Identification and removal of confidential information from documents to be made available to the public by EFSA under Reg. EC 1107/2009 and Reg. EU 844/2012

Regulation EC 1107/2009 and Regulation EU 844/2012 require EFSA to make several types of documents available to the public. Applicants are given the opportunity to request information from the documents to be kept confidential. Applicants should justify the confidentiality claims either by specific reference to the relevant point under Art. 63(2) of Reg. 1107/2009, or by providing evidence showing that the disclosure might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

The following section provides the general guidance information that might be identified as confidential:

1. **Personal Data**

   On 30\(^{th}\) May 2001, the European Parliament and the Council adopted Regulation EC 1049/2001 regarding public access to documents from the European Parliament, Council and Commission. Article 4(1)(b) states that the institutions shall refuse access to a document where disclosure would undermine the protection of "privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data".

   The following data may therefore be removed:
   
   - personal data, such as names, addresses, telephone and fax numbers, e-mail addresses, letterheads;
   - location, addresses and contact information for manufacturing sites (technical material and preparation);
   - names of laboratories (for vertebrate studies only)

   Note: Confidentiality claims shall not apply to:
   
   - the name and address of the applicant;
   - the list of references, title, study and publication dates, holder’s names and claims for data protection.

2. **Confidential Data (Article 63(2) of Regulation EC 1107/2009)**

   Article 63(2) of Regulation EC 1107/2009 states that "disclosure of the following information shall normally be deemed to undermine the protection
of the commercial interests or of privacy and the integrity of the individuals concerned”, and may therefore be requested to be treated as confidential:

- the method of manufacture;
- the specification of impurity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;
- results of production batches of the active substance including impurities\(^1\);
- methods of analysis for impurities in the active substance as manufactured except for methods for impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant\(^2\);
- links between a producer or importer and the applicant or the authorisation holder;
- information on the complete composition of a plant protection product\(^3\);
- names and addresses of persons involved in testing on vertebrate animals.

3. Information of commercial interest (including company know-how (Article 4(2) of Regulation 1049/2001)

Article 4(2) of Regulation EC 1049/2001 states that the institutions shall refuse access to a document where disclosure would undermine the protection of "commercial interests of a natural or legal person, including intellectual property”. The following non-exhaustive list gives examples of when commercial interest may be undermined:

- benefit considerations;
- product registration strategies;
- efficacy/selectivity: direct comparison data with competitive products;
- details of work (not results) conducted to establish:
  - mode of action,
  - sensitivity of target tests (e.g. background sensitivity study),
  - most appropriate anti-resistance strategy;
- specific residue analytical methods based on novel technology used for generating residue data (N.B. this does not apply to residue methods for monitoring/enforcement purposes).

Note: Confidentiality claims shall not apply to:

\(^1\) This does not apply to the batch numbers and to the code(s) used for the active substances and the preparation(s).

\(^2\) It should be noted that this does not imply the methodology itself (e.g. HPLC-UV or GC-FID) as given for example in the list of end points.

\(^3\) Unless they are covered by Regulation EC 1272/2008. It should be noted that this does not apply for information given in Volume 4, Annex C of the DAR, but in cases where individual tests for formulants have been conducted and presented in Volume 3, Annex B.
- the indication of the purity of the active substance, neither as minimum purity as manufactured nor as purity used in studies;
- any proposals for classification and labelling;
- details of representative uses or registered use

This table gives an overview of the various documents that can be “sanitized” (blackened) and the reference to the legislation. The respective workflow is also included.

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Article</th>
<th>Document</th>
<th>Workflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>1107/2009</td>
<td>10</td>
<td>Summary Dossier</td>
<td>1</td>
</tr>
<tr>
<td>844/2012</td>
<td>5</td>
<td>Application for renewal</td>
<td>2</td>
</tr>
<tr>
<td>844/2012</td>
<td>8(4)</td>
<td>Summary Supplementary Dossier</td>
<td>3</td>
</tr>
<tr>
<td>1107/2009</td>
<td>12 (1)</td>
<td>Draft Assessment Report</td>
<td>4</td>
</tr>
<tr>
<td>844/2012</td>
<td>12(2)</td>
<td>Renewal Assessment Report</td>
<td>4</td>
</tr>
<tr>
<td>1107/2009  and</td>
<td>12(2) and 13(2)</td>
<td>Background documents to EFSA</td>
<td>5</td>
</tr>
<tr>
<td>844/2012</td>
<td></td>
<td>Conclusion</td>
<td></td>
</tr>
</tbody>
</table>
Sanitisation Summary Dossier (1107/2009 (NAS))

