to a substance of concern. As such, the data model related to toxicity data should be structured as follows:

[plant name|plant part|type of extract|adverse effect related to the plant preparation|chemical group / substance of concern|toxicity related to the chemical group / substance of concern|reference(s)]

As a priority, the Working Group agreed that the contractor should start first with plant species for which the group could not find any information.

### 5.2 Update of the compendium

The working group reviewed the various contributions received. The resulting updated version of the compendium will be circulated to the working group for further review of the toxicological information related to the plant species.

## 6. Next meetings

The following dates were agreed by the Working Group for the next meetings.

- **11 June** (9.00 – 18.00) – **13 June 2014** (9.00 – 13.00), Parma
- **25 August** (14.00 – 18.00) – **27 August 2014** (9.00 – 16.00), Paris
- **22 October** (9.00 – 18.00) – **24 October 2014** (9.00 – 13.00), Parma
- **16 December – 18 December 2014** (time and location to be determined).



## SCIENTIFIC COMMITTEE

### Minutes of the 7<sup>th</sup> meeting of the Working Group on Compendium Parma, 5 to 7 February 2014

#### Participants

- **WG Experts:**

Robert Anton, Ulla Beckman Sundh<sup>1</sup>, Secundino Lopez, Maria Teresa Nogueira, Kirsten Pilegaard (Chair), Mauro Serafini

- **EFSA:**

SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Qasim Chaudhry and Vittorio Silano.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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.

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<sup>1</sup> Apologised on day 3

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

#### **4. Agreement of the minutes of the 6<sup>th</sup> working group meeting held on 18 and 19 December 2013, Rome**

The participants reviewed the draft minutes of the 6th working group meeting held on 18 and 19 December 2013 in Rome. The minutes will be published on the EFSA website.

#### **5. Scientific topics for discussions ( [EFSA-Q-2012-00486](#) )**

##### **5.1 Conversion of the Excel Compendium into a web-searchable database**

The Plant\_Part list compiling the plant parts used in the compendium and the FoodEx plant parts used for other EFSA databases will be discussed and finalised with the EFSA colleagues in charge of developing the new database.

The working group discussed the need to review the various chemical groups and subgroups used in the compendium and to create of a list of chemical groups / subgroups to be used in a consistent way across the compendium.

The participants were informed about EFSA's intention to outsource the conversion of the information in the Excel database (once it has been validated by the working group) into the new web-searchable format, as well as the collection of further information on substances of concern that have not been yet evaluated by EFSA.

##### **5.2 Update of the compendium**

The working group reviewed the contributions received. The resulting updated version of the compendium will be circulated to the working group for further review of the toxicological information related to the plant species.

#### **6. Next meetings**

The following dates were agreed by the Working Group for the next meetings.

- **28 April** (14.00 – 18.00) – **30 April 2014** (9.00 – 13.00), Madrid
- **11 June** (9.00 – 18.00) – **13 June 2014** (9.00 – 13.00), Parma
- **25 August** (14.00 – 18.00) – **27 August 2014** (9.00 – 16.00), Paris
- **22 October** (9.00 – 18.00) – **24 October 2014** (9.00 – 13.00), Parma
- **16 December – 18 December 2014** (time and location to be determined)

## SCIENTIFIC COMMITTEE

### Minutes of the 6<sup>th</sup> meeting of the Working Group on Compendium

Roma, 18-19 December 2013

(Agreed on 5 February 2014)

#### Participants

- **Working Group Experts:**

Ulla Beckman Sundh, Secundino Lopez, Maria Teresa Nogueira, Kirsten Pilegaard (Chair), Mauro Serafini, Vittorio Silano

- **EFSA:**

SCER Unit: Bernard Bottex

#### 1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Robert Anton and Qasim Chaudhry

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

#### **4. Agreement of the minutes of the 5<sup>th</sup> working group meeting held on 23 and 24 October 2013, Parma**

The participants reviewed the draft minutes of the 5<sup>th</sup> working group meeting held on 23 and 24 October 2013 in Parma. The minutes were agreed and will be published on the EFSA website.

