SUBJECT:

Residue Compliance Assurance Program

FDA Agreement No. 225-95-2000

Notes:

The FDA contact for this EOL is Frank MacKeith, HFS-605

Tel. No. 202-205-4045

This EOL is in effect indefinitely.

EXCHANGE OF LETTERS

10 February 1995

Mr. C. W Cooper
Director
International Activities Staff
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
200 C Street, S.W.
Washington DC 20204
USA

Dear Mr. Cooper:

RESIDUE COMPLIANCE ASSURANCE PROGRAMME (RCAP) FOR THE EXPORT OF NEW ZEALAND HORTICULTURAL PRODUCE TO THE UNITED STATES OF AMERICA

Thank you for your letter of 22 December, 1994 in which you suggest further minor modification/additions to the components of the above programme. We have incorporated these into the following "understanding" albeit we have modified the wording in your suggested "vii" to bring it into context. The following then is the New Zealand Ministry of Agriculture and Fisheries' understanding of the components of the above programme, the implementation of which would result in expedited access for New Zealand produce into the USA. Could you please confirm, or otherwise, that this is also the understanding of the USA Food and Drug Administration.

BEGINS

1 PURPOSE

The purpose of the programme is to facilitate the access of New Zealand horticultural produce into the USA by providing the USA Food and Drug Administration an official assurance from the New Zealand ministry of Agriculture and Fisheries that the produce covered by the programme will comply with the USA entry regulations covering pesticide residues.

2 DEFINITIONS/EXPLANATIONS

The following definitions/explanations apply for the purposes of the residue compliance assurance programme (RCAP) for the export of New Zealand horticultural produce to the United States of America.

Notes:

Chief Plants Officer

The Chief plants Officer of the New Zealand Ministry of Agriculture and Fisheries is accountable for the implementation of the New Zealand Residue Compliance Assurance Programme.

Director, International Activities Staff

The Director, International Activities Staff, Center for Food Safety and Applied Nutrition (CFSAN), USA Food and Drug Administration is accountable for the USA aspects of any international residue compliance assurance programmes for imported plant produce.

Hazard Analysis Critical Control Point (HACCP)

A hazard analysis critical control point approach is a comprehensive programme undertaken to ensure that the appropriate procedures and controls are in place to enable compliance with the USA MRLs. The procedure will involve the identification of the critical control points within the residue compliance assurance programme and the necessary controls to ensure on-going compliance (may include corrective actions) with specifications and other critical limits.

May Proceed Rate

This is a USA Food and Drug Administration determined percentage of import entries of a specific commodity from a particular country which will be automatically cleared by electronic means for entry into US commerce. The "May Proceed Rate" will vary from a high of near 100% for commodity:country combinations in which the USA Food and Drug Administration has a high confidence of compliance with the USA regulations to a low of 0% for commodity:country combinations with a greater likelihood of non-compliance based on past history. The "May Proceed Rate" will be specific to the shipper/exporter designated as participating in the RCAP by the New Zealand Ministry of Agriculture and Fisheries.

New Zealand Ministry of Agriculture and Fisheries

The New Zealand government department with delegate authority to act as the control authority for the certification/assurance of export plant material.

Non-Quantifiable Level

For the purpose of this RCAP,"non-quantifiable level" means "no residue" of any pesticide which does not have a United States Maximum Residue Level (MRL) using state-of-the-art residue analysis methods.

Notes:

Official Assurance

An official statement from the New Zealand Ministry of Agriculture and Fisheries Chief Plants Officer to the Director, International Activities Staff. Center for Food and Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services, that a particular crop is operating within a residue assurance compliance programme and that the New Zealand Ministry of Agriculture and Fisheries will be accountable for the implementation of the programme.

Residue Compliance Assurance Programme (RCAP)

The assurance programme under the jurisdiction of the New Zealand Ministry of Agriculture and Fisheries which utilizes HACCP principles to ensure compliance of a product to meet the USA Food and Drug Administration entry requirements. The RCAP will include such features as; a register of participating producers, a documented pest control programme that takes into account the decay characteristics of the involved chemicals in order to meet USA MRLs, a spray diary for growers to record their pesticide application details, a formal spray diary checking systems, produce sampling and laboratory analysis to document adherence to the programme and an official New Zealand Ministry of Agriculture and Fisheries audit programme.

