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Proposed Registration Decision

Pantoea agglomerans strain E325

(publié aussi en français)

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Overview

Proposed Registration Decision for *Pantoea agglomerans* strain E325

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and Regulations, is proposing conversion from conditional to full registration for the sale and use of Bloomtime Biological Technical and Bloomtime Biological FD Biopesticide, containing the microbial pest control agent *Pantoea agglomerans* strain E325, to suppress fire blight (*Erwinia amylovora*) on apple and pear trees, Saskatoon berries, caneberries and non-bearing pome fruit nursery stock.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Bloomtime Biological Technical (Registration Number 28435) and Bloomtime Biological FD Biopesticide (Registration Number 28436) are currently conditionally registered in Canada. The detailed review of these products can be found under Evaluation Report [ERC2007-03](#), *Pantoea agglomerans* strain E325. The purpose of the current applications is to convert Bloomtime Biological Technical and Bloomtime Biological FD Biopesticide from conditional registration to full registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Bloomtime Biological Technical and Bloomtime Biological FD Biopesticide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value² when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

² "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

Before making a final registration decision on *Pantoea agglomerans* strain E325, the PMRA will consider all comments received from the public in response to this consultation document³. The PMRA will then publish a Registration Decision⁴ on *Pantoea agglomerans* strain E325, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is *Pantoea agglomerans* strain E325?

Pantoea agglomerans is a bacterium that is ubiquitous in nature and occurs naturally on fruit trees. As the active ingredient in Bloomtime Biological FD Biopesticide, it colonizes flowers of fruit trees and occupies sites that would otherwise be colonized by the fireblight pathogen, *Erwinia amylovora*. The growth of *Pantoea agglomerans* strain E325 on fruit blossoms suppresses the ability of *Erwinia amylovora* to grow and reach levels necessary to trigger fireblight disease development.

Health Considerations

Can Approved Uses of *Pantoea agglomerans* strain E325 Affect Human Health?

***Pantoea agglomerans* strain E325 is unlikely to affect your health when Bloomtime Biological FD Biopesticide is used according to label directions.**

Exposure to *Pantoea agglomerans* strain E325 may occur during handling and application of the product. When assessing health risks, several key factors are considered: the micro-organism's biological properties (e.g. production of toxic by-products); reports of any adverse incidents; its potential for pathogenicity, infectivity and toxicity as determined in toxicological studies; and the likely levels to which people may be exposed relative to exposures already encountered in nature to other strains of the micro-organism.

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁴ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Toxicology studies in laboratory animals describe potential health effects from large doses in hopes of identifying any potential pathogenicity, infectivity and toxicity concerns. No significant toxicity and no signs of pathogenicity or infectivity were observed when *Pantoea agglomerans* strain E325 was tested on laboratory animals.

Other strains of *Pantoea agglomerans* found in nature have been associated with minor wound infections involving punctured skin, but there is no indication that it can cause localized infections by penetrating intact skin of healthy individuals. This species of micro-organism is not a primary human pathogen and is not known to produce by-products that are harmful to humans or other animals.

Pantoea agglomerans strains produce a substance on their cell walls called lipopolysaccharide which can be shed from the cells as microscopic vesicles. If inhaled in large amounts, the lipopolysaccharide of *Pantoea agglomerans* can cause a respiratory inflammatory reaction. A condition known as respiratory hypersensitivity could therefore develop in people such as farm workers and applicators upon repeated exposure to this product. And like all bacteria, *Pantoea agglomerans* strain E325 contains other substances that can cause allergic reactions in people who are exposed repeatedly to it at high concentrations. However, these reactions can be avoided if farm workers and applicators follow label recommendations to minimize or limit exposure to Bloomtime Biological FD Biopesticide.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Pantoea agglomerans strains are common in nature and application of Bloomtime Biological FD Biopesticide to apple and pear trees is not expected to significantly increase the natural environmental background levels of this micro-organism. Few bacteria are expected to remain as residues on the fruit at harvest because the product is applied to fruit trees at bloom time, well before fruit are present. No adverse effects have been attributed to dietary exposure from natural populations of *Pantoea agglomerans*. There were also no significant toxicity and no signs of pathogenicity observed when *Pantoea agglomerans* strain E325 was administered orally to rats, and there are no reports of known mammalian toxins being produced by the bacterium. The establishment of a maximum residue limit (MRL) is therefore not required for *Pantoea agglomerans* strain E325.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit. Pesticide MRLs are established for The *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk. Furthermore, the likelihood of residues of *Pantoea agglomerans*

strain E325 contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risk are minimal to non-existent.