#### **5. Scientific topics for discussion ([EFSA-Q-2012-00486](#))**

##### **5.1 Conversion of the Excel Compendium into a web-searchable database**

The participants confronted the plant parts used in the compendium against the FoodEx plant parts used for other EFSA databases. The plant part descriptions used in the Compendium will be adapted to better match the FoodEx classification. Some codes need however to be created or modified. The outcome of this analysis will be communicated to the EFSA colleagues in charge of developing the new database.

The participants expressed their concern about the time it takes to code an entry. In view of the deadline to finalise version 3, the working group will focus on the validation of the information in the compendium. Alternative solutions for the coding of the validated information into the new template structure will be explored.

##### **5.2 Update of the compendium**

The working group reviewed the contributions received. The updated version of the Compendium will be circulated together with these minutes.

##### **5.3 Expansion of the compendium with non-European lists of plants**

It was suggested to also contact the Competent Authorities of the countries the working group would like to get the possible lists of plants.

#### **6. Any Other Business**

The participants were updated on the BELFRIT project.

#### **7. Next meetings**

The following dates were agreed by the Working Group for the next meetings.

- **5 February** (14.00 – 18.00) – **7 February 2014** (9.00 – 13.00), Parma
- **28 April** (14.00 – 18.00) – **30 April 2014** (9.00 – 13.00), Madrid
- **11 June** (9.00 – 18.00) – **13 June 2014** (9.00 – 13.00), Parma
- **25 August** (14.00 – 18.00) – **27 August 2014** (9.00 – 16.00), Paris
- **22 October** (9.00 – 18.00) – **24 October 2014** (9.00 – 13.00), Parma
- **16 December – 18 December 2014** (time and location to be determined)

## SCIENTIFIC COMMITTEE

### Minutes of the 5<sup>th</sup> meeting of the Working Group on Compendium

Held on 23-24 October 2013, Parma

(Agreed on 18 December 2013)

## Participants

- **Working Group Experts:**

- Robert Anton<sup>1</sup>, Ulla Beckman Sundh<sup>1</sup>, Qasim Chaudhry (Chair), Secundino Lopez, Maria Teresa Nogueira, Kirsten Pilegaard, Mauro Serafini, Vittorio Silano<sup>2</sup>

- **EFSA:**

- SCER Unit: Bernard Bottex
- AMU Unit: Andrea Bau<sup>2</sup>, Jane Richardson<sup>2</sup>
- FEED Unit: Claudia Roncanco Pena<sup>1</sup>, Lucilla Gregoretti<sup>1</sup>

### 1. Welcome and apologies

The Chair welcomed the participants.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director implementing this Policy regarding

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<sup>1</sup> Present in Day 2

<sup>2</sup> Present in Day 1

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests<sup>4</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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. Adoption of the minutes of the 4<sup>th</sup> working group meeting held on 29-30 October 2013, Stockholm.**

The participants reviewed the draft minutes of the 4<sup>th</sup> working group which were adopted after several modifications. The minutes will be published on the EFSA website.

#### **5. Scientific topics for discussion**

##### **5.1 Conversion of the Excel Compendium into a web-searchable database**

A presentation was given on the structure of the future web-searchable Compendium, and the template to be used by the Working Group to re-structure the information of the current Excel-based Compendium.

With regard to the substances of concern, the working group will first check whether these substances have already been assessed by EFSA, in which case they will appear in the EFSA Chemical hazard database. The code of this substance in the Chemical Hazard Database will be indicated also in the Compendium so that all toxicology-related information for this specific substance is retrieved automatically from the Chemical Hazard Database in the Compendium.

Substances that have not been assessed by EFSA will be given a specific code (with a different structure than the one for substances already assessed by EFSA) and will be included in a list for future data search outsourcing. The reported adverse effect or the reason for concern will be indicated in the remark column in the meantime.

The working group will use from now on the new template for plant species for which the information has been validated. All pre-validation work will still be done on the old Excel format;

The internal EFSA lists associated to the new database (e.g. taxonomy data, plant parts) will be distributed to the working group who will then check which codes to be used / created for the need of the Compendium.

