UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 27, 2001

Ms. Charlotte A. Sanson
BASF Corporation
P.O. Box 13528
Research Triangle Park, NC 27709-3528

Subject: Pyraclostrobin Joint Review Decision, Level C Deficiencies Review (PMRA), and scope of the Joint Review
BAS 500F Manufacturer's Use Product (Pyraclostrobin Technical Fungicide)
PMRA Sub. No. 2000-0799; EPA File Symbol 7969-RIL
Headline™ Fungicide
PMRA Sub. No. 2000-0800; EPA File Symbol 7969-RIA
Cabrio™ EG
PMRA Sub. No. 2000-3388; EPA File Symbol 7969-RIT

Dear Ms. Sanson:

The United States Environmental Protection Agency (EPA) is the lead agency, with the Pest Management Regulatory Agency (PMRA) of Canada, for the NAFTA Joint Review of the data submitted by BASF Corporation in support of the initial registration of the fungicide pyraclostrobin (BAS 500 F). As part of the NAFTA Joint Review Program described in the document entitled "Procedures for Joint Review Applications for Chemical Pesticides", after PMRA reviews the submission for completeness and consistency with the NAFTA Joint Review procedures, they perform an in-depth deficiency review of all data that they will later review in detail, they review the efficacy data, and EPA and PMRA compare the labeling, revised by the company after the initial deficiency review, if necessary, of the products proposed for registration as a result of the Joint Review.

The submissions to register Pyraclostrobin Technical Product and associated end-use products and to establish various Import Maximum Residue Limits (MRLs) or Tolerances were received by the EPA and the PMRA in April, 2000. The uses were awarded reduced-risk status in April, 2000 by the EPA. Additional information, including revised labels and additional data, was received by the PMRA in May and June, 2000, and by EPA from late September, 2000, to the present. These submissions have been proposed by BASF as candidates for joint review between the EPA and the PMRA.

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One of the goals of the NAFTA Joint Review Program is to avoid or eliminate trade irritants so as to allow all North American growers equal access to alternative pesticide tools. The criteria for acceptance into the joint review program include common formulations, uses, pests, and use patterns. With pyraclostrobin, these criteria for NAFTA Joint Review are now met because two formulated products that are proposed for registration in both the United States and Canada, Headline™ EC Fungicide and Cabrio™ EG Fungicide, have formulations that are similar and labeling that contains crop sites, pests, and use patterns that are similar for crops that are grown in both countries. Headline™ EC Fungicide is proposed for use on the tuberous and corm vegetables (except potatoes) group, citrus fruits group, and peanut in the United States but not in Canada. Cabrio™ EG Fungicide is proposed for use on pistachios and the tree nuts group in the United States but not in Canada. These uses, which are not common to both countries, will be reviewed by the United States only. The other sites on the labels of these two proposed products will be included in the joint review, with completion scheduled for December 31, 2001. Review of the technical product, BAS 500 F Manufacturer's Use Product, will also be a part of the subject joint review. The proposed pyraclostrobin product Insignia™ Fungicide, which is labeled for use only on turf, has been determined not to be eligible for this joint review because the intention to have it be a part of this joint review was not known until after the process had begun and it is also unlikely that enough manpower is available to complete review of the turf use, in addition to the crop uses, by the scheduled December 31, 2001 joint review completion date. It is anticipated that completion of the review of the pyraclostrobin turf use will be completed during the fourth quarter of 2002.

PMRA's review of the data submitted in support of the registration of the pyraclostrobin products, including product chemistry, toxicology, exposure, metabolism/ toxicokinetics, environmental chemistry and fate, environmental toxicology, and efficacy data, have, however, turned up a number of deficiencies that must be addressed before review of these data can be completed. A document detailing these deficiencies, entitled "Deficiency Review NOTES [Pyraclostrobin -Headline-Cabrio- PMRA Sub. Nos. 2000-0799, 2000-0800, 2000-3388]" is attached. In addition, review of the proposed labeling in the attached document entitled "Result of review of Headline data" detail one deficiency and also one aspect of the labeling where either data or a science based rationale are required. In addition, the EPA review has identified the following deficiencies. The two Tier I terrestrial plant studies, "BAS 500 00 F: Tier I - Seedling Emergence Nontarget Phytotoxicity Study" (MRID No. 45118713) and "BAS 00 500 F: Tier I - Vegetative Vigor Nontarget Phytotoxicity Study" (MRID No. 45118714), were performed with an end-use product and not a technical grade active ingredient (TGAI), as is required, and must be repeated. In addition, for each ecotoxicity study the substance that was tested must be clearly identified, including the correct CAS Number. Finally, we note that the Estuarine/Marine Fish Early-life Stage study is still outstanding and must be submitted.

As part of the harmonized review requirements, identical packages must be submitted to the Agencies. The Agencies will retain your submission, however, BASF must satisfactorily address the deficiencies outlined in this letter and attachments immediately. As discussed with BASF the week of April 23rd, we anticipate the submission of these data to EPA and PMRA by n April 27th. Please submit identical and complete response packages to each country.

If you have any questions regarding the review of these submissions, please contact John Bazuin of the EPA at (703) 305-7381 or Richard McDonell of the PMRA at (613) 736-3582.

Sincerely,

/s/

Cynthia Giles-Parker
Product Manager (22)
Fungicide Branch
Registration Division (7505C)

Attachments

cc w/o attachments: Patty Vandierendonk, BASF Canada Inc.;Terri Stowe, EPA;Richard McDonell, PMRA; Lisa Lange, PMRA;

Attachment 1:
Deficiency Review NOTES [Pyraclostrobin-Headline-Cabrio- PMRA Sub. Nos. 2000-0799, 2000-0800, 2000-3388]

Please note, in lieu of submitting the following requests for data, you may submit scientific rationales to waive the data. Upon receiving the rationales, the suitability of any waiver will be assessed during a full evaluation.

During the full evaluation, further clarification of minor information points may be required, but no additional data can be requested/accepted during full evaluation. Once all the review streams are complete and the results of one or more reviews indicate that further data are required, or if other issues are identified, you will be informed in a letter of evaluation deficiency. (*Management of Submissions Policy*, Regulatory Proposal, Pro-96-01).

PART 1 LABEL

DACO: **1.0**
Title: **Label**

Deficiencies: None

Required data: **None**

PART 2 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT

DACO **2.1 -2.14**
Title: **Chemistry Requirement**

Deficiencies: None

Required data: **None for Sub. No. 2000-0799 (pyrclostrobin TGAI)**

PART 3 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF MANUFACTURING CONCENTRATES AND END-USE PRODUCTS FORMULATED FROM REGISTERED TECHNICAL GRADE OF ACTIVE INGREDIENTS OR INTEGRATED SYSTEM PRODUCTS

DACO: **3.1 - 3.7**
Title: **Chemistry Requirement**

Deficiencies: None

Required data: **None for Sub. No. 2000-0800 (Headline EC) and 2000-3388 (Cabrio)**

PART 4 TOXICOLOGY

DACO: **4.1 - 4.8**
Title: **Toxicology**

DACO 4.3.2-2 **Subchronic Oral Toxicity Study in Beagle Dogs; Administration in the Diet for 3 Months.**

Deficiencies: Page 25 contains the text: "Due to technical reasons food efficiency values in the specific tables are given only up to study day 84." No technical reasons were provided for not conducting the study for 90 days.

Requested data: **(For Sub. No. 2000-0799; pyraclostrobin TGAI)**

1) Provide the technical reasons for not continuing the study for 90 d.
2) Can the data for the last one week be provided along with applicable statistical analysis?

No required data for Sub. No. 2000-0800 (Headline EC) and 2000-3388 (Cabrio)

PART 5 EXPOSURE (OCCUPATIONAL AND/OR BYSTANDER)

DACO: **5.2**
Title: **Use Description/Scenario**

Notes: Report Title: Use Site Description for Attitude (Pyraclostrobin) Use in Cereals, Lentils, Field Peas, Sugar Beets and Potatoes (Reg. Doc. 2000/90009).

A comprehensive use site description/scenario (including both application and post application activities) was submitted for the proposed uses of Headline EC Fungicide (the only exception being grasses grown for seed). Re-entry activities and the extent and degree of these re-entry activities were based on data from the Agricultural Reentry Task Force SCOPE survey, which was included in the report.

No use site description/scenario was provided for the proposed uses of Cabrio EG Fungicide. Given the extensive proposed use of Cabrio EG

Fungicide, the applicant should provide use site descriptions of at least one representative crop in each of the proposed group (eg., bulb vegetables). The representative crop should be a major crop produced in both Canada and the U.S., and application and post-application methods in cultivating the crop should be typical and representative of crops in that group.

Clarification: Clarification is required on the following items:

The applicant should provide use site descriptions of at least one representative crop in each of the proposed group (eg., bulb vegetables) for the uses of Cabrio EG Fungicide. The representative crop should be a major crop produced in both Canada and the U.S., and application and post-application methods in cultivating the crop should be typical and representative of crops in that group.

DACO: **5.3**
Title: **Pesticides Handlers Exposure Database Assessment**

Notes: Report Title: Exposure and Margin of Safety Assessments for Mixing, Loading and Applying EC and WG Formulations of BAS 500 F (Reg. Doc. 2000/5089).

PHED is adequate to characterize mixer/loader/applicator exposure for handlers of Headline EC Fungicide and Cabrio EG Fungicide. The specific inputs proposed by the applicant will be evaluated during the Level D evaluation. The applicant should note that the same individual frequently conducts the mix/load function and the applicator function and these exposures will therefore be summed.

The applicant used PHED to derive estimates of handler exposure during application to turf using hand-held equipment. There are limitations to the PHED applicator subset for hand-held wands (e.g., replicate quality, quantity). The applicant is a member of the Outdoor Residential Exposure Task Force (ORETF) and, if estimates of handler exposure during application to turf using hand held equipment are required, ORETF data will be used.

Required Data: None

DACO: **5.6/5.7**
Title: **Post Application**

Notes: Report Title: Reentry Exposure and Margin of Safety Assessments Following the Application of EC and WG

Formulations of BAS 500 F. (Reg. Doc. 2000 5130).

Estimates of worker re-entry exposure from agricultural uses are derived in this report. The general approach proposed by the applicant is acceptable. During the Level D evaluation the results from the dislodgeable residue studies will be coupled with an appropriate transfer coefficient to derive estimates of dermal deposition. Since the applicant is a member of the Agricultural Reentry Task Force (ARTF), transfer coefficients derived from ARTF studies may be used when appropriate.