Residue Standards

These are the legally permitted maximum residue levels (MRL), expressed in mg/kg, established in the USA by the Environmental Protection Agency. Where no USA MRL exists for a particular pesticide:commodity combination, the residue standard is defined as: "No Quantifiable level of the particular pesticide in the commodity to be exported to the USA".

United States of America Food and Drug Administration

The agency of the USA Department of Health and Human Services with delegated authority for ensuring that imported produce complies with pesticide residue standards.

3 RESPONSIBILITIES OF PARTICIPATING PARTIES

3.1 New Zealand Ministry of Agriculture and Fisheries

The New Zealand Ministry of Agriculture and Fisheries will:

I. Be accountable to the USA Food and Drug Administration for the implementation of the New Zealand components of the residue compliance assurance programme.

Notes:

ii. Ensure that participating producer groups within New Zealand are provided with accurate information on the required USA residue standards and other restrictions.

iii. Provide official, ongoing assurance to the FDA of the inclusion of any product under the residue compliance assurance programme.

iv. Provide a documented system for each product for "approval" by the USA Food and Drug Administration as a condition of its inclusion in the residue compliance assurance programme.

v. Provide an up to date list of New Zealand shippers/exporters, for a particular product, eligible to participate in the programme and the USA ports of entry for the produce concerned. All product exported to the USA ports of entry for the produce concerned. All product exported to the USA by the designated shippers/exporters will have been produced under the RCAP.

vi. Monitor/audit the residue compliance assurance programme to ensure ongoing compliance with the USA requirements.

vii. Ensure that all the appropriate horticultural product listed in an eligible shipper/exporter's "commercial invoice" was actually produced under the residue compliance assurance programme administered by the New Zealand Ministry of Agriculture and Fisheries.

3.2 USA Food and Drug Administration

The USA Food and Drug Administration will:

i. Advise the New Zealand Ministry of Agriculture and Fisheries of any USA MRLs, including any modifications that may occur while any RCAP is in operation.

ii. Predetermine (as a result of past history and knowledge of the particular programme) a "may proceed rate" that adequately reflects the confidence in the New Zealand RCAP relative to commodities/countries not covered by such a programme.

iii. Advise the New Zealand Ministry of Agriculture and Fisheries' Chief Plants Officer of any instances of certified shipments found to violate the residue standards.

Notes:

iv. Permit the responsible shipper/exporter to be listed as both the "shipper" and the "Manufacturer" when electronic entry screening data is submitted to the Agency.

4. Specific Programmes

Details of specific programmes are documented on crop basis and will be available to the USA Food and Drug Administration for purposes of approval (prior to implementation) and ongoing audit.

5 Contingencies

5.1 Contingencies Undertaken by the USA Food and Drug Administration Following Any Detection of Non-compliance of any Product Covered by the Residue Compliance Assurance Programme.

Shippers and or exporters/brokers whose products are found violative on Food and Drug Administration analysis will be placed on automatic detention by the Food and Drug Administration pending receipt from the New Zealand Ministry of Agriculture and Fisheries of a report of its investigation indicating the cause of the violation and the corrective actions taken to prevent future violations. If the Food and Drug Administration determines that the residue compliance assurance programme is not performing satisfactorily, it will lower the "may proceed rate" accordingly.

5.2 Contingencies Undertaken by the New Zealand Ministry of Agriculture and Fisheries

i. Failure of a Product to meet Programme Specifications

In the event of the failure of a product to meet the requirements of a specific documented programme, the New Zealand Ministry of Agriculture and Fisheries will take action in accordance with the contingencies outlined in that programme.

ii Detection of Non-compliance in the USA

On the receipt of notification from the USA Food and Drug Administration of non-compliance of a particular product, the New Zealand Ministry of Agriculture and Fisheries will undertake a full audit of the affected programme. Following identification of the problem and implementation of any corrective action, the Chief Plants Officer will supply a report accordingly to the Director, International Activities Staff, CFSAN and request that the product be reinstated into the residue compliance assurance programme.

Notes:

6. Communication

The Director, International Activities Staff, of the Center for Food Safety and Applied Nutrition, FDA (position currently held by C W Cooper) and the Chief Plants Officer (position currently hold by R J Ivess) will communicate from time to time and if appropriate modify the conditions of the residue compliance assurance programme. Communication on operational matters will be undertaken on their behalf by the Strategic Manager. Pesticides and Chemical Contaminants, CFSAN (position currently held by J W Jones) and the New Zealand Ministry of Agriculture and Fisheries National Manager (Market Access - Plants) (position currently held by P R Johnson).