For the chemical structure of the substances of concern, "ChemID Plus" will be used.

##### **5.2 Assessment of botanicals by the FEEDAP Panel**

The FEEDAP guidance for the assessment of plant-based feed additives was presented to the working group. It was underlined that this guidance document was drafted before the Panel had actually started to work on this type of products. The document is flexible enough to allow conclusion on safety using the whole body of knowledge available, including the history of safe use.

So far, the Panel has received dossiers for the assessment of 267 plant-based preparations covering 20 botanical families.

The Panel will use the Compendium to get an idea on the substances of concern to be expected, although it was made clear that the Compendium is not designed to cover animal

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<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

health aspects. For human health, and in case the substance(s) has/have already been assessed by EFSA, the Panel will rely on the conclusion of the CEF Panel, checking that the feed use does not lead to an additional exposure for humans.

The working group underlined the importance for the FEEDAP group dealing with the assessment of the plant-based feed additives to have a/some Representatives of the SC Working Group on botanicals to make the link with the work that has been done by the SC on botanicals' safety assessment, and to avoid diverging approaches.

### 5.3 Update of the Compendium

The working group went through some of the contributions provided by the working group members, identifying accepted botanical species from synonyms and unaccepted names.

The Compendium has been updated by the Secretariat accordingly and the working group will further review the remaining contributions at its next meeting in December 2013

A huge number of Indian plants have been retrieved for possible insertion in the Compendium. Decision was made to consider the ones in the master list of traded medicinal plants as a starting point; the scientific names should be first checked before possible incorporation if not yet existing in the compendium.

## 6. Any Other Business

An email was received from Ayurveda, asking EFSA to remove the species *Withania somnifera* on the basis that products from this plant with the traditionally recommended dosage (up to 6 g per day) have been shown to be safe. A reply will be sent by EFSA explaining that the Compendium is in no way a negative list of plants; as such, there is no indication in the inclusion of a specific botanical species in the Compendium that it could not be safely used as a starting material for manufacturing a food supplements. The working group considered provided by Ayurveda and concluded that there was no need to revise the information on *Withania somnifera* currently displayed in the Compendium available on the EFSA website.

An error was detected in the Compendium currently available on the EFSA website regarding *Syzygium aromaticum*. The draft version of the compendium was corrected and the published version on the EFSA website will be amended accordingly.

## 7. Next meetings

In view of the work to be done by the end of the mandate (end of 2014), the working group decided to increase the duration of its meetings to 2.5 days.

- **18 December** (14.00 - 18.00) - **19 December 2013** (8.30 - 16.30), Rome
- **5 February** (14.00 – 18.00) – **7 February 2014** (9.00 – 13.00), Parma
- **28 April** (14.00 – 18.00) – **30 April 2014** (9.00 – 13.00), Paris (to be confirmed)
- **11 June** (9.00 – 18.00) – **13 June 2014** (9.00 – 13.00), Parma

## **SCIENTIFIC COMMITTEE**

### **Minutes of the 4<sup>th</sup> meeting of the Working Group on Compendium**

**Held on 29-30 August 2013, Stockholm**

**Agreed on 23 October 2013**

#### **Participants**

- **Working Group Experts:**
  - Ulla Beckman Sundh, Qasim Chaudhry (Chair day 1), Secundino Lopez, Maria Teresa Nogueira, Kirsten Pilegaard (Chair day 2), Mauro Serafini, Vittorio Silano
- **EFSA:**
  - SCER Unit (Bernard Bottex)

#### **1. Welcome and apologies for absence**

The Chair welcomed the participants and informed them about the resignation of Dr. Luc Delmulle for personal reasons. The working group underlined the loss of expertise that this resignation represents and asked the Secretariat to find a replacement for Dr. Delmulle. Apologies were received from Robert Anton.

#### **2. Adoption of agenda**

The agenda was adopted without changes.

#### **3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



#### **4. Adoption of the minutes of the 3<sup>rd</sup> working group meeting held on 6-7 June, Barcelona**

The participants reviewed the draft minutes of the 3<sup>rd</sup> working group meeting held on 6 and 7 June 2013 in Barcelona. The minutes were adopted after several modifications. The minutes will be published on the EFSA website.

