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| SECTION IIIA 6 | RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED | Official use only |
| IIIA 6.1 Persistence and likelihood of multiplication in or on treated materials, feedingsuffs or foodstuffs | JUSTIFICATION FOR NON-SUBMISSION OF DATA | |
| Other existing data [] Limited exposure [X] | Technically not feasible [] Scientifically unjustified [X] Other justification [] | |
| Detailed justification: | <i>Bti</i> (Strain AM65-52) is used for the control of mosquito and black fly larvae in contaminated water habitats and filter fly midges in sewage treatment plants. Data on the persistence and likelihood of multiplication on foodstuffs or feedingsuffs are therefore not relevant. Information on residues in the treated water body is not considered necessary. <i>Bti</i> (Strain AM65-52) is not infectious and survives poorly in the environment resulting in a limited spread of the micro-organism. Vegetative cells of <i>Bti</i> have a limited survival time in the environment and spores do not germinate readily, making it highly unlikely that <i>Bti</i> (Strain AM65-52) will multiply and colonise areas of intended use above levels that may occur naturally. | |
| Undertaking of intended data submission [] | Not applicable. | |
| | EVALUATION BY COMPETENT AUTHORITIES | |
| Date | EVALUATION BY RAPPORTEUR MEMBER STATE | |
| Evaluation of applicant's justification | September 2007 | |
| Conclusion | The justification cannot be considered acceptable | |
| Remarks | Detailed calculations need to be provided along with the assessment. Minimum distance with treated areas must be defined. See literature data. Among most recent see Fredriksen et al (2006) Appl.Envir.Microbiol.72, 3435-3440 | |
| Date | COMMENTS FROM OTHER MEMBER STATE | |
| Evaluation of applicant's justification | | |
| Conclusion | | |
| Remarks | | |

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| SECTION IIIA 6 | RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED | Official use only |
| IIIA 6.2 | Further information required | |
| IIIA 6.2.1 Non-viable residues | JUSTIFICATION FOR NON-SUBMISSION OF DATA | |
| Other existing data [] | Technically not feasible [] Scientifically unjustified [X] | |
| Limited exposure [X] | Other justification [] | |
| Detailed justification: | Information provided in Section 7 indicate that vegetative cells of <i>Bti</i> have a limited survival time in non-sterile soil and that spores of the bacteria do not germinate readily in soil, particularly under dry conditions. <i>Bti</i> (Strain AM65-52) is therefore not likely to replicate in soil and opportunities for gene transfer will be minimal since the bacteria is not metabolically active. In water, the vegetative cells and toxins of <i>Bti</i> are readily adsorbed to particulate matter and consequently are inactivated. Further information concerning non-viable residues is not considered necessary. | |
| Undertaking of intended data submission [] | Not applicable. | |
| | EVALUATION BY COMPETENT AUTHORITIES | |
| Date | EVALUATION BY RAPPORTEUR MEMBER STATE September 2007 | |
| Evaluation of applicant's justification | Justification considered not acceptable. | |
| Conclusion | Data along with calculations should be submitted. | |
| Remarks | None | |
| Date | COMMENTS FROM OTHER MEMBER STATE | |
| Evaluation of applicant's justification | | |
| Conclusion | | |
| Remarks | | |

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| SECTION IIIA 6 | RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED | Official use only |
| IIIA 6.2 | Further information required | |
| IIIA 6.2.2 Viable residues | JUSTIFICATION FOR NON-SUBMISSION OF DATA | |
| Other existing data [] | Technically not feasible [] Scientifically unjustified [X] | |
| Limited exposure [] | Other justification [] | |
| Detailed justification: | According to information presented in Document IIIA Section 3, <i>Bti</i> (Strain AM65-52) is not infective and is not toxic or pathogenic to mammalian species. Information concerning viable residues of <i>Bti</i> (Strain AM65-52) is therefore not considered necessary. | |
| Undertaking of intended data submission [] | Not applicable. | |
| | EVALUATION BY COMPETENT AUTHORITIES | |
| Date | EVALUATION BY RAPPORTEUR MEMBER STATE | |
| Evaluation of applicant's justification | September 2007 | |
| Conclusion | Justification considered not acceptable. | |
| Remarks | Data must be submitted | |
| | None. | |
| Date | COMMENTS FROM OTHER MEMBER STATE | |
| Evaluation of applicant's justification | | |
| Conclusion | | |
| Remarks | | |

| SECTION IIIA 6 | RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED | Official use only |
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| IIIA 6.3 Summary and evaluation of residues in or on treated materials, food and feed | <i>Bti</i> (Strain AM65-52) is used for the control of mosquito and black fly larvae in contaminated water habitats and filter fly midges in sewage treatment plants. Data on potential residues of <i>Bti</i> (Strain AM65-52) are therefore not relevant and it is not considered necessary to propose an Acceptable Daily Intake (ADI), calculate the potential exposure of consumers, or propose a Maximum Residue Level (MRL) for <i>Bti</i> (Strain AM65-52). | |

| Evaluation by Competent Authorities | |
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| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | Evaluation by Rapporteur Member State |
| Date | September 2007 |
| Materials and methods | Not applicable |
| Conclusion | Conclusion on residues considered not necessary. |
| Reliability | Not applicable |
| Acceptability | Not acceptable |
| Remarks | None. |
| | Comments from ... |
| Date | |
| Results and discussion | |
| Conclusion | |
| Reliability | |
| Acceptability | |
| Remarks | |