

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

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OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

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#### MEMO RAN DUM

SUBJECT:

ID No. 359-686 (RCB No. 3259) - Lindane Registration

Standard Followup - Residues From Seed Treatment -

MRID No. 404312-07

FROM:

Nancy Dodd, Chemist Mancy Dodd

Residue Chemistry Branch

Hazard Evaluation Division (TS-769C)

THRU:

Charles L. Trichilo, Ph.D., Chief

Residue Chemistry Branch

Hazard Evaluation Division (TS-769C)

TO:

Amy Rispin, Chief

Science Integration Staff

Hazard Evaluation Division (TS-769C)

and

George T. LaRocca, PM 15 Insecticide-Rodenticide Branch Registration Division (TS-767C)

and

Toxicology Branch (Attention: Edwin Budd) Hazard Evaluation Division (TS-769C)

The law firm of McKenna, Conner, and Cuneo on behalf of its client, the Centre International d'Etudes du Lindane and the Centre's 3 members holding U.S. Lindane registrations [Rhone-Poulenc, Inc. (representing Rhone-Poulenc Agrochemie), E.M. Industries, Inc. (representing Shell Agrar GmbH & Co., KG), and Inquinosa (Industrias Quimicas del Noroeste, S.A.)] now submits a seed treatment residue study in response to the Lindane Registration Standard and the Special Data Call-In Notice of January 23, 1986. The study is "The Uptake and Translocation of Radioactive Residues in Plants Grown from Seeds Treated with a <sup>14</sup>C Radiolabeled Lindane Emulsifiable Concentrate (EC) Formulation", M. Piznik, Rhone-Poulenc, Inc. (NJ), ASD No. 87/243, July 1987.

## Summary of Deficiencies That Need Resolution With Regard to Seed Treatment

- For sugar beets (tops and roots), residue data, a processing study, a revised Section B, and tolerances are needed.
- ° For radish (tops and roots), residue data, a revised Section B, and tolerances are needed.
- For spinach, the 0.02 ppm value at 42 days in the seed treatment study indicates that more residue data from seed treatment are not needed. Residue data from soil and foliar applications and reevaluation of the present spinach tolerance are needed. Changes in Section B are needed.
- ° For mustard greens, it is recommended that either the U.S. tolerances be revoked or residue data and labels describing the use and limitations of lindane on mustard greens be undertaken.
- ° For corn, field residue data, corn processing data, a revised Section B, and appropriate tolerances are needed.
- ° For wheat, residue data, a milling study, appropriate tolerances, and a revised Section B are needed.
- 14-C in reserve samples grown from seeds (at least one root and one grain) should be characterized. (See Conclusion section below.)

#### Conclusions re: Data Gaps Covered in this Review

- 1. When seeds of leafy vegetables, root crops, and grain crops are treated at registered rates, residues will usually be found in the plant. This indicates that the various seed treatments reflect a food use requiring tolerances.
- 2. Since residues greater than 1 ppm resulting from seed treatment were found in root crops and grain crops and this use involves a systemic uptake (not involving foliar metabolism), the <sup>14</sup>-C in reserve samples grown from seeds should be characterized.
- 3. Deficiencies related to seed treatment which were listed in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard and reiterated later in this review remain outstanding.

### Recommendations

RCB recommends that the registrant resolve those deficiencies relating to seed treatment (outlined in the 9/30/85 Lindane Registration Standard) after the plant metabolism issues have been resolved and a decision has been made as to whether or not any of the lindane metabolites are of toxicological concern.

#### §158.125 Residue Chemistry

## 171-4: Magnitude of the Residue

o The data gaps relative to the treatment of seeds with lindane have not been fulfilled.

## Seed Treatment

The following additional data are required:

"In this Section, there are several crops for which either seed treatment or seed, soil, and foliar treatments are registered. The following comments will apply to Residue Chemistry data requirements for these situations only.

- 1). If the required <sup>14</sup>C-labeled studies indicate that method sensitivity tolerances would be adequate to cover residues in crops having registered uses for seed treatments, i.e., only very low levels of radioactivity are observed in the raw agricultural commodity, then the geographical representation requirement for residue data reflecting seed treatment may be waived.
- 2). If residue data for crops having registered soil, seed <u>and</u> foliar uses indicate that significant residues result from the foliar treatments, then the residue data requirements for soil and seed treatments may be waived."

For convenience, those issues outlined in the Lindane Registration Standard for each commodity (sugar beet, sugar beet tops, radish, radish tops, spinach, mustard greens, corn, wheat) are given below, followed by the registrant's response, and RCB's Discussion/Conclusion re: the Seed Treatment Study.