#### **5. Scientific topics for discussion**

##### **5.1 Assessment of botanicals by the FEEDAP Panel**

The working group was updated about the fact that the FEEDAP Panel is about to start the evaluation of 267 botanical preparations for feed additives. Dossiers were submitted by the applicants. The panel outsourced the production of data sheets summarising the data regarding the identity and characterisation of the additives. Most of the botanicals used in these preparations for feed additives are already covered in the SC Compendium; even if the focus is on human health aspects, the information on substances of concern and reported adverse effects is considered as relevant of interest for the FEEDAP evaluations.

A Scientific Officer from the FEEDAP Unit will be invited to the next meeting of the working group to present and discuss the risk assessment methodology that will be used by the panel.

##### **5.2 Conversion of the Excel Compendium into a web-searchable database**

The structure of the new database will be presented by the SAS Unit at the next working group meeting.

The reorganisation of the existing information from the Excel-file into the new database structure will be considered for possible outsourcing.

##### **5.3 Update of the compendium ( [EFSA-Q-2012-00486](#) )**

The working group went through the contributions provided by the working group members, identifying accepted botanical species from synonyms and unaccepted names.

The working group decided to focus on plants; fungi and algae will be extracted and be placed on separate lists, pending for review.

The Compendium was updated by the Secretariat accordingly and circulated to the working group members.

#### **6. Next meeting dates**

- 23 October (14 - 18.00) -24 October (9.00 - 16.00), Parma
- 18 December (9.00 - 18.00) -19 December (9.00 - 13.00), Rome

## **SCIENTIFIC COMMITTEE**

### **Minutes of the 3<sup>rd</sup> meeting of the Working Group on Compendium**

**Held on 6-7 June 2013, Barcelona**

**Agreed on 29 August 2013**

#### **Participants**

- **Working Group Experts:**
  - Robert Anton, Secundino Lopez, Maria Teresa Nogueira, Kirsten Pilegaard (Chair), Mauro Serafini, Vittorio Silano<sup>1</sup>, Ulla Beckman Sundh
- **EFSA:**
  - SAS Unit (Andrea Bau<sup>2</sup>, Jane Richardson<sup>3</sup>)
  - SCER Unit (Bernard Bottex)

#### **1. Welcome and apologies for absence**

The Chair welcomed the participants; a tour de table was organised to introduce the various members of the group to Prof. Secundino Lopez recently appointed in the working group for his expertise in plants used as feed.

Apologies were received from Qasim Chaudhry and Luc Delmulle.

#### **2. Adoption of agenda**

The agenda was adopted without changes.

#### **3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>4</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>5</sup>, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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.

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<sup>1</sup> Present on 6 June 2013 only

<sup>2</sup> Via conference call for point 5 of the Secretary notes

<sup>3</sup> Via conference call for point 5 of the Secretary notes

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

#### **4. Adoption of the minutes of the 2nd working group meeting held on 11-12 March 2013, Paris**

The participants reviewed the draft minutes of the 2<sup>nd</sup> working group meeting held on 11 and 12 March 2013 in Paris. The minutes were adopted after several modifications. The minutes will be published on the EFSA website.

#### **5. Scientific topics for discussion**

##### **5.1 Conversion of the Compendium into a web-searchable database**

A presentation was given by Andrea Bau and Jane Richardson (EFSA SAS Unit) on the modification of the structuring of the information currently contained in the Excel-based that will be needed to transfer the information in the EFSA data warehouse and make the compendium compatible with other existing EFSA databases, such as the chemical hazards database. At the end of the conversion, one will be able to search the database from any of the parameters, and the link with the chemical hazard database will allow to gather further information on the toxicity data, such as the existence of health-based guidance values, the critical study from which they were defined etc...

A description of the content of the chemical hazard database will be provided to the working group.

The working group members tested the new structure with a number of examples and made some recommendations for further improvement.