Required Data: None

DACO: **5.8**
Title: **Dermal Absorption**

Notes: Report Title: 14C-BAS 500 F - Study of the Dermal Absorption in Rats (Reg. Doc. 1999/10716)

The applicability of the study results to the proposed end-use formulations will be determined during the Level D evaluation.

The applicant should note that the study design did not permit fate of skin bound residues and these will, therefore, be considered as part of the absorbed dose.

Clarification: Clarification is required on the following items:

Full ingredient disclosure of the commercial formulation (i.e., BAS 501 00 F) used as the vehicle is required to determine applicability to the proposed end-use formulations

Section 3.10.1 of the Final Report refers to Standard Operation Procedures which provide details of preparation of samples and measurement of radioactivity. A copy of these Procedures is required

Residues on the protective covers were uniformly high and the study investigator should clarify whether the gauze was in direct contact with the test material or the skin.

Information on the limits of detection/quantification in the biological matrices analysed is required.

DACO: **5.9**

Title: **Dislodgeable Residue Study in Grapes**

Notes: Report Title: BAS 500 00 F Dislodgeable Foliar Residue Study in Grapes (Reg. Doc. 1999/5090).

This study was conducted at three locations: California, Washington State and Pennsylvania. The applicability of the U.S. sites to Canadian climatic conditions will be evaluated during the Level D evaluation.

Clarification: Clarification is required on the following items:

The use of the "spreader-stickers" used at the sites should be further described.

The irrigation practices in California and Washington State should be further described. Specifically, what is the extent of water foliar contact by the different methods used?

The method of determining the actual application rate should be clarified. Was actual deposition of the active ingredient on the foliage measured? Were tank mix samples taken?

The sampling procedure of the foliage is unclear (eg., directed or non-directed and what parts of the foliage were sampled). Since the study is based on Series 875 - Occupational and Residential Exposure Test Guidelines, it is assumed that the sampling procedure is consistent with these guidelines. The applicant should verify this.

DACO: **5.9**
Title: **Dislodgeable Residue Study in Peanuts**

Notes: Report Title: BAS 500 00 F Dislodgeable Foliar Residue Study in Peanuts (Reg. Doc. 1999/5091).

Although peanuts are not produced in Canada, this study will be evaluated by PMRA since the product is proposed for use on peanuts in the U.S.

Clarification: Clarification is required on the following items:

Pages 25 and 27 of the report should be re-copied and re-submitted, since the header row on the tables are illegible

The method of determining the actual application rate should be clarified.

Was actual deposition of the active ingredient on the foliage measured? Were tank mix samples taken?

The sampling procedure of the foliage is unclear (eg., directed or non-directed and what parts of the foliage were sampled). Since the study is based on Series 875 - Occupational and Residential Exposure Test Guidelines, it is assumed that the sampling procedure is consistent with these guidelines. The applicant should verify this.

DACO: **5.9**
Title: **Dislodgeable Residue Study in Strawberries**

Notes: **Report Title:** **BAS 500 DIF (BAS 500 02F) Dislodgeable Foliar Residue Study in Strawberries (Reg. Doc. 1999/5192).**

This study was conducted at three locations: North Carolina, California and Oregon. In order to assess the dissipation of the active and to assess the relevance of the test sites to strawberry-growing regions of Canada, more extensive meteorological data at the time that the study was conducted is required. In addition, further information is required to verify that the equipment was calibrated and the actual application rate or deposition rate measured.

Clarification: Clarification is required on the following items:

More extensive meteorological data at the study sites are required. Specifically, rainfall at the test sites during the application and dissipation periods, and temperature and humidity during the dissipation period.

The type and extent of irrigation at the test sites should be described and its possible effect on dislodgeable residues.

Was the actual application rate determined? If so, describe the method of determination. Was actual deposition of the active ingredient on the foliage measured? Were tank mix samples taken?

Provide a summary of the calibration data.

The sampling procedure of the foliage is unclear (eg., directed or non-directed and what parts of the foliage were sampled). Since the study is based on Series 875 - Occupational and Residential Exposure Test Guidelines, it is assumed that the sampling procedure is consistent with

these guidelines. The applicant should verify this.

DACO: 5.9
Title: **Dislodgeable Residue Study in Peaches**

Notes: Report Title: BAS 500 DIF (BAS 500 02F) Dislodgeable Foliar Residue Study in Peaches (Reg. Doc. 1999/5190).

This study was conducted at three locations: California, Georgia and Pennsylvania. In order to assess the dissipation of the active and to assess the relevance of the test sites to peach-growing regions of Canada, more extensive meteorological data at the time that the study was conducted is required. In addition, further information is required to verify that the equipment was calibrated and the actual application rate or deposition rate measured.

Clarification: Clarification is required on the following items:

More extensive meteorological data at the study sites are required. Specifically, rainfall at the test sites during the application and dissipation periods, and temperature and humidity during the dissipation period.

The type and extent of irrigation at the test sites should be described and its possible effect on dislodgeable residues.

Was the actual application rate determined? If so, describe the method of determination. Was actual deposition of the active ingredient on the foliage measured? Were tank mix samples taken?

Provide a summary of the calibration data.

The sampling procedure of the foliage is unclear (eg., directed or non-directed and what parts of the foliage were sampled). Since the study is based on Series 875 - Occupational and Residential Exposure Test Guidelines, it is assumed that the sampling procedure is consistent with these guidelines. The applicant should verify this.

DACO: 5.9
Title: **Dislodgeable Residue Study in Grapes Comparing Two Formulations**

Notes: Report Title: Dislodgeable Foliar Residue Study in Grapes Comparing Two Formulations of BAS 500 F. (Reg.

Doc. 1999/5194).

This study was conducted at three locations: California, Washington State and Pennsylvania. In order to assess the dissipation of the active and to assess the relevance of the test sites to growing regions of Canada, more extensive meteorological data at the time that the study was conducted is required. In addition, further information is required to verify that the equipment was calibrated and the actual application rate or deposition rate measured.

Clarification: Clarification is required on the following items:

Page 28 of the report is missing and should be submitted

More extensive meteorological data at the study sites are required. Specifically, rainfall at the test sites during the application and dissipation periods, and temperature and humidity during the dissipation period.

The type and extent of irrigation at the test sites should be described and its possible effect on dislodgeable residues.

Was the actual application rate determined? If so, describe the method of determination. Was actual deposition of the active ingredient on the foliage measured? Were tank mix samples taken?

Provide a summary of the calibration data.

The sampling procedure of the foliage is unclear (eg., directed or non-directed and what parts of the foliage were sampled). Since the study is based on Series 875 - Occupational and Residential Exposure Test Guidelines, it is assumed that the sampling procedure is consistent with these guidelines. The applicant should verify this.

PART 6 METABOLISM/TOXICOKINETICS STUDIES

DACO: **6.1 - 6.4**
Title: **Metabolism/Toxicokinetics Studies**

Comments: PMRA did not do a Level C review for this part. EPA is the LEAD Reviewer for Part 6.

PART 7 FOOD, FEED AND TOBACCO RESIDUE STUDIES

DACO: 7.1 - 7.8
Title: **Food, Feed and Tobacco residue Studies**

Comments: PMRA did not do a Level C review for this part. EPA is the LEAD Reviewer for Part 7.

PART 8 ENVIRONMENTAL CHEMISTRY AND FATE

DACO: 8.1 - 8.6
Title: **Environmental Chemistry and Fate**

DACO 8.2.2 **Analytical Methodology** (Sub. No. 2000-0799)

Deficiencies The company has provided analytical methods for the determination of the parent compound and its metabolites in environmental samples. All provided methods were fully validated and were assessed to be valid and acceptable. However, only some of the metabolites were analysed in particular samples.

Required Data What was the rationale used when choosing the metabolites to be analysed.

DACO 8.2.3.2
Title: **Hydrolysis** (Sub. No. 2000-0799)

Deficiencies: The submitted report (Reg. Doc. 1999/10060) did not have data to support the Registrant's claim that the pH, temperature, and sterility were maintained. In addition, the author did not indicate whether the studies were carried out in darkness.

Required data: 1) data on the periodical measurement of pH, temperature, and sterility.
2) indicate whether the study was conducted in darkness.

DACO 8.2.3.3.2
Title: **Phototransformation in water** (Sub. No. 2000-0799)

Deficiencies: The applicant stated that there was no transformation of the parent in the dark samples. No data or chromatograms, however, were submitted to support this claim. The report (Reg. Doc. 1999/11286) had only the total ^{14}C content at different sampling times. In addition, the report did not have data to support the claim that the pH, temperature, and sterility were

maintained.

Required data: 1) data or chromatograms showing that most of the applied radioactivity was present as the parent compound at different sampling times, i.e., information on the % distribution of parent and transformation products (if any) at different sampling times.

2) data on the periodical measurement of pH, temperature, and sterility.

DACO 8.2.3.4.2
Title: **Biotransformation -Aerobic soil** (Sub. No. 2000-0799)

Deficiencies: The submitted reports (Reg. Doc. 1999/10090; 1998/11201) did not clearly indicate the number of replicate samples used at each sampling time.

Required data 1) indicate the number of replicate samples used at each sampling time.
2) submit the % distribution of parent and transformation products for each replicate samples at different sampling intervals.

DACO 8.2.3.4.4
Title: **Biotransformation -Anaerobic soil** (Sub. No. 2000-0799)

Deficiencies: The submitted reports (Reg. Doc. 1999/11103; 1999/10079) had mean values showing the % distribution of parent and transformation products. Results of the replicate analysis were not submitted.

Required data: Submit the % distribution of parent and transformation products for each replicate samples at different sampling times

DACO 8.2.3.5.2
Title: **Biotransformation -Aerobic water** (Sub. No. 2000-0799)

Deficiencies: The study (Report No. 1999-11241) was carried out with a sediment:water of 1:2.4 (v/v). The redox measurements indicated that the water was aerobic and the sediment was anaerobic. Please note that the depth at which the redox measurements were taken in sediment was not reported. In addition, results of the replicate analysis were not reported. The second study (1999-11791) is considered as a supplementary information for this data requirement because the study was done under light. The need for a separate study will be assessed at Level D review.

Required data: 1) indicate the depth in sediment at which the redox measurements were made.

2) submit the % distribution of parent and transformation products for each replicate samples at different sampling times.

DACO 8.2.4.2
Title: **Adsorption/desorption** (Sub. No. 2000-0799)

Deficiencies: Only mean values were reported. No replicate values were submitted. Also, the preliminary review indicated that some of the transformation products were adsorbed to the walls of the test vessels. The influence of this adsorption to the walls will be assessed during the Level D review.