Sugar Beet (Registered for seed treatment only).

1. The treatment of sugar beet seeds with lindane is

considered a food use, requiring tolerances, because a radioactive study demonstrating that there is no transfer in plants is not available. No tolerance for residues of lindane on sugar beets has been established. An appropriate tolerance, supported by adequate residue data, should be proposed for residues of lindane on sugar beets arising from the treatment of sugar beet seeds. Alternatively, a radiolabeled study showing the degree of transfer of residues from the seed to edible portions of the plant could be used to support the position that sugar beet seed treatment is a nonfood use not requiring a tolerance. The lack of adequate residue data or a radiolabeled study following seed treatment constitutes a data gap.

- 2. Residue data reflecting seed treatment of sugar beets are required from California, Minnesota/North Dakota, Idaho, Washington, Nebraska, Wyoming, and Michigan to support a tolerance on sugar beets (roots and tops). This is a data gap.
- 3. A processing study showing whether concentration of lindane residues occurs in sugar, molasses, and pulp may be required if significant levels of lindane residues are detected in sugar beets grown from beet seed treated at exaggerated application rates. This constitutes a possible future data gap.
- 4. Recommendations for tank mixtures of lindane with other pesticides not having established tolerances on sugar beets (roots and tops) should be removed from the label. This is a data gap.
- 5. The nature of the residue is not adequately understood. If plant metabolism studies indicate the presence of other residues besides parent, residue data will be required for these residues as well as for lindane. This constitutes a possible future data gap.

## Sugar Beet Tops (Registered for seed treatment only)

- 1. Sugar beet tops are a feed item, and residue data and a tolerance are needed for this commodity. The data should reflect the maximum intended use and analysis for the terminal residue of concern in the raw agricultural commodity. This is a data gap.
- 2. The treatment of sugar beet seeds with lindane is considered a food use, requiring tolerances, because a radioactive study demonstrating that there

is no transfer in plants is not available. No tolerance for residues of lindane on sugar beets has been established. An appropriate tolerance, supported by adequate residue data, should be proposed for residues of lindane on sugar beets arising from the treatment of sugar beet seeds. Alternatively, a radiolabeled study showing the degree of transfer of residues from the seed to edible portions of the plant could be used to support the position that sugar beet seed treatment is a nonfood use not requiring a tolerance. The lack of adequate residue data or a radiolabeled study following seed treatment constitutes a data gap.

- 3. Residue data reflecting seed treatment of sugar beets are required from California, Minnesota/North Dakota, Idaho, Washington, Nebraska, Wyoming, and Michigan to support a tolerance on sugar beets (roots and tops). This is a data gap.
- 4. A processing study showing whether concentration of lindane residues occurs in sugar, molasses, and pulp may be required if significant levels of lindane residues are detected in sugar beets grown from beet seed treated at exaggerated application rates. This constitutes a possible future data gap.
- Recommendations for tank mixtures of lindane with other pesticides not having established tolerances on sugar beets (roots and tops) should be removed from the label. This is a data gap.
- 6. The nature of the residue is not adequately understood. If plant metabolism studies indicate the presence of other residues besides parent, residue data will be required for these residues as well as for lindane. This constitutes a possible future data gap.

## Radish (Registered for seed treatment only)

1. The treatment of radish seeds with lindane is considered a food use, requiring tolerances, because a radioactive study demonstrating that there is no transfer of residues from the treated seed to the rest of the plant is not available. No tolerance for residues of lindane on radishes has been established. An appropriate tolerance, supported by adequate residue data, should be proposed for residues of lindane on radishes arising from the treatment of radish seeds. Alternatively, a radio-

labeled study showing the degree of transfer of residues from the seed to edible portions of the plant could be used to support the position that radish seed treatment is a nonfood use not requiring a tolerance. The lack of adequate residue data or a radiolabeled study following seed treatment constitutes a data gap.

- 2. Residue data reflecting seed treatment of radishes are required from California and Florida to support a tolerance. This is a data gap.
- 3. Recommendations for tank mixtures of lindane with other pesticides not having established tolerances on radishes should be removed from the label. This is a data gap.
- 4. The nature of the residue is not adequately understood. If plant metabolism studies indicate the presence of other residues besides parent, residue data will be required for these residues as well as for lindane. This constitutes a possible future data gap.