To facilitate the conversion work, the working group will have to work on Access rather than Excel. Colleagues from the SAS Unit will prepare an Access-based template to enter new data. A training will be provided to the members of the working group during the 5<sup>th</sup> working group meeting (23-24 October 2013 – Parma). In the meantime SAS will provide the working group with an interim Excel template to structure the compendium data according to the new agreed rules.

Only the Compendium itself will be converted into a web-searchable database format. The preamble of the compendium, the “insufficient information list”, and the list of plants for which the Scientific Committee could not identify any substance of concern or other data for the inclusion in the compendium will remain as separate Word or Excel files.

##### **5.2 Update of the compendium**

- Incorporation of feed consideration in the compendium

The members of the working group discussed the relevance of inserting information in the compendium on adverse effects linked to the consumption of botanicals by animals. It was noted that adverse effects will differ depending on the animal species considered, which makes the exercise of systematically updating the compendium with feed considerations quite complex and highly resource-demanding.

- Preparation of version 3 of the compendium

The working group went through the contributions provided by the working group members, identifying accepted botanical species from synonyms and unaccepted names.

The Compendium has been updated by the Secretariat accordingly and is circulated to the working group members together with these secretary notes.

## **6. Next meeting dates**

- 29 August (9.00 - 18.00) - 30 August (9.00 - 13.00), Stockholm
- 23 October (14 - 18.00) -24 October (9.00 - 16.00), Parma
- 18 December (9.00 - 18.00) -19 December (9.00 - 13.00), Rome

## **6. Next meeting dates**

- 29 August (9.00 - 18.00) - 30 August (9.00 - 13.00), Stockholm
- 23 October (14 - 18.00) -24 October (9.00 - 16.00), Parma
- 18 December (9.00 - 18.00) -19 December (9.00 - 13.00), Rome

Parma, 13 March 2013

## **SCIENTIFIC COMMITTEE**

### **Minutes of the 2<sup>nd</sup> meeting of the Working Group on Compendium**

**Paris, 11-12 March 2013**

**(Adopted by the WG on 6 June 2013)**

## **Participants**

### **Working Group Experts:**

- Robert Anton
- Qasim Chaudhry (Chair)
- Luc Delmulle
- Maria Teresa Nogueira
- Kirsten Pilegaard
- Mauro Serafini
- Vittorio Silano
- Ulla Beckman Sundh

### **EFSA:**

- SCOM Unit: Bernard Bottex

### **1. Welcome and apologies**

The Chair welcomed the participants.

### **2. Adoption of agenda**

The agenda was adopted without changes.

### **3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

#### **4. Background information**

Participants were provided with the list of botanicals submitted to the FEEDAP Panel for (re)evaluation. The FEEDAP Panel will launch a call for tender to prepare summary data sheets for 267 botanical preparations used as feed flavourings. The working group decided to put on hold the discussion on the priority to give to the FEEDAP list of botanicals until additional expertise on the use of botanicals for feed / feed supplements applications have been brought to the working group.

#### **5. Data collection**

- Lists of “exotic” plants

Participants discussed the lists already collected by the working group; these lists cover the following countries: Argentina, Australia, Brazil, China, Mexico, and the French overseas territories: Guadeloupe, Martinique, La Reunion.

The participants underlined the need to collect additional plant lists to cover Africa, India and North America.

- Contracting out some of the data collection

The members of the working group underlined that most of the data needed for the compendium have already been collected and can be retrieved from databases owned by other parties. Access fees or licences need to be paid to access these databases but the budget involved would be much lower than the one needed for outsourcing the data search .

It was also suggested to get information on existing plant databases, making use of the EFSA Focal Points.

#### **6. Update of the Compendium**

The Secretariat updated the “screening pending” list of the Compendium with the new version of the AESGP herbals list annexed to their Legal and Regulatory Framework for Food Supplements (2012). Plants that have not been so far considered by the working group have been added to the “screening pending list”.

These botanicals have then been inserted in the compendium and distributed among the members of the working group who should start looking for some information to fill-in the various columns.

When updating the information, the responsible persons are requested to:

1/ check if the botanical name is an accepted one or a synonym of another accepted botanical species. If it is a synonym, check in the Compendium but also in the “no info” as well as the “no tox” list if the accepted species is already mentioned.

