



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate E - Food Safety: production and distribution chain
E3 - Chemicals, Contaminants and Pesticides

SANCO/10043/2007 –rev. 2
8 June 2007

GUIDANCE DOCUMENT
on the Check of Completeness for new active substance dossier
submissions under Directive 91/414/EEC

Working document
(does not necessarily represent the views of the Commission services)

This document has been conceived as a working document of the Commission Services. It does not intend to produce legally binding effects and by its nature does neither prejudice any measure taken by a Member State within the implementation prerogatives under Council Directive 91/414/EEC nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

Table of contents

General Remarks	3
The Procedure of Check of Completeness	3
New active substance information sheet	6
Standard e-mail 1: Completeness-Check NAS (information on the report on the Completeness-Check)	Error!
Bookmark not defined.	
Standard e-mail 2: Dossier receipt NAS (acknowledgement of receipt)	7
Standard e-mail 3: Dossier receipt NAS (acknowledgement of receipt, no reply)	8
Standard e-mail 4: Completeness-Check NAS (opening commenting period)	9
Abbreviations	10

General Remarks

This guidance document sets out the procedure to be followed in the framework of a decision on completeness of a dossier submitted according to Article 6 of Directive 91/414/EEC¹ for active substances which were not on the market on 26 July 1993.

From November 2000 on, the ECCO-Team (BVL) co-ordinated the check of completeness (CoC) for new active substances on behalf of the European Commission. The standard procedure for check of completeness was described in ECCO Manual D10 at that time. Some provisions of that document showed to be less appropriate for routine use, and therefore have been amended in practice. Moreover, after the end of the ECCO project in November 2006, some further changes in the procedure became necessary, in order to reflect the revised allocation of responsibilities.

However, since the procedure stays the same in principle, it was deemed enough to reflect all these changings, in a thorough amendment of the former ECCO Manual, which is now presented as a guidance document of the European Commission.

The Procedure of Check of Completeness

1. RMS => COM

Following application of Article 6 (2) and (3) of Council Directive 91/414/EEC for the inclusion of a new active substance in Annex I, the rapporteur Member State sends the completed information sheet (the template in annex to this guidance document shall be used) to the European Commission electronically.

2. COM

COM checks the completeness of the information sheet. If a CIPAC No. is not available, COM will take care that it will be allocated and added to the information sheet.

3. COM => MSs, EFSA

COM will upload the information sheet on the relevant active substances folder on CIRCA (Interest Group Plant protection products and their Residues) and will inform the MSs and EFSA thereof within the Standing Committee of the Food Chain and Animal Health.

4. RMS

RMS has to run the CoC within a 6-month time frame from the date of application.

5. RMS => COM

After six months at the latest, the RMS sends the report of the CoC to COM electronically.

6. COM => MSs, EFSA and APL => MSs, COM

¹ OJ L 230, 19.8.1991, p. 1.

COM will upload the report on the CoC on CIRCA and inform the MSs and EFSA within the Standing Committee of the Food Chain and Animal Health about the upload.

Simultaneously the rapporteur Member State is requested to ask the applicant to distribute the dossier to all Member States, to the European Commission and to the EFSA. Information on the respective number and format of dossiers to be submitted is specified in a document which is available on the internet (http://ec.europa.eu/food/plant/protection/evaluation/new_subs_en.htm)

The dossier should be submitted in accordance with the format foreseen in the “Guideline developed within the Standing Committee on the Food Chain and Animal Health on the Preparation and Presentation of Complete Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)” ([SANCO/10518/2005](#) rev. 5 of 27 June 2005)

When submitting the dossier, the applicant should ask COM, MSs and EFSA by letter or electronically (standard e-mail 1, in annex to this guidance document can be used) to acknowledge receipt of the dossier within 15 working days.

7. APL => RMS => COM

When the dossier is distributed to all parties involved the applicant informs the RMS about the date. RMS submits this information to COM.

If, after expiry of the deadline set under 2.6, not all MS have acknowledged receipt, APL should contact again those MSs which did not react yet by asking for acknowledgement of non-receipt (standard e-mail 2, in annex to this guidance document can be used) within 5 working days.

8. APL => RMS => COM

When the dossier has been received by all parties involved, the applicant informs the RMS. RMS submits this information to COM.