Required data: Provide the replicate values for all adsorption studies submitted under this DACO No.

DACO 8.3.2.
Title: **Terrestrial Field study** (Sub. No. 2000-0800; 2000-3377; 2000-3388)

Deficiencies: The preliminary review indicated low zero-time and storage recovery values in many sites. Also, some of the field studies were conducted using BCH 8900S as adjuvant. The significance of low recoveries will be assessed during the Level D review.

Required data: None

PART 9 ENVIRONMENTAL TOXICOLOGY

DACO: **9.1 - 9.9**
Title: **Environmental toxicology**

Comments: PMRA did not do a Level C review for this part. EPA is the LEAD Reviewer for Part 9.

PART 10 VALUE

DACO: **10.1 - 10.6**
Title: **Efficacy studies/adverse effects on use site/sustainability**

Headline; Sub. No. 2000-0800 (see attachment Headline Efficacy Review.wpd)

DACO: **10.2.3.3 (Headline; Sub No. 2000-0800)**
Title: **Efficacy: Small scale trials - Aerial application**

Deficiencies: The use of lower application volume (25 and 50 L of water/ha) to simulate aerial application is a questionable extrapolation.

Required Data: Provide bridging aerial application data or a science based rationale to support the use of aerial application.

Cabrio; Sub. No. 2000-3388

DACO: **10.2.3.3**
Title: **Efficacy: Small scale trials on strawberries**

Deficiencies: Application schedule for trial 1 and 5 was not provided.
Summary Tables for trial 6 and 7 were not provided.
No data is available for common leaf spot.

Required data: Provide application schedule for trial 1 and 5.
Provide summary Tables for trial 6 and 7.
Provide efficacy data or a good science based rationale for control of common leaf spot.

DACO: **10.2.3.3**
Title: **Efficacy: Small scale trials on the berry group**

Deficiencies: Data only available on blueberries.
No data is available for Botrytis grey mold, powdery mildew and rust.

Required data: Provide bridging data on other crops of the berry group if it is available or a science based rationale.
Provide efficacy data or a good science based rationale for control of Botrytis grey mold, powdery mildew and rust.

DACO: **10.2.3.3**
Title: **Efficacy: Small scale trials on stone fruits**

Deficiencies: Statistical analysis was not available for trials 4, 5, 6, 7, 8, 9, 10, 11, 12, and 15.
Only 2 trials each were provided for powdery mildew, anthracnose and 3 trials for scab.

Required data: Provide statistical analysis available for trials 4, 5, 6, 7, 8, 9, 10, 11, 12 and 15.
Provide new trials supporting control of powdery mildew, anthracnose

and scab or a good science based rationale.

DACO:	**10.2.3.3**
Title:	**Efficacy: Small scale trials on grapes**
Deficiencies:	Application schedule was not available for trial 7, 11, 15 and 17. Statistical analysis was not available for trial 14, 20, 21 and 22.
Required data:	Provide application schedule for trial 7, 11, 15 and 17. Provide statistical analysis for trial 14, 20, 21 and 22.

DACO:	**10.2.3.3**
Title:	**Efficacy: Small scale trials on bulb vegetables**
Deficiencies:	Application schedule was not available for trial 8. Statistical analysis was not available for trial 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21 and 26.
Required data:	Provide application schedule for trial 8. Provide statistical analysis for trial 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21 and 26.

DACO:	**10.2.3.3**
Title:	**Efficacy: Small scale trials on cucurbits**
Deficiencies:	Statistical analysis was not available for trial 1, 11, 16, 27, 33, 48 and 49. No data was available for Cercospora leaf spot and Michrodochium blight.
Required data:	Provide application schedule for trial 1, 11, 16, 27, 33, 48 and 49. Provide new trials supporting control of Cercospora leaf spot and Michrodochium blight or a good science based rationale.

DACO:	**10.2.3.3**
Title:	**Efficacy: Small scale trials on fruiting vegetables**
Deficiencies:	Application schedules were not available for trial 14, 15, 16, 17 and 18.. Statistical analysis was not available for trial 3, 21, 22, 23, 27, 28, 29, 30, 31, 32 and 33.

Required data:	Provide application schedule for trial 14, 15, 16, 17 and 18.. Provide statistical analysis for trial 3, 21, 22, 23, 27, 28, 29, 30, 31, 32 and 33.
DACO:	**10.2.3.3**
Title:	**Efficacy: Small scale trials on root vegetables**
Deficiencies:	Application schedule was not available for trial 9. Statistical analysis was not available for trial 5, 11, 12 and 13.
Required data:	Provide application schedule for trial 9. Provide statistical analysis for trial 5, 11, 12 and 13.
General comment:	***A rationale is needed to extend the control claim for a given disease from a crop where trials are available to a different crop in the same crop grouping when no bridging data are available.***

Attachment 1:
For letter of (PMRA) screening acceptance dated
Re: Pyraclostrobin Technical Fungicide (pyraclostrobin); Sub. No. 2000-0799

PEST MANAGEMENT REGULATORY AGENCY
DATA REQUIREMENTS FOR
USE SITE CATEGORIES (USCs) # 13/14:Terrestrial Feed/Food Crops - TGAI

Data Code	Title	Data required	Conditions	Volume No and Pages
0	Index	R		hard and electronic copies
1	Label	R.		hard and electronic copies
	Chemistry requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product.			
2.1	Applicant's Name and Office Address	R	Reg. Doc. 2000-90008	1 of 1; pg. 1
2.2	Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address	R	"	1 of 1; pg. 1
2.3	Product Trade Name	R	"	1 of 1; 2 pp.
2.3.1	Other Names	R	"	1 of 1; 2 pp.
2.4	Common Name	R	"	1 of 1; pg. 2
2.5	Chemical Name	R	"	"
2.6	Chemical Abstracts Registry Number	R	"	"
2.7	Structural Formula	R	"	"
2.8	Molecular Formula	R	"	"
2.9	Molecular Weight	R	"	"
2.11	**Manufacturing Methods for the TGAI**			
2.11.1	Manufacturing Summary	R	Reg. Doc. 2000/90026	1 of 1; 2 pp.
2.11.2	Description of Starting Materials	R	Reg. Doc. 2000/5110	1 of 1; 147 pp.
2.11.3	Detailed Production Process Description	R	"	Refer to 2.11.2
2.11.4	Discussion of Formation of Impurities	R	"	Refer to 2.11.2
2.12	Specifications			
2.12.1	Establishing Certified Limits	R	Reg. Doc. 2000/5116	1 of 1; 185 pp.
2.12.2	Control Product Specification Form	R		Refer to Sub., 3 pp.
2.13	Preliminary Analysis			
2.13.1	Methodology/Validation	R	Reg. Doc. 2000/5116 (cross reference: pgs. 62-78 of 178)	Refer to 2.12.1

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Data Code	Title	Data required	Conditions	Volume No and Pages
2.13.2	Confirmation of Identity	R	**Reg. Doc. 2000-5116 (cross reference: pgs. 1 - 49 of 178)**	Refer to 12.2.1
2.13.3	Batch Data	R	**Reg. Doc. 2000-5116 (cross reference: pg. 21 of 178)**	Refer to 12.2.1
2.13.4	Impurities of Toxicological Concern	CR	If applicable	-
2.14	**Chemical and Physical Properties**			
2.14.1	Colour	R	**Reg. Doc. 1998/10768**	1 of 1; 15 pp.
2.14.2	Physical State	R	**Reg. Doc. 1998/10768 (pg. 8)**	Refer to 2.14.1
2.14.3	Odour	R	**Reg. Doc. 1998/10768 (pg. 9)**	Refer to 2.14.1
2.14.4	Melting Point / Melting Range	R	Solid at room temperature. **Reg. Doc. 1996-10327**	1 of 1; 11 pp.
2.14.5	Boiling Point / Boiling Range	R	Liquid at room temperature.	-
2.14.6	Density or Specific Gravity	R	**Reg. Doc. 1998/10768 (pg. 13)**	Refer to 2.14.1
2.14.7	Water Solubility (mg/L)	R	See 8.2.1 **Reg. Docs. 1999/10110 + 1999/10120 + 1999/10121 + 1999/10810 + 1996/10939 + 1997/10693**	1 of 1; 6 studies: 16 + 16 + 16 + 11 + 22 + 16 pp.
2.14.8	Solvent Solubility (mg/L)	R	**Reg. Doc. 1996/10954**	1 of 1; 18 pp.
2.14.9	Vapour Pressure	R	See 8.2.1 **Reg. Doc. 1997/10646**	1 of 1; 13 pp.
2.14.10	Dissociation Constant	R	See 8.2.1 **Reg. Doc. 2000/90023**	1 of 1; refer to Co. note
2.14.11	Octanol/Water Partition Coefficient	R	See 8.2.1 **Reg. Doc. 1996/10383**	1 of 1; 19 pp.
2.14.12	UV/Visible Absorption Spectra	R	See 8.2.1 **Reg. Doc. 1996/10955**	1 of 1; 14 pp.
2.14.13	Stability (Temperature, Metals)	R	**Reg. Docs. 1999/5114 + 1998/10793**	1 of 1; 2 studies: 13 + 14 pp.
2.14.14	Storage Stability Data	CR	Required for integrated system products; **Reg. Doc. 2000/1000267**	1 of 1; 12 pp.
2.15	Sample(s) of Analytical Standards and ROC	R	**Reg. Doc. 2000/90043**	1 of 1; refer to Co. note
2.16	Other Studies/Data/Reports	CR	If available	-
4	**Toxicology**			
4.1	Summaries - Toxicology Profile	R	**Reg. Doc. 2000/90032**	1 of 16; 93 pp.

