Bacillus amyloliquefaciens QST 713

Microbial Pest Control Agent against plant pathogenic fungi and bacteria

Dossier according to OECD dossier guidance for microbial pest control agents and microbial pest control products – August 2006

Summary documentation, Tier II

Annex IIM, Section 6

Point IIM 9: Summary and evaluation of environmental impact

Date: September 2015

Applicant

Bayer CropScience AG

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Introduction

The company Bayer CropScience AG is submitting a dossier for the re-approval of the microorganism *Bacillus amyloliquefaciens* QST 713 as an active substance under regulation (EC) 1107/2009, previously designated as *Bacillus subtilis* QST 713. Due to most current information on taxonomy, *B. subtilis* QST 713 is classified as a member of *B. amyloliquefaciens* group. As a consequence, the active substance is now named as *B. amyloliquefaciens* subsp. *plantarum* QST 713, hereinafter named as *B. amyloliquefaciens* QST 713.

The initial evaluation of *Bacillus subtilis* QST 713 was performed under Directive 91/414. Data provided in the initial dossier and in subsequent additional submissions according to the OECD dossier guidance (2006) are submitted as a "Baseline Dossier", separately.

Here we submit all new data and information basing on previous literature searches and studies.

IIM 9 Summary and Evaluation of Environmental Impact

IIM 9.1 Distribution and fate of MPCA

Fate and behaviour in soil

B. amyloliquefaciens QST 713 is ubiquitous bacterium. Thus, *B. amyloliquefaciens* spores may germinate and proliferate in soils. However it has been shown that *B. amyloliquefaciens* QST 713 populations strongly decline by time in soil after application. Transportation through soil may happen, but it was shown for close related *B. subtilis* strains, that vertical dispersal is limited.

For background information, please refer to the baseline dossier.

Fate and behaviour in water

Surface water

It has been shown, that *Bacillus* species occur worldwide and were also isolated from marine organisms (please refer to Annex II, Doc IIM, Point 8.2).

For the background information, please refer to the baseline dossier.

Ground water

Translocation of *B. amyloliquefaciens* QST 713 after application through soil may occur, but it is strongly limited as the spores are readily absorbed by soil particles. Therefore, the risk of groundwater contamination appears negligible after field application of *B. amyloliquefaciens* QST 713. More over, it is unlikely that spores occur in groundwater environments due to insufficient nutrient availability. Dilution due to continuous water flux and predation by the groundwater flora will cause a continuous decline of the spore populations and accumulation will not occur.

For the background information, please refer to the baseline dossier.

Fate and behaviour in air

B. amyloliquefaciens QST 713 spores may occur in areal samples due to transportation via drift. However, due to lack of nutrients and stress factors as UV-radiation or desiccation, survival of living cells is limited. Since no information from open literature on *B. amyloliquefaciens* in air is provided and air is not known to be a habitat for spores, fate and behaviour of *B. amyloliquefaciens* in air is negligible.

IIM 9.2 Identification of non-target species at risk and extent of their exposure

B. amyloliquefaciens QST 713 acts specifically against plant-pathogenic fungi and bacteria. Non-target species are considered not to be at risk. This has been confirmed by numerous studies and the literature reviewed in Point 8 of this dossier section.

Please refer to the baseline dossier for the background information.

IIM 9.3 Identification of precautions necessary to minimize environmental contamination and to protect non-target species

As numerous studies and literature reviews have shown, *B. amyloliquefaciens* QST 713 is not toxic to aquatic and terrestrial species, and considering the expected environmental concentration, no hazard to populations of non-target species is expected. In conclusion, special precautions to minimize environmental contamination and to protect non-target species are not relevant.

For more details on risk to non-target organisms, please refer to the baseline dossier and Annex IIIM, Doc IIIM, Point IIIM 11.