Occupational Risks From Handling Bloomtime Biological FD Biopesticide

Occupational risks are not of concern when Bloomtime Biological FD Biopesticide is used according to label directions, which include protective measures.

Pesticide applicators handling or applying Bloomtime Biological FD Biopesticide, and field workers re-entering orchards where trees were sprayed, can come into direct contact with *Pantoea agglomerans* strain E325 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that farm workers exposed to Bloomtime Biological FD Biopesticide must wear waterproof gloves, long-sleeved shirts, long pants, shoes, socks and a dust/mist filtering mask. Furthermore, early entry workers will be restricted from entering orchards treated with Bloomtime Biological FD Biopesticide for up to 4 hours after spraying unless they are wearing the appropriate personal protective equipment.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Bloomtime Biological FD Biopesticide Is Introduced Into the Environment?

Environmental risks are not of concern.

There are no published reports of disease associated with *Pantoea agglomerans* in wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish, algae and aquatic plants. Therefore, Bloomtime Biological FD Biopesticide is expected to present a negligible risk to these non-target organisms. Only rare cases of disease caused by wild strains of *Pantoea agglomerans* have been reported in plants, including cotton, onion, garlic, beach pea and seedlings of such conifer (evergreen) species as Douglas fir. *Pantoea agglomerans* does not affect apple or other pome fruit trees. Given the narrow range of plant species that have been infected by wild strains of this bacterium, and the limited use pattern of *Pantoea agglomerans* strain E325 in apple and pear orchards, the likelihood of non-target plants of commercial or environmental importance being impacted by Bloomtime Biological FD Biopesticide is minimal. However, as a precautionary measure to protect commercially important stands of conifer trees, the product label will instruct users to avoid spraying orchards adjacent to newly planted conifer forestry blocks.

Value Considerations

What Is the Value of Bloomtime Biological FD Biopesticide?

Bloomtime Biological FD Biopesticide is registered to suppress fireblight on apples, pears, Saskatoon berries, caneberries and non-bearing pome fruit nursery stock.

Bloomtime Biological FD Biopesticide is an alternative product to Streptomycin 17, a bactericide currently registered for fireblight control which has important resistance management issues. Bloomtime Biological FD Biopesticide is compatible with streptomycin and should be used in an integrated fireblight suppression program. Suppression of the fireblight pathogen (*Erwinia amylovora*) with Bloomtime Biological FD Biopesticide will reduce grower reliance on streptomycin.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Bloomtime Biological FD Biopesticide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**

Due to a concern with users developing allergic reactions through repeated high exposures to *Pantoea agglomerans* strain E325, anyone handling or applying Bloomtime Biological FD Biopesticide must wear waterproof gloves, long-sleeved shirt, long pants, shoes, socks and a dust/mist filtering mask. Furthermore, early-entry workers will be restricted from entering orchards treated with Bloomtime Biological FD Biopesticide for up to four hours after spraying unless the appropriate personal protective equipment is worn.

- **Environment**

As wild strains of *Pantoea agglomerans* have been known to cause gall disease in some conifer tree species, including the commercially important Douglas fir, the Bloomtime Biological FD Biopesticide label will direct users to avoid applying the product to apple or pear orchards that are adjacent to newly planted conifer forestry blocks.