Data Code	Title	Data required	Conditions	Volume No and Pages
4.2	**Acute Studies**			
4.2.1	Acute Oral	R	**Reg. Doc. 1998/10965**	1 of 16; 23 pp.
4.2.2	Acute Dermal	R	**Reg. Doc. 1998/10966**	1 of 16; 23 pp.
4.2.3	Acute Inhalation	R	**Reg. Doc. 1997/11472**	1 of 16; 33 pp.
4.2.4	Primary Eye Irritation	R	**Reg. Doc. 1998/10963**	1 of 16; 18 pp.
4.2.5	Primary Dermal Irritation	R	**Reg. Doc. 1998/10959**	1 of 16; 17 pp.
4.2.6	Dermal Sensitization	R	**Reg. Doc. 1998/10964**	1 of 16; 50 pp.
4.3	**Short-Term Studies**			
4.3.1	Short-Term Oral (90 day) (rodent)	R	Could be a satellite study of 4.4.1 **Reg. Docs. 1998/11345 + 1999/11900 + 1999/10195 + 1999/11899 + 1999/11870**	1 +2 of 16; 5 studies; 360 + 9 + 358 + 5 + 285
4.3.2	Short-Term Oral (6-12 month) (Non-rodent, e.g. dog)	R	**Reg. Docs. 1999/11677 + 1999/11678**	3 + 4 of 16; 2 studies: 770 + 443
4.3.6	Short-Term Inhalation (90 day)	CR	Depending on use pattern and volatility	-
4.4	**Long-Term Studies**			
4.4.1	Chronic (rodent)	R	4.4.1 and 4.4.2 could be combined as 4.4.4 **Reg. Doc. 1999/11672**	5 + 6 of 16; 1139 pp.
4.4.2	Oncogenicity (rodent species 1)	R	See 4.4.1 **Reg. Doc. 1999/11871**	7 of 16; 846 pp.
4.4.3	Oncogenicity (rodent species 2)	R	**Reg. Doc. 1999/11868**	8 - 10 of 16; 1524 pp.
4.4.4	Combined Chronic/Oncogenicity (rodent)	CR	See 4.4.1	-
4.5	**Special Studies**			
4.5.1	Multigeneration-Reproduction (rodent)	R	**Reg. Doc. 1999/11869**	11 + 12 of 16; 953 pp.
4.5.2	Teratogenicity (rodent)	R	**Reg. Doc. 1999/11511**	13 of 16; 283 pp.
4.5.3	Teratogenicity (non-rodent)	R	**Reg. Doc. 1999/11512**	13 of 16; 264 pp.
4.5.4	Genotoxicity: Microbial Point Mutation	CR	One of 4.5.4 or 4.5.5 is required **Reg. Docs. 1997/10973 + 1998/10235**	13 of 16; 2 studies: 36 pp.
4.5.5	Genotoxicity: Mammalian (cell) Point Mutation	CR	See 4.5.4	-

Data Code	Title	Data required	Conditions	Volume No and Pages
4.5.6	Genotoxicity: *In vitro* Chromosomal Aberration	R	**Reg. Docs. 1999/11403 + 1998/11421 + 2000/1000270 + 1998/11422 + 2000/1000279**	14 of 16; 5 studies: 88 + 44 + 3 + 56 + 3pp.
4.5.7	Genotoxicity: *In vivo* Chromosomal Aberration	R	**Reg. Doc. 1998/10460**	14 of 16; 53 pp.
4.5.8	Other Genotoxicity Studies	CR	Depending on results from 4.5.4 to 4.5.7	-
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animal)	R	**Reg. Docs. 1998/10997 + 1999/11781**	14 of 16; 2 studies: 83 + 212 pp.
4.5.10	Acute Delayed Neurotoxicity	CR	Required if there is neurotoxic potential	-
4.5.11	Short-Term Neurotoxicity	CR	See 4.5.10 **Reg. Docs. 1999/11329 + 1999/11111**	15 + 16 of 16; 2 studies: 499 + 356 pp.
4.8	Other Studies/Data/Reports	CR	If available	-
6	**Metabolism/Toxicokinetics Studies (TGAI or EP)**			
6.1	Summaries	R	**Reg. Doc. 2000/90033**	1 of 2; 44 pp.
6.2	Livestock	R	**Reg. Docs. 2000/1000004 + 1999/11480 + 1998/10636 + 1998/10637**	1 of 2; 4 studies: 216 + 131 + 63 + 46 pp.
6.3	Plants	R	**Reg. Docs. 2000/90025 + 1999/11419 + 1998/10988 + 1999/11137 + 1998/11205**	2 of 2; 5 studies; 7 + 175 (potato) + 91 (grapes) + 216 (wheat) +28 (wheat)
6.4	Other Studies/Data/Reports	CR	If available	-
8	**Environmental Chemistry and Fate**			
8.1	Summaries	R	**Reg. Doc. 2000/90034 + 2000/90036**	1 of 3; 2 studies: 70 + 28 pp.
8.2	**Laboratory Studies**			
8.2.1	Summary of Physicochemical Properties to Include, Solubility in Water, Vapour Pressure, Dissociation Constant, Octanol: Water Partition Coefficient, UV-Visible Absorption (See part 2) (TGAI)	R	Data submitted under 2.14.7; 2.14.9; 2.14.10; 2.14.11; and 2.14.13 **BCI # 2000-90022**	1 of 3; 1 pg.
8.2.2	**Analytical Methodology (parent compound and transformation products)**			
8.2.2.1	Soil	R	**Reg. Docs. 1999/5087 + 1999/5089 + 1999/10076 + 1998/10657**	1 of 3; 4 studies: 118 + 57 + 57 + 41 pp.

Data Code	Title	Data required	Conditions	Volume No and Pages
8.2.2.2	Sediment	R	**cross reference to Reg. Doc. 1999/5087**	Refer to 8.2.2.1
8.2.2.3	Water	R	**Reg. Docs. 1998/11352 + 1999/10701 + 1998/11182**	1 of 3; 3 studies: 9 + 60 = 33 pp.
8.2.2.4	Biota	R	**Reg. Doc. 2000/90037**	1of 3; 23 pp.
8.2.3	**Laboratory Studies of Transformation**			
8.2.3.1	Summary	R	**cross reference to Reg. Doc. 2000/90034 (3 - 20; 47 -61 pp.)**	Refer to 8.1
8.2.3.2	Hydrolysis	R	**Reg. Docs. 1998/10480 + 1999/10060**	1 of 3; 2 studies: 20 + 43 pp.
8.2.3.3	**Phototransformation**			
8.2.3.3.1	Soil	R	**Reg. Doc. 1999/11300**	2 of 3; 71 pp.
8.2.3.3.2	Water	R	**Reg. Doc. 1999/11286**	2 of 3; 66 pp.
8.2.3.3.3	Air	CR	If volatilization is indicated by vapour pressure or Henry's Law Constant	-
8.2.3.4	**Biotransformation in Soil**			
8.2.3.4.2	Aerobic Soil 20°-30°C	R	**Reg. Docs. 1999/10090 + 1998/11201 + 2000/5050**	2 of 3; 3 studies: 71 + 69 + 60 pp.
8.2.3.4.4	Anaerobic Soil (Flooded) 20°-30°C	CR	Can be satisfied by 8.2.3.5.6 **Reg. Docs. 1999/11103 + 1999/10079**	2 of 3; 2 studies: 55 + 57 pp.
8.2.3.5	**Biotransformation in Aquatic Systems**			
8.2.3.5.2	Aerobic Water 20°-30°C	R	Preferred over part 8.2.3.5.4 **Reg. Docs. 1999/11241 + 1999/11791**	2 of 3; 2 studies: 133 + 111 pp.
8.2.3.5.4	Aerobic Water/Sediment 20°-30°C	CR	If partitioning into sediment is expected.	-
8.2.3.5.6	Anaerobic Sediment/Water 20°-30°C	R	**Reg. Doc. 1999/5171**	3 of 3; 124 pp.
8.2.4	**Laboratory Studies of Mobility**			
8.2.4.1	Summary	R	**cross reference to Reg. Doc. 2000/90034 (35 -42 pp.)**	Refer to 8.1
8.2.4.2	Adsorption/Desorption	CR	One of 8.2.4.2; 8.2.4.3.1; 8.2.4.3.2; or 8.2.4.4 is required (R) **Reg. Docs. 1998/10650 + 1999/10695 + 1999/10684 + 1999/10686 + 1999/11293 + 2000/90028**	3 of 3; 5 studies: 65 + 49 + 33 + 33 + 64 pp.
8.2.4.3	**Soil Column Leaching**			
8.2.4.3.1	Unaged Soil	CR	See 8.2.4.2	-

Data Code	Title	Data required	Conditions	Volume No and Pages
8.2.4.3.2	Aged Soil	CR	See 8.2.4.2	-
8.2.4.4	Soil TLC Leaching	CR	See 8.2.4.2	-
8.2.4.5	Volatilization	CR	If volatilization is indicated by vapour pressure or Henry's Law Constant	-
8.4	**Storage, Disposal and Decontamination (TGAI and EP)**			
8.4.1	Summary	R	**Reg. Doc. 2000/90028**	3 of 3; 2 pp.
8.5	**Other Environmental Fate Studies (TGAI and EP)**			
8.5.1	Summary	CR	Based on concerns arising from results of other studies	-
8.6	Other Studies/Data/Reports	CR	If available	-
9	**Environmental Toxicology**			
9.1	Summary	R	**Reg. Doc. 2000/90044**	1 of 4; 82 pp.
9.2	**Non-Target Terrestrial Invertebrates**			
9.2.1	Summaries	R	**cross reference to Reg. Doc. 2000/90044**	Refer to 9.1
9.2.3	**Earthworms**			
9.2.3.1	Acute Toxicity	R	**Reg. Doc. 1999/10708**	1 of 4; 19 pp.
9.2.4	**Bees/Pollinators**			
9.2.4.1	Acute Contact	CR	If there is a potential for exposure **Reg. Doc. 1999/5142**	1 of 4; 20 pp.
9.2.4.2	Acute Oral	CR	See 9.2.4.1	-
9.2.4.3	Hive Study (including brood)	CR	If there is a potential for exposure, especially for Insect Growth Regulators (IGRs)	-
9.2.5	Predators	CR	If there is a potential for exposure **Reg. Docs. 1998/10469 + 1998/10534 + 1999/10168 + 1999/10368 + 1999/10437 + 1999/10439 + 1999/10476 + 1999/10517 + 1999/11233 + 1999/11533 + 2000/100028**	1 of 4; 11 studies: 57 + 28 + 18 + 25 + 20 + 22 + 19 + 28 + 29 + 39 + 24 pp.
9.2.6	Parasites	CR	See 9.2.5 **Reg. Docs. 1998/11229 + 1999/10881**	1 of 4; 2 studies: 20 + 21 pp.
9.2.7	Other Terrestrial Invertebrates	CR	See 9.2.5	-
9.3	**Non-Target Freshwater Invertebrates**			
9.3.1	Summary	R	**cross reference to Reg. Doc. 2000/90044**	Refer to 9.1
9.3.2	*Daphnia* sp. Acute	R	**Reg. Docs. 1999/10444 + 1999/10739 + 1999/11917 + 1999/11921 + 1999/11910**	1 of 4; 5 studies: 26 + 2 – 27 + 28 – 33 pp.