2/ Add the Author(s) name

3/ add the family name

4/ look for relevant info to fill in the other columns

## **7. Use of commercial databases and the Quantitative Structure-Activity Relationship (QSAR) approach for botanicals**

The illustration on how the above-mentioned tools can be used to complete the information in the Compendium was postponed to the next working group meeting.

## **8. Discussion of the layout of the compendium database format**

The Secretariat will discuss internally with colleagues responsible for developing EFSA databases on the possibilities for converting the Excel compendium into a web-based searchable database. The following needs were highlighted by the Working Group:

- In addition to a searchable database, the compendium will be available in table format.
- The searchable terms of the compendium should include:
  - Accepted and correct botanical name (family, species, subspecies, including most common synonyms) according to the information found on [www.Plantlist.org](http://www.Plantlist.org), [www.ars-grin.gov](http://www.ars-grin.gov), [www.indexfungorum.org](http://www.indexfungorum.org) and [www.algaebase.org](http://www.algaebase.org)
  - Chemical compound (according to IUPAC nomenclature), compound mixture and plant part of concern
  - Chemical group of concern (i.e. colchicine alkaloids, flavones, *etc.*)
  - Nature of the adverse effect (i.e. hepatotoxic, photosensitizing, *etc.*)
- The data base entries will contain all available information in a user friendly format. If only insufficient information is available or no compounds of concern have been identified, a generic remark will be added to the database entry, similar to the preface of Annex A and Annex B respectively. Each data base entry will display the latest maintenance date.

A report back on the discussion and on what is feasible will be provided to the Working Group at the next meeting.

## **9. Next meeting dates**

- **6 June** (9.00 - 18.00) - **7 June** (9.00 - 13.00), Barcelona
- **29 August** (9.00 - 18.00) - **30 August** (9.00 - 13.00), *venue to be determined*



## SCIENTIFIC COMMITTEE

### Minutes of the 1<sup>st</sup> meeting of the Working Group on Compendium of botanicals V3

Held on 28 - 29 November 2012, Parma

(Agreed by written procedure on 13 May 2013)

#### Participants

- **Working Group Experts:**

- Robert Anton
- Qasim Chaudhry (Chair)
- Luc Delmulle
- Maria Teresa Nogueira
- Kirsten Pilegaard
- Mauro Serafini
- Ulla Beckman Sundh

- **EFSA:**

- SCOM Unit: Bernard Bottex, Sarah Maria Trattnig

#### 1. Welcome and apologies for absence

The Chair welcomed the participants and started a tour de table to introduce all participants. Apologies were received from Vittorio Silano.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, EFSA screened the Annual Declaration of interest and the Specific

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests 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**

##### **Background**

The participants were presented with previous EFSA work on botanicals:

In May 2012 EFSA published the latest version of a compendium, a “living document” comprising botanicals used as ingredients in food supplements by at least one Member State (MS) reported to contain substances that may be of human health concern<sup>3</sup>. The table-formatted compendium contains two annexes: the first one (Annex A) lists botanicals for which not enough information on possible substances of concern could be found, or for which the information present could not be verified. The second one (Annex B) lists botanicals for which, although some data were available, the Scientific Committee could not identify substances of concern, or other reasons for the inclusion in the compendium.

The Scientific Committee published a guidance document identifying the data needed to assess the safety of botanicals and suggesting a two-tiered approach for the safety assessment, depending on the available knowledge on a given botanical and the identified substance(s) of concern<sup>4</sup>. Currently, the Working Group (WG) on Botanicals/Qualified Presumption of Safety is testing and developing a generic system for the safety assessment of botanicals.

In a survey relevant authorities of the MS reported to greatly benefit from the use of the compendium during premarket assessment and expressed the wish for EFSA to continue and intensify the work on the compendium.

##### **Presentation of the EFSA mandate**

The mandate was introduced to the participants.