Next Steps

Before making a final registration decision on *Pantoea agglomerans* strain E325, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on *Pantoea agglomerans* strain E325 (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Pantoea agglomerans strain E325

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active micro-organism	<i>Pantoea agglomerans</i> strain E325
Function	Suppress <i>Erwinia amylovora</i> populations (fireblight) on apple and pear trees
Binomial name	<i>Pantoea agglomerans</i> strain E325
Taxonomic designation	
Kingdom	Eubacteria
Phylum	Proteobacteria
Class	Gammaproteobacteria
Order	Enterobacteriales
Family	Enterobacteriaceae
Genus	<i>Pantoea</i>
Species	<i>agglomerans</i>
Strain	E325
Patent status information	United States patent number 5, 919, 446
Nominal purity of active ingredient	1×10^{10} CFU/g
Identity of relevant impurities of toxicological, environmental and/or significance	The technical grade active ingredient does not contain any impurities or micro-contaminants known to be TSMP Track 1 substances. The product must meet microbiological contaminants release standards and, except for lipopolysaccharide a component of all Gram negative bacteria, no mammalian toxins are known to be produced by <i>Pantoea agglomerans</i> strain E325.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Bloomtime Biological Technical Biopesticide

Not required. Bloomtime Biological FD Biopesticide is manufactured following a continuous manufacturing process that does not involve an intermediate stand-alone technical product.

End-Use Product—Bloomtime Biological FD Biopesticide

Property	Result
Colour	Light yellow
Odour	Not reported
Physical state	Powder
Formulation type	Live organism
Guarantee	336 g/L (limits: 325–345 g/L)
Container material and description	Aluminum foil lined pouches
Density	0.195 g/mL
pH of 1% dispersion in water	Not reported
Oxidizing or reducing action	n/a
Storage stability	27 months at between -10°C and 4°C
Explosibility	n/a

1.3 Directions for Use

Directions for use for apples and pears can be found in ERC2007-03, Section 1.3. Bloomtime Biological FD Biopesticide is applied to Saskatoon berries, caneberries and non-bearing pome fruits at a rate of 375–500 g per hectare in a minimum of 1000–2000 L of water per hectare. The first application should be made at 15–20% bloom and a second application at full bloom to petal fall.

1.4 Mode of Action

Please refer to ERC2007-03, Section 1.4, for more information on the mode of action of Bloomtime Biological FD Biopesticide.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The containing the microbial pest control agent is identified to the species level based on colony and cell morphological characteristics using conventional bacteriological media, gas chromatography of fatty acid methyl ester (GC-FAME), carbon utilization analysis (Biolog) and sequence analysis of the 16S rDNA gene.

Strain specific identification of *Pantoea agglomerans* strain E325 is achieved by its resistance to antibiotics rifampicin and streptomycin, and by polymerase chain reaction analyses using repetitive DNA sequences (“BOX elements”) and enterobacterial repetitive intergenic consensus primers.

2.2 Method for Establishment of Purity of Seed Stock

Please refer to ERC2007-03, Section 2.2, for more information on the methods for establishment of purity of seed stock for Bloomtime Biological FD Biopesticide.

2.3 Methods to Define the Content of the Micro-organism in the Manufactured Material Used for the Production of Formulated Products

Please refer to ERC2007-03, Section 2.3, for more information on the methods to define the content of the micro-organism in the manufactured material used for the production of formulated products for Bloomtime Biological FD Biopesticide.

2.4 Determination and Quantification Residues (viable or non-viable) of the Active Micro-organism and Relevant Metabolites

Please refer to ERC2007-03, Section 2.4, for more information on determination and quantification residues (viable or non-viable) of the active micro-organism and relevant metabolites in Bloomtime Biological FD Biopesticide.

2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

Microbial contamination during the manufacturing of Bloomtime Biological FD Biopesticide is minimized by sterilizing the starting and intermediate materials, and the equipment to ensure a sterile biological growth medium prior to fermentation.

Standard microbial plating procedures and commercial detection kits are used to monitor for microbiological contamination during manufacturing, and of the stored product.