Data Code	Title	Data required	Conditions	Volume No and Pages
9.3.3	*Daphnia* sp. Chronic (Life-Cycle)	CR	Most sensitive (i.e., one of) daphnid (9.3.3); marine crustacean or estuarine/marine mollusk (9.4.5); or fish (9.5.3.1), where there is concern based on acute effects, persistence, potential for exposure or frequency of application **Reg. Doc. 1999/11864**	1 of 4; 46 pp.
9.3.4	Laboratory Studies with Other Species	CR	If there is a potential for exposure	-
9.4	**Non-Target Marine Invertebrates**			
9.4.1	Summary	CR	If there is a potential for estuarine/marine exposure; **cross reference to Reg. Doc. 2000/90044**	Refer to 9.1
9.4.2	Acute (Crustacean)	CR	See 9.4.1 **Reg. Doc. 2000/5031**	2 of 4; 33 pp.
9.4.3	Mollusk embryo larvae	CR	One of 9.4.3 or 9.4.4 is required, if there is a potential for estuarine/marine exposure	-
9.4.4	Mollusk shell deposition	CR	See 9.4.3 **Reg. Doc. 2000/5042**	2 of 4; 33 pp.
9.4.5	Chronic (Mollusk or Crustacean)	CR	Most sensitive (i.e., one of) daphnid (9.3.3); marine crustacean or estuarine/marine mollusk (9.4.5); or fish (9.5.3.1), where there is concern based on acute effects, persistence, potential for exposure or frequency of application	-
9.4.8	Bioconcentration/Depuration (bivalve or Crustacean)	CR	If there is a potential for exposure and log Kow is greater than or equal to 3	-
9.5	**Fish**			
9.5.1	Summaries	R	**cross reference to Reg. Doc. 2000/90044**	Refer to 9.1
9.5.2	**Acute Studies**			
9.5.2.1	Cold Water Fish (rainbow trout)	R	**Reg. Docs. 1999/11837 + 1999/11909 + 1999/11913 + 2000/5034**	2 of 4; 4 studies: 43 + 44 + 45 + 33 pp.
9.5.2.2	Warm Water Fish (bluegill sunfish)	R	**Reg. Doc. 2000/5033**	2 of 4; 33 pp.
9.5.2.3	Other Freshwater Fish Species	CR	If there is a potential for exposure	-
9.5.2.4	Marine/Estuarine Fish	CR	If there is a potential for estuarine/marine exposure **Reg. Doc. 2000/5032**	2 of 4; 33 pp.
9.5.2.4.1	Salinity Challenge	CR	For estuarine fish; to follow part 9.5.2.4 (if there is a potential for exposure)	-

Data Code	Title	Data required	Conditions	Volume No and Pages
9.5.3	**Sublethal and Chronic Studies**			
9.5.3.1	Fish, Early Life Cycle Tox. Test	CR	Most sensitive (i.e., one of) daphnid (9.3.3); marine crustacean or estuarine/marine mollusk (9.4.5); or fish (9.5.3.1), where there is concern based on acute effects, persistence, potential for exposure or frequency of application **Reg. Docs. 1999/11343 + 2000/5053**	2 of 4; 2 studies: 230 + 63 pp.
9.5.3.2	Fish, Life Cycle Tox. Test	CR	Where there is concern based on acute effects, persistence, potential for exposure or frequency of application	-
9.5.6	Bioaccumulation	CR	If log Kow is greater than or equal to 3 **Reg. Doc. 1999/11348**	2 of 4; 141 pp.
9.6	**Wild Birds**			
9.6.1	Summary	R	**cross reference to Reg. Doc. 2000/90044**	Refer to 9.1
9.6.2.1	Oral (LD50) Bobwhite Quail	CR	One of 9.6.2.1 or 9.6.2.2 **Reg. Doc. 1997/11136**	3 of 4; 35 pp.
9.6.2.2	Oral (LD50) Mallard Duck	CR	See 9.6.2.1	-
9.6.2.3	Oral (LD50) Other Species	CR	If avian acute oral toxicity is of concern and there is a potential for exposure	-
9.6.2.4	Dietary (LC50) Bobwhite Quail	R	**Reg. Doc. 1998/10932**	3 of 4; 40 pp.
9.6.2.5	Dietary (LC50) Mallard Duck	R	**Reg. Doc. 1998/10933**	3 of 4; 75 pp.
9.6.2.6	Dietary (LC50) Other Species	CR	If avian acute dietary toxicity is of concern and there is a potential for exposure	-
9.6.3	**Chronic Studies**			
9.6.3.1	Avian Reproduction Bobwhite Quail	CR	Triggered by acute effects, persistence, bioconcentration potential, mammalian reproductive effects, potential for exposure or frequency of application **Reg. Doc. 1999/11207**	3 of 4; 166 pp.
9.6.3.2	Avian Reproduction Mallard Duck	CR	See 9.6.3.1 **Reg. Doc. 1999/11206**	3 of 4; 196 pp.
9.6.3.3	Avian Reproduction Other Species	CR	See 9.6.3.1	
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI and EP)	CR	Based on concerns arising from the results of other studies	
9.7	**Wild Mammals**			
9.7.1	Summary	CR	Based on concerns arising from the results of other studies	-
9.8	**Non-Target Plants**			

Data Code	Title	Data required	Conditions	Volume No and Pages
9.8.1	Summary	R	**cross reference to Reg. Doc. 2000/90044 (67 -82 pp.)**	Refer to 9.1
9.8.2	Fresh Water Algae	R	**Reg. Docs. 1999/11020 + 2000/5036 + 2000/5046 + 1999/11918 + 1999/11922 + 1999/11914**	4 of 4; 6 studies: 28 + 34 + 35 + 29 + 30 + 28 pp.
9.8.3	Marine Algae	CR	If there is a potential for estuarine/marine exposure **Reg. Doc. 2000/5035**	4 of 4; 34 pp.
9.8.4	Terrestrial Vascular Plants	R	**Reg. Docs. 1999/5181 + 1999/5198**	4 of 4; 2 studies: 144 + 125 pp.
9.8.5	Aquatic Vascular Plants	R	**Reg. Doc. 2000/5037**	4 of 4; 35 pp.
9.9	Other Studies/Data/Reports	CR	If available	
12.5	**Foreign Reviews**			
12.5.2	Foreign Reviews of Chemistry Requirements for TGAIs or Integrated System Products	CR		-
12.5.4	Foreign Reviews of Toxicology	CR		-
12.5.6	Foreign Reviews of Metabolism / Toxicokinetics Studies	CR		-
12.5.8	Foreign Reviews of Environmental Chemistry and Fate	CR		-
12.5.9	Foreign Reviews of Environmental Toxicology	CR		-
12.7	**Comprehensive Data Summaries**	R	**Reg. Doc. 2000/90045**	1 of 1; hard & electronic copies

Attachment 2:
For letter of screening acceptance dated August 10, 2000
Re: Attitude EC Fungicide (pyraclostrobin); Sub. No. 2000-0800

PEST MANAGEMENT REGULATORY AGENCY
DATA REQUIREMENTS FOR
USE SITE CATEGORIES (USCs) 13/14: Terrestrial Feed/Food Crops - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
0	**Index**	**R**	**Reg. Doc. 2000/90010**	hard and electronic copies
1	**Label**	**R**		hard and electronic copies
3	**Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered technical grade of active ingredients or integrated system products.**			
3.1	**Product Identification**			
3.1.1	Applicant's Name and Office Address	R	**Reg. Doc. 2000/90010**	1 of 1; 1 pp.
3.1.2	Formulating Plant's Name and Address	R		"
3.1.3	Trade Name	R		"
3.1.4	Other Names	R		"
3.2	**Formulation Process**			
3.2.1	Description of Starting Materials	R	**Reg. Doc. 2000/5114**	1 of 1; 1-26 pp.
3.2.2	Description of the Formulation Process	R	cross reference to **Reg. Doc. 2000/5114 (pgs. 21 - 24 of 26)**	Refer to 3.2.1
3.2.3	Discussion of the Formation of Impurities of Toxicological Concern	CR	If applicable. cross reference to **Reg. Doc. 2000/5114 (pg. 26 of 26)**	Refer to 3.2.1
3.3	**Specifications**			
3.3.1	Establishing Certified Limits	R	**Reg. Doc. 2000/5117**	1 of 1; 11 pp.
3.3.2	Control Product Specification Form	R		1 of 1; 1 pg.
3.4	**Product Analysis**			
3.4.1	Enforcement Analytical Method	R	**Reg. Doc. 1997/11514 + 1997/10709**	1 of 1; 2 studies: 14 + 19
3.4.2	Impurities of Toxicological Concern	CR	If applicable.	-

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Data Code	Title	Data required	Conditions	Volume No and Pages
3.5	**Chemical and Physical Properties**			
3.5.1	Colour	CR	Required for manufacturing concentrates only **Reg. Doc. 1997/11398**	1 of 1; pgs. 10 -23
3.5.2	Physical State	R	**Cross ref. to Daco 3.5.1**	1 of 1; 1 pg 9.
3.5.3	Odour	CR	Required for manufacturing concentrates only **Cross ref. to Daco 3.5.1 (pg. 10)**	1 of 1; pg. 1
3.5.4	Formulation Type	R	**Reg. Doc. 2000/90013**	1 of 1; 1 pg.
3.5.5	Container Material and Description	R	**Reg. Doc. 2000/90014**	1 of 1; 1 pg.
3.5.6	Density or Specific Gravity	R	**Cross ref Daco 3.5.1 (pg. 15) + Reg. Doc. 1999/10526**	1 of 1; 2 studies: ref. + 12 pp.
3.5.7	pH	R	**Cross ref. Daco 3.5.1 (pg. 11)**	1 of 1; 1 pg.
3.5.8	Oxidizing or Reducing Action (Chemical Incompatibility)	R	**Reg. Doc. 1999/5135 (pg. 13)**	1 of 1; 1 pg.
3.5.9	Viscosity	R	**Cross ref Daco 3.5.1 (pg. 14)**	1 of 1; 1 pg.
3.5.10	Storage Stability Data	R	**Reg. Docs.1999/10574 + 1999/10561**	1 of 1; 2 studies: 12 + 20 pp.
3.5.11	Flammability	R	**Cross ref Daco 3.5.1 (pg 10) + Reg. Doc. 1997/11421**	1 of 1; pg. 10 +
3.5.12	Explodability	R	**Document 2000/90020**	Tab 3.5.12
3.5.13	Miscibility	R	**Cross ref Daco 3.5.1 (pg. 19)**	1 of 1; 1 pg.
3.5.14	Corrosion Characteristics	R	**Reg. Doc. 1998/11419**	1 of 1; 4 pp.
3.5.15	Dielectric Breakdown Voltage	R	**Reg. Doc. 2000/90021**	1 of 1;
3.6	Sample(s)	CR	If requested by PMRA	-
3.7	Other Studies/Data/Reports	CR	If available	-
4	**Toxicology**			
4.1	Summaries - Toxicology Profile	R	**Reg. Doc. 2000/90031**	1 of 1; 12 pp.
4.6	Acute Studies			
4.6.1	Acute Oral	R	**Reg. Doc. 1998/10804**	1 of 1; 27 pp.

