

Document Title

**Tier 2 Summary  
of Metabolism and Residue Data  
for the Plant Protection Product Fenhexamid WG 50 (500 g/kg)  
(Specification No.: 102000007271)**

Substance(s)

**FENHEXAMID  
(Annex I renewal)**

Data Requirements

**Regulation EC/1141/2010**  
on the renewal of the inclusion of A/R2 active substances  
in conjunction with  
**Directive 91/414/EEC and Regulation EC/1107/2009**

According to OECD format guidance for industry data submissions  
(SANCO/10387/2010 rev 8 - on the renewal of active substances included in Annex I)

**Annex IIIA  
Section 4, Point 8  
Document M**

Date

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### III A 8 Metabolism and Residues Data on the Plant Protection Product

This document intends to support the application for the Annex I renewal of the active substance fenhexamid (AIR2) and applies in conjunction with the corresponding chapter of the Annex II dossier (IIA, section 4, point 6) where all updated information on metabolism and residue of this compound is included.

The *representative uses* chosen for the Annex I renewal are: grapes, strawberries and tomatoes and the *GAPs supported for the inclusion renewal* are the same as those evaluated for the first inclusion.

During the EU review further grape trials conducted in the EU were submitted and subsequently evaluated (ECCO Peer Review Meetings, 'Full Report on Fenhexamid' - BBA, Braunschweig, February 2000). As a registration on grapes was granted in the USA during the Peer Review process, Bayer AG recommended reconsidering the grape MRL proposal given in the draft assessment report (2 mg/kg) by submitting the US data so that the MRL would also cover imports (ECCO Peer Review Meetings, 'Full Report on Fenhexamid' ECCO Team - BBA, Braunschweig, 2000, pages 155 – 186). The data submitted were considered sufficient to derive processing factors, but one open point was the recalculation of material balancing where the necessary data are available. Two processing studies on grapes are to be submitted with this AIR dossier providing information on mass balances (preparation of wine and raisins).

Relative to the metabolism and residue section all further data requirements addressed in the 'Full Report on Fenhexamid' (ECCO Peer Review Meetings, ECCO Team at BBA, Braunschweig of 28 February) were fulfilled.

In the process of the MRL review program under Article 12 of the MRL Reg. 396/2005, Tier I Summaries from all trials (trials from the original dossier, additional European grape trials and US data on grapes) were provided to the RMS (UK /CRO) so that all necessary data are already available.

The residues arising from the supported uses were concluded in the original EU review as not being harmful to human or animal health. The TMDI for a 60-kg adult was 5.4% of the ADI, based on the FAO/WHO European diet (Final EU review report 6497/VI/99-rev. 2 of 19 October 2000). The total NEDIs (UK diet) for adults, children and infants were max. 4% of the ADI (ECCO Peer Review Meetings, 'Full Report on Fenhexamid' ECCO Team at BBA, Braunschweig, 28 February 2000).

The chronic dietary risk assessment was updated applying the EFSA PRIMo model (version 2) for estimation on the dietary intake of pesticide residues. The TMDI calculations using the EFSA PRIMo model (rev. 2) yielded a maximum usage of the ADI of 20 %. The estimate of the short term exposure was not considered necessary and thus not performed since an ARfD is not allocated. It can be concluded that a risk for the consumer does not arise from the long term or short term exposure to fenhexamid.

*Since all metabolism and residue information revised in the context of AIR renewal of fenhexamid is presented in the Annex II dossier and did not trigger any additional information that would need to be reported in this Annex III dossier chapter – reference can be made to the updated Annex II dossier, section 4, point 6.*

*Therefore, the preparation of a separate Annex III residue chapter is not necessary as long as all required information is entirely covered in the Annex II dossier.*

- IIIA 8.1 Stability of Residues
  - IIIA 8.1.1 Stability of residues during storage of samples
  - IIIA 8.1.2 Stability of residues in sample extracts
- IIIA 8.2 Supplementary studies on metabolism in plants or livestock
- IIIA 8.3 Supplementary residue trials (supervised field trials)
  - IIIA 8.3.1 Grapes
  - IIIA 8.3.2 Strawberries
  - IIIA 8.3.3 Tomatoes
- IIIA 8.4 Supplementary Livestock Feeding Studies
  - IIIA 8.4.1 Poultry
  - IIIA 8.4.2 Lactating Ruminants (goat or cow)
  - IIIA 8.4.3 Pigs
  - IIIA 8.4.4 Nature of residue in fish
- IIIA 8.5 Supplementary Studies on Industrial Processing and/or Household Preparation
  - IIIA 8.5.1 Nature of residues
  - IIIA 8.5.2 Distribution of the residue in peel/pulp
  - IIIA 8.5.3 Balance studies on a core set of representative processes
  - IIIA 8.5.4 Follow-up studies; potable waters; irrigated crops
    - IIIA 8.5.4.1 Follow-up studies to determine concentration or dilution factors

- IIIA 8.5.4.2 Potable waters
- IIIA 8.5.4.3 Irrigated crops
- IIIA 8.6 Supplementary Studies for Residues in Representative Succeeding Crops
- IIIA 8.7 Proposed Residue Definition and Maximum Residue Levels
  - IIIA 8.7.1 Proposed residue definition
  - IIIA 8.7.2 Proposed maximum residue levels (MRLs)
- IIIA 8.8 Proposed Pre-Harvest Intervals, Re-Entry or Withholding Periods
  - IIIA 8.8.1 Pre-harvest interval (in days) for each relevant crop
  - IIIA 8.8.2 Re-entry period (in days) for livestock, to areas to be grazed
  - IIIA 8.8.3 Re-entry period for man to crops, buildings or spaces treated
  - IIIA 8.8.4 Withholding period (in days) for animal feedingstuffs
  - IIIA 8.8.5 Waiting period before sowing or planting crop to be protected
  - IIIA 8.8.6 Waiting period between application and handling treated products
  - IIIA 8.8.7 Waiting period (in days) before sowing or planting succeeding crops
- IIIA 8.9 Other/Special Studies
- IIIA 8.10 Estimation of Exposure Through Diet and Other Means
  - IIIA 8.10.1 TMDI calculations
  - IIIA 8.10.2 NEDI calculations
  - IIIA 8.10.3 NESTI calculations
- IIIA 8.11 Summary and Evaluation of Residue Behaviour