2.6 Methods to Show Absence of Any Human and Mammalian Pathogens

As noted under Section 2.5, contamination is limited in Bloomtime Biological FD Biopesticide by ensuring a sterile biological growth medium prior to fermentation and conducting the entire manufacturing process, including formulating of the final product under aseptic conditions. This virtually eliminates the introduction of contaminating micro-organisms, including human pathogens. Representative data for general bacterial contamination from five batches of Bloomtime Biological FD Biopesticide verify that the end-use product is free from fecal coliform contamination, including *Escherichia coli*. This information supports the claim that the manufacturing conditions effectively limit contamination by human pathogens.

2.7 Methods to Determine Storage Stability, Shelf-life of the Micro-organism

Please refer to ERC2007-03 Section 2.7 for more information on the methods to determine storage stability and shelf-life of the micro-organism in Bloomtime Biological FD Biopesticide.

3.0 Impact on Human and Animal Health

Please refer to ERC2007-03 for a detailed summary of the toxicology review, the occupational exposure assessment and the food residue exposure assessment.

4.0 Impact on the Environment

Please refer to ERC2007-03 for a detailed summary of the environmental fate and environmental toxicology assessment.

5.0 Value

5.1 Effectiveness Against Pests

For information on the effectiveness of Bloomtime Biological FD Biopesticide against fireblight on pears and apples, refer to ERC2007-03, Section 5.1. A value assessment was not required for Saskatoon berries, caneberries and non-bearing pome fruit nursery stock because the use pattern is consistent with the registered uses for apple and pear.

5.1.1 Acceptable Efficacy Claims

Information on acceptable efficacy claims for apple and pear can be found in ERC2007-03, Section 5.1.1. In addition to suppressing fireblight on apples and pears, Bloomtime Biological FD Biopesticide is also registered for the suppression of this disease on Saskatoon berries, caneberries and non-bearing pome fruit nursery stock at 375–500 g/ha. Applications to apple and pear should be made at a rate of 375 g/ha. Applications should be made at 15–20% bloom followed by a second application at full bloom to petal fall. The higher rate should be applied to Saskatoon berries, caneberries and non-bearing pome fruit nursery stock under conditions of high disease pressure. Ensure thorough coverage of blooms.

5.2 Phytotoxicity to Target Plants

For information on phytotoxic effects on apple and pear, refer to ERC2007-03, Section 5.2.

5.3 Impact on Succeeding Crops

No information on the impact of Bloomtime Biological FD Biopesticide on succeeding crops was provided.

5.4 Economics

No market analysis was done for this submission.

5.5 Sustainability

5.5.1 Survey of Alternatives

Fireblight disease on apples and pears is currently managed by cultural practices such as removal of overwintering cankers during the dormant season and growing relatively tolerant cultivars. Active ingredients registered for fireblight control on apples and pears include streptomycin and fixed copper in the form of copper oxychloride. Copper products are registered on pears in British Columbia only. The product Apogee (prohexadione calcium) is also registered as a plant growth regulator on apple trees to reduce vegetative growth. Controlling vegetative growth will suppress fireblight infection by decreasing host susceptibility. The addition of Bloomtime Biological FD Biopesticide as a tool to suppress fireblight will provide growers with another means to protect their fruit crops and minimize losses. Bloomtime Biological FD Biopesticide will reduce the reliance of growers on streptomycin, which will help delay the development of resistance in *Erwinia amylovora* and decrease occupational exposure to this bactericide.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

For information on the compatibility of Bloomtime Biological FD Biopesticide with current management practices including integrated pest management refer to ERC2007-03, Section 5.5.2.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

For information on the occurrence or possible occurrence of development of resistance, refer to ERC2007-03, Section 5.5.3.

5.5.4 Contribution to Risk Reduction and Sustainability

For information on risk reduction and sustainability, refer to ERC2007-03, Section 5.5.4.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

In its review, the PMRA took into account the federal Toxic Substances Management Policy and followed its Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with its use were also considered, including microcontaminants in the technical product, Bloomtime Biological Technical, and formulants in the end-use product, Bloomtime Biological FD Biopesticide. The PMRA has reached the following conclusions.