Data Code	Title	Data required	Conditions	Volume No and Pages
4.6.2	Acute Dermal	R	**Reg. Doc. 1998/10646**	1 of 1; 24 pp.
4.6.3	Acute Inhalation	R	**Reg. Doc. 1998/11185**	1 of 1; 33 pp.
4.6.4	Primary Eye Irritation	R	**Reg. Doc. 1998/10645**	1 of 1; 18 pp.
4.6.5	Primary Dermal Irritation	R	**Reg. Doc. 1998/10644**	1 of 1; 17 pp.
4.6.6	Dermal Sensitization	R	**Reg. Doc. 1998/11034**	1 of 1; 37 pp.
4.7	Short-Term Studies	CR	Depending on use pattern, required if any component of the EP may increase absorption of the active ingredient(s) or potentiate toxic or pharmacologic effects.	-
4.8	Other Studies/Data/Reports	CR	If available	-
5	**Exposure (Occupational and/or Bystander)**			
5.1	Summaries	R	**Reg. Doc. 2000/90039**	1 of 2; 20 pp.
5.2	Use Description/Scenario (Application and Post Application)	R	**Reg. Doc. 2000/90009**	1 of 2; 54 pp.
5.3	Pesticides Handlers Exposure Database Assessment (or other database)	R	One of 5.3, 5.4 or 5.5 is required **Reg. Doc. 2000/5089**	1 of 2; 310 pp.
5.4	Mixer/Loader/Applicator- Passive Dosimetry Data	R	See 5.3	-
5.5	Mixer/Loader/Applicator-Biological Monitoring Data	R	See 5.3	-
5.6	Post Application-Passive Dosimetry Data	CR	5.6 or 5.7 may be required if there is potential for post application exposure	-
5.7	Post Application-Biological Monitoring Data	CR	See 5.6	-
5.8	Dermal Absorption	CR	Required if margin of safety not adequate **Reg. Doc. 1999/10716**	1 of 2; 44 pp.
5.9	Dislodgeable Residues (Foliar, Soil and Surface)	CR	Required if there is potential for post-application exposure or to establish re-entry times **Reg. Docs. 1998/5091 + 1998/5098 + 1998/5089 + 1999/5063 + 1999/5091 + 1999/5190 + 1999/5192 + 1999/5090 + 1999/5194**	2 of 2; 9 studies: 100 + 50 + 69 + 111 + 108 + 78 + 79 + 113 + 90 pp.

Data Code	Title	Data required	Conditions	Volume No and Pages
5.11	Glove/Clothing Penetration Data	CR	May be required for risk mitigation purposes or for inadequate margin of safety	-
5.13	Package Integrity Study	CR	Required if packaged in water soluble bags	-
5.14	Other Studies/Data/Reports	CR	If available **Reg. Doc. 2000/5130**	2 of 2; 27 pp.
6	**Metabolism/Toxicokinetics Studies (TGAI or EP)**		N/A	
6.1	Summaries	R		Refer to TGAI (Sub. No. 2000-0799)
6.2	Livestock	R		Refer to TGAI (Sub. No. 2000-0799)
6.3	Plants	R		Refer to TGAI (Sub. No. 2000-0799)
6.4	Other Studies/Data/Reports	CR	If available	-
7	**Food, Feed and Tobacco Residue Studies EP**			
7.1	Summaries	R	**Reg. Doc. 2000/90040**	1 of 9; 189 pp.
7.2	**Analytical Methodology (Food Crops & Tobacco)**			
7.2.1	Supervised Residue Trial Analytical Methodology	R	**Reg. Docs. 1999/5179 + 1999/11134 + 1999/11075 + 1999/11138 + 1999/11782 + 1999/11079**	1 of 9; 6 studies: 105 + 114 + 112 + 24 + 16 + 45 pp.
7.2.2	Enforcement Analytical Methodology	R	**Reg. Docs. 2000/5138 + 2000/5139**	2 of 9; 2 studies: 21 + 32 pp.

Data Code	Title	Data required	Conditions	Volume No and Pages
7.2.3	Inter-laboratory Analytical Methodology Validation	R	**Reg. Docs. 1999/5184 + 1999/5787 + 2000/5004 + 2000/100001 + 2000/5002 + 1999/11369**	2 of 9; 6 studies: 68 + 96 + 73 + 55 + 58 + 58 pp.
7.2.4	Multi-residue Analytical Methodology Evaluation	R	**Reg. Doc. 2000/5015**	2 of 9; 106 pp.
7.2.5	Storage Stability of Working Solutions in Analytical Methodology	R	**Reg. Doc. 1999/11136**	2 of 9; 41 pp.
7.3	Freezer Storage Stability Tests	CR	If stored for more than 30 days and/or volatile or labile study required **Reg. Docs. 1999/5064 + 2000/1000002**	2 of 9; 2 studies: 80 + 41 pp.
7.4	**Crop Residue Data**			

Data Code	Title	Data required	Conditions	Volume No and Pages
7.4.1	Supervised Residue Trial Study	R	Reg. Docs. 1999/5096 (wheat) + 2000/5137 (wheat) + 1999/11509 (barley) + 1999/11825 (cereals) + 1999/5079 (cereals) + 1999/5159 (lentils) +1999/5154 (dry field peas)+ 1999/5148 (potatoes) + 2000/90041(potatoes) + 2000/90046 (rationale re: potatoes) + 2000/90027 (rationale re: potatoes) + 1999/5107 (rye) + 1999/5157 (sugar beets) + 1999/5160 (grass for seed) + 1999/5140 (strawberries) + 1999/5143 (raspberries + blue berries) + 1999/5144 (citrus) + + 1999/5146 (stone fruit) + 1999/5149 (radishes) +1999/5751 (bell/chile peppers) + 1999/5084 (tomato) + 1999/5155 (carrots) + 1999/5158 (dry bulb/onions) + 1999/5150 (pistachios) +1999/5152 (pecans) + 1999/5071 (peanuts -1997) + 1999/5078 (peanuts - 1998) +1999/5010 (grapes - 1997) + 1999/5092 (grapes -1998) + 1999/5153 (grapes - 1999) + 1999/5161 (almonds) + 1999/5083 (cucurbits) + 1999/5095 (bananas) + 1999/5145 (bridging study) + 1999/10980 (grapes - Germany & /France) 1999/10981 (grapes - Spain, Germany & France) + 1999/11638 (grapes - Italy)	3 - 6 of 9; 37 studies: 173 + 57 + 57 +25 + 117 + 55 + 76 + 97 + 2 + 6 + 8 + 63 + 74 + 94 + 67 + 64 + 106 + 92 + 59 + 64 + 79 + 61 + 64 +54 + 56 + 73 + 62 + 67 + 69 + 66 + 64 + 92 + 74 + 74 + 41 + 45 + 53
7.4.2	Residue Decline Study	R	Document 1999-5096 **(18) cross references to DACO 7.4.1**	7 of 9
7.4.3	Confined Crop Rotation Trial Study	CR	Depends on size of crop **Reg. Doc. 1999/11829**	7 of 9; 277 pp.
7.4.4	Field Crop Rotation Trial Study	CR	Depends on cropping practice **Reg. Doc. 1999/5126**	7 of 9 78 pp.

Data Code	Title	Data required	Conditions	Volume No and Pages
7.4.5	Processed Food/Feed	CR	Depends on commodities **Reg. Docs. 1999/5122 (wheat) + 1999/5123 (potato) + 1999/5156 (sugar beet) + 1999/5011 (grapes) + 1999/5120 (oranges) + 1999/5085 (tomatoes) + 1999/5072 (peanuts) + 1999/5147 (plum) + 1999/10982 (grapes - Germany)**	8 of 9: 9 studies: 98 + 50 + 81 + 84 + 119 + 77 + 72 + 77 + 81
7.4.6	Residue Data for Crops used as Livestock Feed (if needed for forage crops)	R	**(18) cross references to DACO 7.4.1**	9 of 9
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)	R	**Reg. Docs. 2000/1000003 + 2000/5005 + 1999/11895**	9 of 9; 3 studies: 113 + 213 + 63
7.7	Tobacco Residue Data	CR	Depends on label instructions	-
7.8	Other Studies/Data/Reports	CR	If available **Reg. Docs. 2000/5086 + 1999/5185 + 1999/5106 + 2000/5003**	9 of 9; 4 studies: 16 + 27 + 35 + 27
8	**Environmental Chemistry and Fate**			
8.1	Summaries	R	**Reg. Doc. 2000/90034**	1 of 4; 70 pgs.
8.2	**Laboratory Studies**			
8.2.1	Density or Specific Gravity	R	See 3.5.6 **BCI# 2000/90035**	1 of 4; 1 pg.
8.2.3	**Laboratory Studies of Transformation**			
8.2.3.1	Summary	R	**Cross ref Daco 8.1 pg 3-20 and 47-61, Reg. Doc 2000/90034**	1 of 4; 1 pg.
8.2.3.6	Special Studies Related to Use-Pattern or Formulation	CR		-
8.2.4	**Laboratory Studies of Mobility**			
8.2.4.1	Summary	R	**Cross ref Daco 8.1 pg 35-42, Reg. Doc 2000/90034**	1 of 4; 1 pg.
8.2.4.6	Special Studies Related to Use-Pattern or Formulation	CR		-
8.3	**Field Studies of Dissipation/Accumulation [May be Small or Large-Scale]**			
8.3.1	Summary	R	**Cross ref Daco 8.1 section 7.1.2.2 pg 20-34, Reg. Doc 2000/90034**	1 of 4; 1 pg.
8.3.2	**Terrestrial**			