WORKFLOW 1

**Applicant**

- Submit Application, Dossier and Summary Dossier + request for information to be kept confidential (use template form)

**RMS**

- Assess completeness of the Dossier + evaluate the requests for information to be kept confidential
- Completeness decision and agreement/comments on request for confidential information (endorsement of justification form)

**APDESK**

- Prepare Sanitised Summary Dossier in accordance with agreement/comments of RMS
- Send Sanitised Summary Dossier (stand alone pdf files) and the justification form with agreement/comments of the RMS
- Publish Sanitised Summary Dossier in Register of Questions

SD: Supplementary Dossier

SED: Summary Supplementary Dossier

SSSD: Sanitised Summary Supplementary Dossier

RAR: Renewal Assessment Report
Sanitisation Application (844/2012 (AIR))

WORKFLOW 2

**Applicant**

- Submit Application (non-confidential and confidential part) + request for information to be kept confidential (use template form)

**RMS**

- Assess if Application submitted in time and contains all elements + evaluate and requests for information to be kept confidential

- Decision of completeness of Application and agreement/comments on request for information to be kept confidential (endorsement of justification form)

**APDESK**

- Prepare Sanitised Application in accordance with agreement/comments of RMS

- Send Application and Sanitised Application (pdf files) and the justification form with agreement/comments of the RMS

- Publish Sanitised Application in Register of Questions

14 days
Sanitisation Summary Supplementary Dossier (844/2012 (AIR))

WORKFLOW 3

**Applicant**
- Submit **SD** + request for information to be kept confidential in the **SSD** (use Justification form template)
- Prepare **SSSD** in accordance with agreement/comments of **RMS**
- Send **SSSD** (stand alone pdf files) and the justification form with agreement/comments of the **RMS**

**RMS**
- Assess **SD** and evaluate requests for information to be kept confidential
- Admissibility decision and agreement/comments on request for confidential Information (endorsement of justification form)
- Preparation of **RAR** (time elapsing between **SD** and **RAR** dispatch)

**APDESK**
- Publish **SSSD** in Register of Questions

**AFTER RAR DISPATCH**
- Upload updated **SSSD** + request for information to be kept confidential in the updated parts (use template form) in temporary DMS folder**
- Reach agreement on sanitisations
- Publish updated **SSSD** in Register of Questions

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* for guidance on the format of the Updated SSSD consult SANCO/2012/11251/rev3
** for more information see workflow DAR/RAD dispatch
New workflow for DAR/RAR dispatch (1107/2009 (NAS) and 844/2012 (AIR))

**WORKFLOW 4**

<table>
<thead>
<tr>
<th>APDESK</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivers DAR/RAR (by uploading on DMS)</td>
<td>Activate temporary DMS project and upload DAR/RAR plus utility files</td>
</tr>
<tr>
<td>Fax (+ email) “Letter for sanitisation”</td>
<td>Download DAR/RAR + utility files from temporary project</td>
</tr>
</tbody>
</table>

14 days NAS
2 weeks AIR III

Sanitise DAR/RAR (+ updated SSSD (AIR III))

Upload sanitised DAR/RAR files + (updated SSSD (AIR III)) + justification form in temporary project

Reach agreement on sanitisations

Upload updated dossiers

Deactivate temporary DMS project

14 days NAS
2 weeks AIR III

Upload updated dossiers

Start commenting period

Prepare Public version of the DAR/RAR

Deactivate temporary DMS project

Publish public version DAR/RAR on EFSA website for public commenting + upload updated SSSD in Register of Questions (AIR)

Fax (+ email) “Letter for commenting”

DAR/RAR dispatch (1107/2009 (NAS) and 844/2012 (AIR))
Sanitisation background documents to the EFSA Conclusion (1107/2009 (NAS) and 844/2012 (AIR)) WORKFLOW 5

Applicant

1. 
   - Activate temporary DMS project and upload background documents to EFSA Conclusion + justification form template

2. 
   - Email link to temporary DMS folder and deadline for sanitisation

3. 
   - Reach agreement on sanitisations

4. 
   - Sanitise background documents to EFSA Conclusion

5. 
   - Upload background documents to EFSA Conclusion + justification form in temporary project

6. 
   - Prepare public version of the background documents to EFSA Conclusion

7. 
   - Deactivate temporary DMS project

8. 
   - Publish public version of background documents to EFSA Conclusion

Pesticides Unit

2 weeks