Pantoea agglomerans strain E325 does not meet the Track 1 criteria because the active ingredient is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products. There are also no formulants, contaminants or impurities present in the end-use product that would meet the TSMP Track 1 criteria.

Therefore, the use of Bloomtime Biological Technical is not expected to result in the entry of Track 1 substances into the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

Bloomtime Biological Technical and the end-use product Bloomtime Biological FD Biopesticide do not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

7.0 Summary

7.1 Methods for Analysis of the Micro-organism as Manufactured

The product characterization data for both *Pantoea agglomerans* strain E325 and Bloomtime Biological FD Biopesticide are adequate to assess their safety to human health. The technical material was fully characterized, and strain-specific methods exist to identify *Pantoea agglomerans* strain E325 from other naturally occurring strains of *Pantoea agglomerans*.

The manufacturing process for Bloomtime Biological FD Biopesticide virtually eliminates the introduction of contaminating micro-organisms, including human pathogens, by ensuring a

sterile biological growth medium prior to fermentation and conducting the entire manufacturing process under aseptic conditions. Furthermore, representative data from five batches of Bloomtime Biological FD Biopesticide verify the end-use product is free from fecal coliform contamination, including *Escherichia coli*. This information supports the claim that the manufacturing conditions effectively limit contamination by human pathogens.

7.2 Human Health and Safety

Please refer to ERC2007-03 for a detailed summary of the toxicology review, the occupational exposure assessment and the food residue exposure assessment.

7.3 Environmental Risk

Please refer to ERC2007-03 for a detailed summary of the environmental fate and environmental toxicology assessment.

7.4 Value

The claim for suppression of fireblight on apples, pear, Saskatoon berry, caneberries and non-bearing pome fruit nursery stock is acceptable based on the submitted scientific data.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing conversion from conditional to full registration for the sale and use of Bloomtime Biological Technical and Bloomtime Biological FD Biopesticide containing the microbial pest control agent *Pantoea agglomerans* strain E325 to suppress fire blight (*Erwinia amylovora*) on apple and pear trees, Saskatoon berries, caneberries and non-bearing pome fruit nursery stock.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

CFU	colony forming units
DNA	deoxyribonucleic acid
g	gram
GC-FAME	gas chromatography of fatty acid methyl ester
L	litre
mg	milligram
mL	millilitre
MRL	maximum residue limit
n/a	not applicable
PMRA	Pest Management Regulatory Agency
ppm	parts per million
TSMP	Toxic Substances Management Policy

Appendix I Tables and Figures**Table 1 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported**

Applicant-proposed Label Claims	Accepted Label Claims	Unsupported Label Claims and Comments
Suppression of fireblight (<i>Erwinia amylovora</i>) on apples, pears, Saskatoon berry, caneberries and non-bearing pome fruit nursery stock	Suppression of fireblight (<i>Erwinia amylovora</i>) on apples, pears, Saskatoon berry, caneberries and non-bearing pome fruit nursery stock	n/a

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1525866	DACO: 0.8
1525877	2007. Bloomtime Biological FD Biopesticide, Product Characterization and Analysis: Manufacturing Method and Quality Assurance. Project ID 07-PRA-NAP-002. November 30, 2007. DACO: M2.8
1525881	DACO: 0.0
1605528	2008. PMRA Clarification Response. June 6, 2008.
1525539	2007. Correspondence- Applicant. December 10, 2007. DACO: 0.8
1525552	United States Department of Agriculture- Agriculture Research Service-Tree Fruit Research Laboratory. 2007. Bloomtime Biological Technical Biopesticide, Product Characterization and Analysis: Origin, Derivation, and Identification of the MPCA(s). Project ID 07-PRA-NAP-001. November 30, 2007. DACO: M2.7.1
1525557	DACO: 0.0 Index

2.0 Value

PMRA Document Number	Reference
1461141	2007-5793, PMUC cover letter and rationale, DACO: 0.8
1461142	2007-5793, Registrant letter of support and rationale, DACO: 0.8.3