Data Code	Title	Data required	Conditions	Volume No and Pages
8.3.2.1	Canada	R	**Reg. Docs. 2000/5040(Manitoba + PEI) + 2000/5041 (Ontario + Alberta)**	1 & 2 of 4; 2 studies: 481 + 430
8.3.2.2	Northern U.S.	CR	Can substitute for some Canadian studies **Reg. Docs. 2000/5020 (New York + California) + 2000/5059 (S. Dakota)**	3 & 4 of 4; 2 studies: 710 + 264
8.3.3	**Aquatic**			
8.3.3.1	Canada	CR	Based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, non-target aquatic toxicity or bioaccumulation	-
8.3.3.2	Northern U.S.	CR	Can augment Canadian studies	-
8.3.4	Special Studies Related to Intended Use Pattern	CR	Based on concerns arising from results of other studies	-
8.4	**Storage, Disposal and Decontamination (TGAI and EP)**			
8.4.1	Summary	R	**Reg. Doc. 2000/90029**	4 of 4; 2 pp.
8.5	**Other Environmental Fate Studies (TGAI and EP)**			
8.5.1	Summary	CR	Based on concerns arising from results of other studies	-
8.6	Other Studies/Data/Reports	CR	If available	-
9	**Environmental Toxicology**			
9.1	Summary	R	**Reg. Doc. 2000/90044**	1 of 1; 82 pp.
9.2	**Non-Target Terrestrial Invertebrates**			
9.2.1	Summaries	R	**Cross ref Daco 9.1 pg 2-28, Reg. Doc. 2000/90044**	1 of 1; 1 pg.
9.2.8	Laboratory Studies	CR	If there is a potential for exposure and components of the EP are of concern	-
9.2.9	Field Studies	CR	Based on concerns arising from results of other studies	-
9.3	**Non-Target Freshwater Invertebrates**			
9.3.1	Summary	R	**Cross ref Daco 9.1, pgs. 29-38, Reg. Doc. 2000/90044**	Tab 9.3.1 Pg 29-38
9.3.5	Laboratory Studies	CR	If components of the EP are of concern	-

Data Code	Title	Data required	Conditions	Volume No and Pages
9.3.6	Field Studies	CR	Based on concerns arising from results of other studies	-
9.4	**Non-Target Marine Invertebrates**			
9.4.1	Summary	CR	If there is a potential for estuarine/marine exposure	-
9.4.6	Laboratory Studies	CR	If there is a potential for exposure and components of the EP are of concern	-
9.4.7	Field Studies	CR	Based on concerns arising from results of other studies	-
9.5	**Fish**			
9.5.1	Summaries	R	**Cross ref Daco 9.1, pg 38-57, Reg. Doc. 2000/90044**	1 of 1; 1 pg.
9.5.4	Laboratory Studies	CR	If components of the EP are of concern	-
9.5.5	Field Studies	CR	Based on concerns arising from results of other studies	-
9.6	**Wild Birds**			
9.6.1	Summary	R	**Cross ref Daco 9.1, pg 58-66, Reg. Doc. 2000/90044**	1 of 1; 1 pg.
9.6.4	Laboratory Studies	CR	If there is a potential for exposure and components of the EP or the EP itself (e.g., granular formulations) are of concern	-
9.6.5	Field Studies	CR	Based on concerns arising from results of other studies	-
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI and EP)	CR	See 9.6.5	-
9.7	**Wild Mammals**			
9.7.1	Summary	CR	Based on concerns arising from the results of other studies	-
9.7.2	Field Studies	CR	See 9.7.1	-
9.8	**Non-Target Plants**			
9.8.1	Summary	R	**Cross ref Daco 9.1, pg 67-82, Reg. Doc. 2000/90044**	1 of 1; 1 pg.
9.8.6	Laboratory Studies	CR	If components of the EP are of concern	-
9.8.7	Field Studies	CR	Based on concerns arising from results of other studies	-
9.9	Other Studies/Data/Reports	CR	If available	-
10	**Value (applicable to each pest/site or host combination)**			

Data Code	Title	Data required	Conditions	Volume No and Pages
10.1	Value Summaries	R	**Reg. Doc. 2000/90011 Note: Value data includes info./data from Reg. Doc. 2000/90048 (Summary tables - 1 vol.) and Reg. Doc. 2000/90042 (Raw Abstracts - 2 vols.): Total no vols. for value = 4**	1 of 1; pg. 8-10
10.2	**Efficacy Studies**			
10.2.1	Mode of Action	R		1 of 1; pg 11
10.2.2	Description of Pest Problem	R		1 of 1; pgs 12-36
10.2.3	**Efficacy Trials**			
10.2.3.1	Summaries	R	**Refer to Note for DACO 10.1 Summary Tables - Appendices 6 -15 (Reg. Doc. 2000/90048)**	1 of 1; pgs. 37-39
10.2.3.2	Efficacy: Laboratory, Growth Chamber Trials	CR		Refer to 10.2.3.3
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	R	One or both of 10.2.3.3. or 10.2.3.4 **Refer to Note for DACO 10.1**	1 of 1; pgs. 40 - 96
10.2.3.4	Efficacy: Operational Trials	CR	See 10.2.3.3	Refer to 10.2.3.3 (Co. Note - pg. 97)
10.3	**Adverse Effects on Use Site**			
10.3.1	Summaries	R	**Refer to Note for DACO 10.1 Summary Tables - Appendices 16 -25 (Reg. Doc. 2000/90048)**	1 of 1; pgs. 98-100
10.3.2	Non-Safety Adverse Effects [e.g.: to crop, site of application (discoloration, corrosion), etc.]	R		1 of 1; pgs.101-113
10.3.3	Damage to Rotational Crops	CR		1 of 1; pgs.114-115
10.4	Economics	CR		1 of 1 pgs. 116-119
10.5	**Sustainability**			
10.5.1	Survey of Alternatives (chemical and non-chemical)	CR		1 of 1; pg.120
10.5.2	Compatibility with Current Management Practices Including IPM	CR		"

Data Code	Title	Data required	Conditions	Volume No and Pages
10.5.3	Resistance Management	CR		1 of 1; 121-122
10.5.4	Contribution to Risk Reduction	CR		1 of 1; pgs 123-125
10.6	Other Studies/Data/Reports	CR	If available	-
12.5	**Foreign Reviews**			
12.5.3	Foreign Reviews of Chemistry Requirements for MAs and EPs formulated from registered TGAIs or ISPs	CR		-
12.5.4	Foreign Reviews of Toxicology	CR		-
12.5.5	Foreign Reviews of Exposure (Occupational and/or Bystander)	CR		-
12.5.6	Foreign Reviews of Metabolism / Toxicokinetics Studies	CR		-
12.5.7	Foreign Reviews of Food, Feed and Tobacco Residue Studies	CR		-
12.5.8	Foreign Reviews of Environmental Chemistry and Fate	CR		-
12.5.9	Foreign Reviews of Environmental Toxicology	CR		-
12.5.10	Foreign Reviews of Value	CR		-
12.7	**Comprehensive Data Summaries**	**R**	**Reg. Doc. 2000/90047**	**1 of 1; hard & electronic copies**

Attachment 3 :
For letter of (PMRA) screening acceptance dated
Re: Pyraclostrobin Technical Fungicide (pyraclostrobin); Sub, No. 2000-0799

SCREENING COMMENTS

These items do not need to be addressed for this submission, but should be considered for future submissions.

No.	ELEMENT	DEFICIENCY	COMMENTS
1.	**General Organization/Format**		The data/information provided by the applicant were legible and well organized (by DACO Nos). Screens completed by the applicant were well done. Hard copies were included at the beginning of the related studies. These were very useful to the Screening Section. In addition, the (draft) screening forms completed by the applicant for some environmental chemistry and fate/environmental toxicology studies will be examined by the Environmental Assessment Division. With respect to the completed screens examined by the Screening Section, it was noted that the notation "NA" was included for some screening elements without an obvious explanation for missing information." In future, it would be useful to the Screening Section to know whether "NA" means "not available" (i.e., no information available in the study) or "not applicable". In some cases, "No" would be sufficient.
2.	**Part 0 - Index** (paper/electronic copy)	The hard/electronic copy of the index mentions Part 1 - Chemistry.	This should be Part 2 - Chemistry since Part 1 refers to the product label.

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No.	ELEMENT	DEFICIENCY	COMMENTS
3.	**Part 2 - Technical Grade Active Ingredient Chemistry**		Information concerning GLP and non-GLP information/data for Part 2 studies has been noted and has been flagged for further examination by the PMRA.
4.	**Part 4 - Toxicology**	DACO 4.3.1 - Short-Term Oral (90 day) (rodent) (Co. code 4.3.1-1): The screening form prepared by the applicant indicates that no data from opthamological examinations for control and high dose groups prior to/at study termination groups were provided. It was specified as "NA" No historical data were provided for this study .	This screening element has been flagged for further examination by the PMRA. In order to expedite the review of this submission, please submit available historical control data for blood chemistry, haematology, tumour incidences, skeletal variations and malformations for this study.
5.		DACO 4.3.1 - Short-Term Oral (90 day) (rodent) (Co. code 4.3.1-3 and 4.3.1-5): No historical data were provided for these studies	Refer to comment concerning historical control data for data element No. 4.
6.		DACO 4.4.2 - Oncogenicity (rodent species 1): The screening form prepared by the applicant indicates that no data concerning clinical chemistry were provided. No historical data were provided for this study	This screening element has been flagged for further examination by the PMRA. Refer to comment concerning historical control data for data element No. 4.
7.		DACO 4.4.3 - Oncogenicity (rodent species 2): No historical data were provided for this study	Refer to comment concerning historical control data for data element No. 4.

No.	ELEMENT	DEFICIENCY	COMMENTS
8.		DACO 4.5.2 - Teratogenicity (rodent): It is unclear whether a referenced dose range finding study (i.e., "preceding maternal dose ranging study for Wistar rats") was supplied with this submission.	This screening element has been flagged for further examination by the PMRA. However, it would be useful if the applicant could provide further clarification at this time concerning the general dose ranging reference provided on pg. 16 of 283 of Reg. Doc. 1999/11511.
9.	**Part 4 - Toxicology** (cont'd)	DACO 4.5.3 - Teratogenicity (non-rodent): It is unclear whether a referenced dose range finding study (i.e., "preceding maternal dose ranging study for Himalayan rabbits") was supplied with this submission.	This screening element has been flagged for further examination by the PMRA. However, it would be useful if the applicant could provide further clarification at this time concerning the general dose ranging reference provided on pg. 17 of 284 of Reg. Doc. 1999/11512.
10.		DACO 4.5.9 - Metabolism/ Toxicokinetics in Mammals (laboratory animal) (Co. code 4.5.9-1 and 4.5.9-2): The screening forms prepared by the applicant indicates that no proposed metabolic pathway was provided in these studies.	This screening element has been flagged for further examination by the PMRA.
11.	**Part 6 - Metabolism/Toxicokinetics**	DACO 6.2 Metabolism/Toxicokinetics Studies (TGAI or EP) - Livestock (Co. code: 6.2-1 and 6.2-2): The screening forms prepared by the applicant indicates that the Chemical name (IUPAC) of the parent/ metabolites and the Level of Detection (LOD) have not been provided in these studies.	These screening elements have been flagged for further examination by the PMRA.