9. COM => MSs

When all parties involved have received the dossier, COM opens the comment period on the CoC for MS (standard e-mail 3, in annex to this guidance document can be used).

10. MSs => RMS, COM => SCFCAH

Member States may comment on the CoC within a time frame of 15 working days. All comments on the CoC have to be sent electronically to RMS, with copy to COM.

The Commission prepares a draft Decision recognising the completeness of the dossier and presents the draft to the SCFCAH for a vote.

11. COM

After a positive vote in the SCFCAH, COM services prepare the adoption of the Decision by COM and its publication in the Official Journal of the European Union.

12. COM => MS

COM informs MS of the date of publication.

The date of publication of the decision on completeness in the Official Journal of the European Communities will be listed in Annex II (a) of document SANCO/629/00 (Overview of the State of Main Works).

This is the starting date of the detailed examination (date to be listed in Annex II (b) of document SANCO/629/00 (Overview of the State of Main Works)).

NEW ACTIVE SUBSTANCE INFORMATION SHEET

(to be sent to European Commission by e-mail)

1.	Date of application:	
2.	Rapporteur Member State:	
3.	Information on the active substance	
3.1	Name of the New Active Substance (NAS): (ISO-common name)	
3.2	Status: (proposal, adopted)	
3.3	CIPAC-No.:	
3.4	Applicants development code: (always required)	
3.5	Function(s) of NAS: (E.g. herbicide, fungicide...)	
4.	Information on the reference product	
4.1	Trade name (product):	
4.2	Content of NAS in product:	
4.3	Other active substance(s): (name/content)	
4.4	Type of formulation: (GIFAP code)	
4.5	Main uses of product (crop/pest):	
5.	Information on the applicant/manufactur	
5.1	Applicant: (contact name/ address plus e-mail)	
5.2	Status (e.g. manufacturer, sole representative)	
6.	Date of start of Completeness-Check:	
7.	National provisional authorisations	
7.1	Application for provisional authorisation:	
7.2	(if yes, crops/pest applied for)	

(lines will adjust automatically)

please send this sheet to: SANCO-E3-secteurPP@ec.europa.eu

with copy to: wolfgang.reinert@ec.europa.eu

7453/VI/98 –rev. 7

**Standard e-mail 1:
Dossier receipt NAS (acknowledgement of receipt)**

Dear colleagues,

Further to our application for inclusion in Annex I to Directive 91/414/EEC for <AS> (RMS:XXX, Appl.: XXX, Devel. Code: XXX) on <date> we are pleased to announce having submitted the dossier.

You are kindly asked to acknowledge receipt within 15 working days (on <date> at the latest), preferably by e-mail.

Yours sincerely,

N.N.

For the applicant

**Standard e-mail 2:
Dossier receipt NAS (acknowledgement of receipt in case of no reply)**

Dear colleagues,

Further to our application for inclusion in Annex I to Directive 91/414/EEC for <AS> (RMS:XXX, Appl.: XXX, Devel. Code: XXX) on <date> we forwarded you a dossier and kindly asked to acknowledge receipt within 15 working days.

We were not aware of having received a reply from your side following our request up to now. Please contact us within 5 working days if you did not receive the aforementioned dossier. If we receive no further reply from your side by <date> we must assume that you indeed have received the dossier and will report this back to the rapporteur Member State.

Yours sincerely,

N.N.

For the applicant

**Standard e-mail 3:
Completeness-Check NAS (opening commenting period)**

Dear colleagues,

With reference to the Completeness-Check for <AS> (RMS:XXX, Appl.: XXX), Dev. Code: XXX) the dossier has been distributed to all Member States. I therefore open the commenting period of 15 working days.

Please send your comments electronically to the rapporteur Member State and a copy to me by <date> at the latest.

Yours sincerely,

N.N.

For the European Commission

Abbreviations

APL	Applicant
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, (Federal Office of Consumer Protection and Food Safety)
CIPAC	Collaborative International Pesticides Analytical Council
CoC	Completeness-Check
COM	European Commission
ECCO	European Community Co-ordination
EFSA	European Food Safety Authority
MS	Member State
NAS	new active substance
RMS	Rapporteur Member State
SCFCAH	Standing Committee on Food Chain and Animal Health