- ✓ The objective of this WG is to update the compendium and include botanicals used in non-European countries or marketed in the EU that have not been considered in the previous versions.
- ✓ Botanicals for which health claim requests have been made will be prioritized in the work flow of the group.
- ✓ The toxicological profiles (mode of action, target organs, nature of adverse effects) of identified compounds or compound mixtures of plant parts will be detailed, pending the availability of such data.
- ✓ The creation of a searchable database containing the information of the compendium is foreseen and will be guided by this WG.
- ✓ The WG will outsource part of the data collection and a systematic literature review for non-European plants and plants with particular interest for any of the EFSA panels. The WG will define the scope and the priorities of the data collection and the questions to be answered in the systematic literature review.

##### **4.1 Discussions on the on the work-plan and table of content of the opinion ([EFSA-Q-2012-00486](http://www.efsa.europa.eu/en/efsajournal/pub/2663.htm))**

- The third version of the compendium will mark substances of concern and toxicological information for species of botanicals. When a genus (spp.) was indicated in the second

<sup>3</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/2663.htm>

<sup>4</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/1249.htm>

version of the compendium, the various related species indicated by the member states will be inserted.

- A number of plant subspecies will be derived from the recently updated Association of the European Self-Medication Industry (AESGP) list of botanicals. New entries in the AESGP list not appearing in the compendium or any of the annexes will be identified.
- So far, the compendium was intended to address human health concerns. However, it was suggested to start up preliminary data collection for botanicals used in feed, taking into account that only limited information will be retrievable and a full coverage of all animal species in a compendium is not feasible. The need for additional expertise in the WG on botanicals used in feed was identified. An expert in this field will be invited to join the WG.
- The safety of a large number of botanicals has been requested to be reviewed by EFSA in the following areas:
  - Food Contact Materials, Enzymes, Flavourings and Processing Aids - CEF (requested to evaluate a number of botanicals used as source materials for flavourings)
  - Additives and Products or Substances used in Animal Feed - FEEDAP
  - Food Additives and Nutrient Sources Added To Food – ANS (ongoing evaluation of Ephedra and Yohimbe botanical species)

The prevalence of these botanicals in the compendium or any of the annexes will be determined and their inclusion will be prioritised during data collection.

- In addition to all toxicological information available, also biological interaction or cumulative action of the botanical with other compounds (i.e. drugs) will be considered to be included in the compendium, including subgroup population (i.e. infants, elderly, pregnant or breastfeeding women) specific effects, if sustained by scientific evidence.
- The information on observed adverse effects will be linked to a chemical compound, however, in cases where this is not feasible the botanical preparation or botanical to which the adverse effect has been linked will be mentioned.
- A database of natural products (<http://dnp.chemnetbase.com/intro/index.jsp>) will be used to search for additional information for the botanicals listed under Annex A of the Compendium.
- The QSAR approach is a complementary tool used in risk assessment aiding the prediction of harmful effects, based on the structure of a compound<sup>5,6</sup>. Since data gaps are expected for potential toxicological effects for a plethora of plant derived compounds, we will in a test run use a QSAR tool to retrieve additional information for substances in botanicals for which only insufficient information could be retrieved (see Annex A of compendium). Members of the working group underlined the importance of having these data confirmed in *in vivo* studies, considering the important variations in observed responses, depending on the botanical species and chemotypes.
- In addition to a searchable database, the compendium will be available in table format. The data base entries will contain all available information in a user friendly format. If only insufficient information is available or no compounds of concern have been identified, a generic remark will be added to the database entry, similar to the preface of Annex A and Annex B respectively. Each data base entry will display the latest maintenance date.

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<sup>5</sup> See <http://www.efsa.europa.eu/en/supporting/pub/169e.htm>

<sup>6</sup> See <http://www.efsa.europa.eu/en/supporting/pub/159e.htm>

- The activity of the WG should be completed by the end of 2014.
- Out-contracting of data collection aspects, terms of reference

The WG experts will provide the contractor with a list of botanicals, which have been identified to be of relevance for the work on the compendium. This list will contain botanicals from non-European countries currently expected to be marketed in the EU and plants that are of prior interest for EFSA but are not covered by the latest compendium.

#### **5. Next meeting dates**

**11 - 12 March, 6 - 7 June, 29 - 30 August.**