No.	ELEMENT	DEFICIENCY	COMMENTS
12.		DACO 6.2 - Metabolism/Toxicokinetics Studies (TGAI or EP) - Livestock (Co. code: 6.2-3 and 6.2-4): The screening forms prepared by the applicant indicates that the Chemical name (IUPAC) of the parent/ metabolites, the LOD and a record of (test animal) facility conditions have not been provided.	These screening elements have been flagged for further examination by the PMRA.
13.	**Part 6 - Metabolism/Toxicokinetics** (cont'd)	DACO 6.3 - Metabolism/Toxicokinetics Studies (TGAI or EP) - Plants (Co. code 6.3 - 2 and 3) The screening form prepared by the applicant indicates that the Chemical name (IUPAC) of the parent/ metabolites has not been provided. In addition, no control plot was used and there is no information provided in these studies concerning the number of samples per replication or the number of sample replications per treatment level. A description of the environmental test conditions has been included but no records of these conditions were included in these studies.	These screening elements have been flagged for further examination by the PMRA.
14.		DACO 6.3 - Metabolism/Toxicokinetics Studies (TGAI or EP) - Plants (Co. code 6.3 - 4) The screening form prepared by the applicant indicates that the Chemical name (IUPAC) of the parent/ metabolites has not been provided	These screening elements have been flagged for further examination by the PMRA.

No.	ELEMENT	DEFICIENCY	COMMENTS
15.	**Part 8 - Environmental Chemistry and Fate**	DACO 8.2.4.2 - Adsorption/Desorption (Co. code 8.2.4.2-1): As noted by the applicant in a letter dated June 29, 2000 (P. Vandierendonck to R. McDonell), certain study information was provided in German.	The PMRA acknowledges receipt (on June 30, 2000) of translated pages 48 - 50 (German to English text) for Reg. Doc. 1998/10650.

Attachment 4 :
For letter of (PMRA) screening acceptance dated
Re: Attitude EC Fungicide (pyraclostrobin); Sub. No. 2000-0800

SCREENING COMMENTS

These items do not need to be addressed for this submission, but should be considered for future submissions.

No.	ELEMENT	DEFICIENCY	COMMENTS
1.	**General Organization/Format**		The data/information provided by the applicant were legible and well organized (by DACO Nos). Screens completed by the applicant were well done. Hard copies were included at the beginning of the related studies. These were very useful to the Screening Section. In addition, the (draft) screening forms completed by the applicant for some environmental chemistry and fate/environmental toxicology studies will be examined by the Environmental Assessment Division. With respect to the completed screens examined by the Screening Section, it was noted that the notation "NA" was included for some screening elements without an obvious explanation for missing information." In future, it would be useful to the Screening Section to know whether "NA" means "not available" (i.e., no information available in the study) or "not applicable". In some cases, "No" would be sufficient.

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No.	ELEMENT	DEFICIENCY	COMMENTS
2.	**Non Data Components/Documents**	Control Product Specification Form (CPSF) - Box 9: Formulation Ingredients: It was noted that this product contains [redacted], a substance included on EPA Inerts List 2. Consequently, it may be subject to future regulatory action.	The applicant may wish to replace this formulant with one which is not of toxicological concern. Alternately, the (precautionary) statement specified in element No. 6 should be added to the label.
3.	**Part 1 - Labels** (paper/electronic copy)	Label components (brochure): It was noted that the proposed product label drafts (April 7 and May 31, 2000) specified that the user should "READ THE LABEL AND ATTACHED BROCHURE". However, the related label components included a "sleeve" and "carton" only.	Clarification is required as to whether there is a brochure associated with the product label.
4.		Directions for Use: As per the draft Attitude EC label, this product is proposed for ground and aerial application. However, no "generic aerial application label instructions" were found on the product label.	"Generic aerial application label instructions" (as per Regulatory Directive Dir96-04, Appendix II) should be added to this section of the label.
5.		Directions for Use: As discussed, the Pre-harvest Intervals (PHIs) for field peas and lentils specified on the draft label has been revised from 32 and 45 days, respectively, to 30 days. The applicant has indicated that the data supplied with the initial submission will support these amended PHIs.	The PMRA acknowledges receipt (on May 31, 2000) of the revised Attitude EC Fungicide/BAS 500 label.

No.	ELEMENT	DEFICIENCY	COMMENTS
6.		Precautionary Statements: If applicant intends to use [redacted] as a formulant, a mitigating precautionary statement is required on the label.	Add the following statement to the end of the precautionary statements (i.e. as item no. 9.): "This product contains a petroleum distillate which is highly toxic to aquatic organisms. Avoid contamination of aquatic systems during application. Do not contaminate these systems through direct application, disposal of waste or cleaning equipment."
7.	**Part 5 - Exposure**	DACO 5.3 - Pesticides Handlers Exposure Database Assessment - PHED(or other database): The screening forms prepared by the applicant indicates that no date of the PHED was provided in the study. No rationale for subsets were provided.	This screening element has been flagged for further examination by the PMRA.
8.		DACO 5.8 - Dermal Absorption: The screening forms prepared by the applicant indicated that no information concerning the appropriateness for Canadian registration was provided.	This screening element has been flagged for further examination by the PMRA.
9.	**Part 5 - Exposure** (cont'd)	DACO 5.9 - Dislodgeable Residues (Foliar, Soil and Surface) (Co. code 5.9-4): The screening forms prepared by the applicant indicted that no information concerning verification of total deposition or the appropriateness of the sampling test system. In addition, there were deviations from GLP related to collection of weather data and field site information.	This screening element has been flagged for further examination by the PMRA.

No.	ELEMENT	DEFICIENCY	COMMENTS
10.		DACO 5.9 - Dislodgeable Residues (Foliar, Soil and Surface) (Co. code 5.9-5): The screening forms prepared by the applicant indicated that the proposed formulation was not used in the study. There was no verification of total deposition. In addition, there were deviations from GLP related to collection of weather data and field site information.	This screening element has been flagged for further examination by the PMRA.
11.		DACO 5.9 - Dislodgeable Residues (Foliar, Soil and Surface) (Co. code 5.9-6): The screening forms prepared by the applicant indicted that the proposed formulation was not used in the study. In addition, there was no information concerning environmental conditions during th dissipation interval, storage stability or the appropriateness for Canadian registration.	This screening element has been flagged for further examination by the PMRA
12.		DACO 5.9 - Dislodgeable Residues (Foliar, Soil and Surface) (Co. code 5.9-7): The screening forms prepared by the applicant indicated that the proposed formulation was not used in the study. In addition, there was no information specified in the screen concerning storage stability or selection of sites	This screening element has been flagged for further examination by the PMRA

No.	ELEMENT	DEFICIENCY	COMMENTS
13.	**Part 5 - Exposure** (cont'd)	DACO 5.9 - Dislodgeable Residues (Foliar, Soil and Surface) (Co. code 5.9-8/9): The screening forms prepared by the applicant indicted that the proposed formulation was not used in the study. No information was specified in the screens for storage stability, QA/QC data or selection of sampling sites. In addition, there were deviations from GLP related to collection of weather data and field site information. storage stability, QA/QC data or selection of sampling sites. There was no verification of total deposition.	This screening element has been flagged for further examination by the PMRA.
14.		DACO 5.9 - Dislodgeable Residues (Foliar, Soil and Surface) (Co. code 5.9-9): The applicant has provided a bridging study between two BAS 500F formulations, i.e., BAS 500 00F (EC) and BAS 500 DIF (WG)	This screening element has been flagged for further examination by the PMRA.
15.	**Part 7 - Food, Feed & Tobacco Residues**	DACO 7.2.1 - Supervised Residue Trial Analytical Methodology (Co. codes 7.2.1-1/2/2/4/5/6/7: No chemical name (IUPAC) of parent/ metabolites was provided.	This screening element has been flagged for further examination by the PMRA.
16.		DACO 7.2.1 - Supervised Residue Trial Analytical Methodology (Co. code 7.2.1-6): The recovery of BAS 500 F in 2 fortified samples (i.e., cow milk and eggs) was below 70.0% but the means of all recovery values is greater than 70.0%.	This screening element has been flagged for further examination by the PMRA.

No.	ELEMENT	DEFICIENCY	COMMENTS
17.		DACO 7.2.3 - Inter-laboratory Analytical Methodology Validation (Co. code 7.2.3-5): Recovery means were not provided	This screening element has been flagged for further examination by the PMRA.
18.	**Part 7 - Food, Feed & Tobacco Residues** (cont'd)	DACO 7.2.5 - Storage Stability of Working Solutions in Analytical Methodology: No chemical name (IUPAC) of parent/ metabolites was provided.	This screening element has been flagged for further examination by the PMRA.
19.		DACO No. 7.4.1- Supervised Residue Trial Study (Co. codes 7.4.1-1 to 37) 11 studies were provided in support of proposed uses on the Attitude EC Fungicide. In addition, 26 studies were included in this submission to support the establishment of Import Maximum Residue Limits (MRLs) for uses specified on 3 proposed U.S. labels.	This screening element has been flagged for further examination by the PMRA.
20.		DACO No. 7.4.1- Supervised Residue Trial Study (Co. code 7.4.1-2): The applicant has provided a rationale for proposed tolerance for residues of pyraclostrobin and its metabolite BF500-3 in Wheat	This screening element has been flagged for further examination by the PMRA.
21.		DACO No. 7.4.1- Supervised Residue Trial Study (Co. codes 7.4.1-10): The applicant has provided a rationale to support the number of applications for use on potatoes.	This screening element has been flagged for further examination by the PMRA.

No.	ELEMENT	DEFICIENCY	COMMENTS
22.		DACO No. 7.4.1- Supervised Residue Trial Study (Co. codes 7.4.1-11): The applicant has provided a rationale to support the equivalence of BAS 500 00F (250 g/L EC formulation) and BAS 500 02F/BAS 500 DIF (20% WG formulation) in potatoes	This screening element has been flagged for further examination by the PMRA.
23.		DACO No. 7.4.1- Supervised Residue Trial Study (Co. codes 7.4.1-1 ff). No chemical name (IUPAC) of parent/ metabolites was provided.	This screening element has been flagged for further examination by the PMRA.