## Radish Tops (Registered for seed treatment only)

- 1. Radish tops are a food item, and residue data and a tolerance are needed for this raw agricultural commodity. The data should reflect the maximum intended use and analysis of the commodity for the terminal residue of concern. This is a data gap.
- The treatment of radish seeds with lindane is 2. considered a food use, requiring tolerances, because a radioactive study demonstrating that there is no transfer of residues from the treated seed to the rest of the plant is not available. No tolerance for residues of lindane on radishes has been established. An appropriate tolerance, supported by adequate residue data, should be proposed for residues of lindane on radishes arising from the treatment of radish seeds. Alternatively, a radiolabeled study showing the degree of transfer of residues from the seed to edible portions of the plant could be used to support the position that radish seed treatment is a nonfood use not requiring a tolerance. The lack of adequate residue data or a radiolabeled study following seed treatment constitutes a data gap.

- 3. Residue data reflecting seed treatment of radishes are required from CA and FL to support a tolerance. This is a data gap.
- 4. Recommendations for tank mixtures of lindane with other pesticides not having established tolerances on radishes should be removed from the label. This is a data gap.
- 5. The nature of the residue is not adequately understood. If plant metabolism studies indicate the presence of other residues besides parent, residue data will be required for these residues as well as for lindane. This constitutes a possible future data gap.

Spinach (Registered for soil, foliar, and seed application)

- 1. There are no lindane residue data available on spinach. Therefore, the tolerance level of 1.0 ppm is not supportable. Residue data from California, Texas/Oklahoma, New Jersey, Maryland/Virginia, and Colorado/Arizona are required to support a tolerance on this crop. The lack of residue data reflecting the current use constitutes a data gap.
- 2. The available residue data do not support the established tolerance for the following reasons:
  - a. The residue data reflect an application which is equivalent to foliar treatment only.
  - b. The description of the analytical methodology was not adequate; residues which were absorbed and translocated may not have been quantitated.
- If spinach is to be subjected to all 3 modes of application--seed treatment, soil treatment, and foliar treatment--then residue data reflecting collectively all 3 modes of application at the maximum application rates are needed. If it can be shown that seed treatment results in negligible residues in the edible portion of the plant, then residue data reflecting soil and foliar application collectively at the maximum application rates would be adequate. Residue data reflecting application of the EC formulations should be included, as residues would be expected to be higher from EC formulations than from the other formulations. This lack of residue data constitutes a data gap. If treatment is restricted to seed, soil, or foliar application, then a revised label is needed.

- 4. The label instructions limiting lindane application to spinach in the seedling stage are too vague. A more definite PHI should be imposed in a revised label. The PHI should be expressed in terms of days or could be related to the height of the seedling. This constitutes a data gap.
- 5. The number of applications per growing season and the time between applications should be specified in a revised label. This is a data gap.
- 6. Recommendations for tank mixtures of lindane with other pesticides not having established tolerances on spinach should be removed from the label. This is a data gap.
- 7. The nature of the residue is not adequately understood. If plant metabolism studies reveal the presence of other residues of toxicological concern besides lindane per se, residue data will also be required for these residues. This constitutes a possible future data gap.

## Mustard Greens (No registered use)

Since there is no current use for lindane on mustard greens, it is recommended that either the U.S. tolerance be revoked or, in order to support a tolerance on this crop, that residue data be submitted from Texas/Arizona, California, and Florida along with an appropriate label describing the current uses. The lack of residue data and labels describing the use and limitations of lindane on mustard greens constitutes a data gap.

## Corn (Registered for seed treatment only)

1. Seed treatments are considered to be food uses, unless a radiolabeled study has shown that there is no transfer of radioactive residues from the seed to the aerial portion of the plant. Such a study is not available for the treatment of corn. Therefore, this use is considered to be a food use requiring tolerances. No tolerance for residues of lindane on corn has been established. An appropriate tolerance, supported by adequate residue data, should be proposed for residues of lindane on corn grown from treated grain. Alternatively, a radiolabeled study showing the degree of transfer of residues from the seed to aerial portions of the plant could be used to support the position that grain treatment is a nonfood use

not requiring a tolerance. The lack of adequate residue data or a radiolabeled study following seed treatment constitutes a data gap.