ENDS

I look forward to your reply in due course.

Best regards.

Yours sincerely,

R J Ivess
Chief Plants Officer

March 13, 1995

Mr. Richard J. Ivess
Chief Plants Officer
MAF Regulatory Authority (Plants)
Ministry of Agriculture and Fisheries
ASB Bank House
101-103 The Terrace
P.O. Box 2526
Wellington
New Zealand

Dear Mr. Ivess:

The purpose of this letter is to clarify my letter to you of February 14, 1995. Except for the clarifying statements, all else from the February 14, 1995 acceptance letter remains the same.

It gives me great pleasure to accept your Residue Compliance Assurance Program (RCAP) for the export of New Zealand Horticultural Produce to the United States as contained in your February 10, 1995 letter. Although coming to this point has been a tortuous process, I believe that the result has been worth all the effort of both countries.

Notes:

The RCAP covering each horticultural product will become effective one month after receipt of the list of New Zealand shippers/exporters eligible to participate and the identification of the ports of entry into the United States (3.1v).

The Food and Drug Administration (FDA) intends that all horticultural products covered by the RCAP receive a "May Proceed Rate" of 99%.

Of the 1% for which paperwork will be required to be submitted, FDA intends that any resulting samples be taken after the product is in United States domestic status.

Sincerely yours,

Charles W. Cooper
Director
International Activities Staff
Center for food Safety
and Applied Nutrition

MINISTRY OF AGRICULTURE NEW ZEALAND

30 May 1996

Mr. C. W. Cooper
Director
International Activities Staff
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
200 C Street, S.W.
Washington DC 20204
USA

Dear Mr. Cooper:

REVISION TO THE RESIDUE COMPLIANCE ASSURANCE PROGRAMME (RCAP) FOR THE EXPORT OF NEW ZEALAND HORTICULTURAL PRODUCE TO THE UNITED STATES OF AMERICA

Further your visit to New Zealand early May 1996, I have made the minor modifications suggested in your meeting with Peter Johnston, to the above programme. The following is the New Zealand Ministry of Agriculture's current understanding of the components of the above

Notes:

programme, the implementation of which would result in expedited access for New Zealand produce into the USA. Could you please confirm, or otherwise, that this is also the understanding of the USA Food and Drug Administration.

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1 PURPOSE

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Director, International Activities Staff

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a high confidence of compliance with the USA regulations to a low of 0% for commodity:country combinations with a greater likelihood of non-compliance based on past history. The "May Proceed Rate" will be specific to the shipper/exporter designated as participating in the RCAP by the New Zealand Ministry of Agriculture.

New Zealand Ministry of Agriculture

The New Zealand government department with delegated authority to act as the control authority for the certification/assurance of export plant material.

Non-Quantifiable Level

For the purpose of this RCAP, "non-quantifiable level" means "no residue" of any pesticide which does to have a United States Maximum Residue Level (MRL) using state-or-the-art residue analysis methods.

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3 RESPONSIBILITIES OF PARTICIPATING PARTIES

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The New Zealand Ministry of Agriculture will:

i Be accountable to the USA Food and Drug Administration for the implementation of the New Zealand components of the residue compliance assurance programme.

ii Ensure that participating producer groups within New Zealand are provided with accurate information on the required USA residue standards and other restrictions.

iii Provide official, ongoing assurance to the FDA of the inclusion of any product under the residue compliance assurance programme.

iv Provide a documented system for each product for "approval" by the USA Food and Drug Administration as a condition of its inclusion in the residue compliance assurance programme.

v Provide an up to date list of New Zealand Shippers/exporters, their US importers, contact names, phone and fax numbers, for a particular product, eligible to participate in the programme and the USA ports of entry for the produce concerned. **All product exported to the USA by designated shippers/exporters will have been produced under the RCAP.**

vi Monitor/audit the residue compliance assurance programme to ensure ongoing compliance with the USA requirements.

vii Ensure that all the appropriate horticultural product listed in an eligible shipper/exporter's "commercial invoice" was actually produced under the residue compliance assurance programme administered by the New Zealand Ministry of Agriculture.

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ENDS

I look forward to your reply in due course.

Best regards

Yours sincerely.

R J Ivess
Chief Plants Officer