General guidance on information that may be removed (blackened) from rapporteur Member State assessment reports before provision to third parties

1. Personal Data

On 30th May 2001, the European Parliament and the Council adopted Regulation 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 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) No 1107/2009)

Article 63(2) of Regulation 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 batch analytical reports 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;

[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 implies the methodology itself (e.g. HPLC-UV or GC-FID) as given for example in the list of end points.

- information on the complete composition of a plant protection product[3];
- names and addresses of persons involved in testing on vertebrate animals.

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

Article 4(2) of Regulation 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 shall <u>not</u> apply to:

- 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 uses.

[3] Unless they are covered by Regulation (EC) No 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.