- Since the use is on the commodity corn, residue data 2. for field corn, sweet corn, and pop corn are required. Residue data on sweet corn (including kernels plus cobs with husks removed) grown from treated seed are required from Florida, California, New York, Texas, Ohio/Pennsylvania, Massachusetts/ New Jersey, Oregon/Washington/Idaho, Michigan/ Minnesota/Wisconsin, and Illinois. Residue data on field corn grown from treated grain are required from all areas across the country. Residue data on popcorn grown from treated grain are required from İmdiana/Illinois/Ohio, Kentucky, and Nebraska. Residue data is needed on all 3 kinds of corn because seed treatment is involved. The lack of residue data on sweet corn, field corn, and popcorn grown from treated grain constitutes a data gap.
- 3. Residue data on forage and fodder from second generation popcorn and field corn are required as well as residue data on forage from second generation sweet corn.
- 4. The available data on the use of lindane on stored corn is not pertinent to the current use (seed treatment).
- 5. A food additive tolerance will not be necessary for refined corn oil from second generation corn, if it is established that corn oil is always deodorized and/or hydrogenated during the refining process. It has been shown that lindane residues do not survive the hydrogenation or deodorization step. This constitutes a possible data gap.
- 6. If detectable limitane residues on second generation corn result from seed treatment of corn at exaggerated rates, a milling study will be required. This constitutes a possible data gap.
- 7. Recommendations for tank mixtures of lindane with other pesticides not having established tolerances on corn should be removed from the label. This is a data gap.
- 8. The nature of the residue is not adequately understood. If plant metabolism studies indicate the presence of other residues besides parent, and

if significant levels of these metabolites are found in second generation corn seed, then a processing study would be required to determine if these residues concentrate in processed commodities. Residue data would be required for these residues as well as for lindane on the raw agricultural commodities. This constitutes a possible future data gap.

9. The states of MT, ND, MN, WA, SD, and OR have seed treatment uses [24 (c)] for corn. These uses reflect application rates which are less than or equal to the Federally registered use. However, until the data and tolerances required above for these seed treatments are submitted/reviewed/established, the state registrations should be revoked. This is a data gap.

## Wheat (Registered for seed treatment only)

- Seed treatments are considered to be food uses, unless a radiolabeled study has shown that there is no transfer of radioactive residues from the seed to the aerial portion of the plant. Such a study is not available for the treatment of wheat grain. Therefore, this use is considered to be a food use requiring tolerances. No tolerance for residues of lindane on wheat has been established. An appropriate tolerance, supported by adequate residue data, should be proposed for residues of lindane on wheat grown from treated seed. Alternatively, a radiolabeled study showing the degree of transfer of residues from the seed to aerial portions of the plant could be used to support the position that seed treatment is a nonfood use not requiring a tolerance. lack of adequate residue data or a radiolabeled study following seed treatment constitutes a data gap.
- 2. There are no reliable residue data reflecting lindane use on wheat grain. Residue data on wheat grown from treated seed in all areas across the country are required for a tolerance on this crop. Since wheat forage, straw, and hay are feed items, it will also be necessary to either submit residue data on forage, straw, and hay grown from treated seed or to prohibit feeding wheat straw, forage, and hay to livestock in a revised label. This lack of residue data constitutes a data gap.
- 3. If detectable residues of lindane are found in wheat (that is, in second generation wheat grain) after exaggerated seed treatment rates, a milling study

will also be necessary. Although milling studies on wheat have been carried out, these studies involved grain which had been treated and milled. Spiking and processing a commodity is not generally acceptable when the pesticide is systemic. Lindane is systemic; the residues in second generation wheat would result from translocation and would not be only surface residues. This constitutes a possible data gap.

- 4. The nature of the residue is not adequately understood. If plant metabolism studies indicate the presence of other residues besides parent, and if significant levels of these metabolites are found in second generation wheat grain, then a processing study would be required to determine if these residues concentrate in processed commodities. Residue data would be required for these residues as well as for limitane on the raw agricultural commodities. This constitutes a possible future data gap.
- 5. Recommendations for tank mixtures of lindane with other pesticides not having established tolerances on wheat should be removed from the label. This is a data gap.
- 6. The States of Montana, North Dakota, Minnesota, Washington, South Dakota, and Oregon have seed treatment uses [24(c)] for wheat. These uses reflect application rates which are less than or equal to the Federally registered use. However, until the data and tolerances required above for these seed treatments are submitted/reviewed/established, the state registrations should be revoked. This is a data gap.

## CIEL's Response

The petitioner has submitted a study on residues in plants from various seeds treated with a <sup>14</sup>C-Lindane formulation. This study was planned to determine whether residues from treated seeds could be found in crops and to identify any residues which could be found.

An addendum to this report will be provided for mature sugar beets since the sugar beets were in the early growth stages at the time the report was written.

Radish, sugar beet, spinach, mustard, field corn, sweet corn, and spring wheat seeds were coated with <sup>14</sup>C Lindane EC containing 20.92% lindane. Seeds were planted in soil outdoors.

Samples were analyzed for <sup>14</sup>C periodically by oxidative combustion and autoradiography. When significant residues were found, the sample was extracted and analyzed for <sup>14</sup>C by liquid scintillation counting (LSC) and for lindane by gas liquid chromatography (GLC).

According to the method protocol, seeds were to be treated at label rates as follows:

Seed	Label Rate (oz active/ 100 lb seed)	<u>PPM</u>	Mg Lindane 100 gm seeds	Grams Formulated
Radish	0.5	312	31.22	0.155
Sugar Beets	4.0	2508	250.82	1.242
Spring Wheat	0.5**	312	31.22	0.155
Field Corn	2.0	1249	124.86	0.619
Spinach	1.0	624	62.43	0.309
Mustard	1.0*	624	62.43	0.309

<sup>\*</sup>There is no current use.

The petitioner submits the following tables containing data:

TABLE 1

THE COATING OF VARIOUS SEEDS WITH 14-C
RADIOLABELED LINDANE EC FORMULATION

				ACTUAL TREATMENT			
SEED	SAMPLE	AMOUNT	THEO RETICAL	COMBUSTION	EXTRAC		
	WEIGHT	EC FORM.	TREATMENT		LSC	GLC	
·	(gm)	(gm)	(ppm)	(ppm)	(ppm)	(ppm)	
RADISH	100	0.1709	312	381	25 4	257	
SUGAR BEET	100	1.3620	25 08	2288	2194	2333	
MUSTARD	15	0.0512	624	5 86	575	547	
SPINACH	11	0.486	624	817	395 (704) 1	425 (734) <sup>1</sup>	
SPRING WHEAT	100	0.1706	312	369	288	286	
FIELD CORN	100	0.6841	1249	1774	900	972	
SWEET CORN	100	0.6802	1249	1444	1112	1125	

Approximately 50% of the radioactivity was found to be absorbed into the seeds. The amount of activity absorbed was determined by the combustion of the extracted seeds.

<sup>\*\*</sup>Registered at 0.5 but also up to 3.3 oz ai/100 lb seed.

TABLE 2

SAMPLING SCHEDULE AND TOTAL RESIDUE FOUND IN PLANTS GROWN FROM SEEDS TREATED WITH 14-C RADIOLABELD LINDANE EC FORMULATION

		TREATED	MITH	RESULTS	JIOLABE S EXPRE	OLABELD LINDANE EXPRESSED IN PPM	TREATED WITH 14-C KADIOLABELD LINDANE EC FORMULATION RESULTS EXPRESSED IN PPM	OKMULAT	Z O				
SUBSTRATE	7 DAY	14 DAY	21 DAY	22 DAY	32 DAY	42 DAY	46 DAY	60 DAY	74 DAY	90 DAY	113 DAY	5 MONTH	
SUGAR BEET ROOTS SUGAR BEET FOLIAGE	; ;		; ;	1 1		1 1	; ;	1.025	0.953	0.536	0.836 0.355	0.297	
WHEAT ROOTS WHEAT FOLIAGE WHEAT GRAIN	111	111	111	111	0.470 8.588 1.607	1 1 1	1 1 1	2.596 0.581 0.059	4.759 0.795 0.033	2.748 0.923 0.090	4.216 2.150 0.097	2.925 0.052	
RADISH ROOTS RADISH LEAVES	1.234	0.130	1 1	0.056	! !	1 1	} }	; ;	1 1	1 1	1 1	11	
MUSTARD FOLIAGE MUSTARD ROOTS	1.960	1 }	1 1	0.021	11	1 }	< 0.01 0.055	1 }	1 I	1 1	1 1	1 1	
SWEET CORN GRAIN SWEET CORN HUSKS SWEET CORN FOLIAGE SWEET CORN ROOTS	11111	11111	11111	1111	0.218 1.043			11111	<ul><li>0.01</li><li>0.01</li><li>0.01</li><li>0.158</li></ul>	< 0.01 < 0.01 < 0.01 0.051 0.355	11111	11111	
FIELD CORN GRAIN FIELD CORN HUSKS FIELD CORN FOLIAGE FIELD CORN ROOTS		11111		11111	0.109		11111	 0.063	< 0.01 < 0.01 < 0.01 0.022 0.543	< 0.01 < 0.01 0.025 0.064 0.837			
SPINACH LEAVES	1	1	0.105	1	-	0.020	!	1	!	1	}	1	

TABLE 3

THE DETERMINATION OF EXTRACTABLE (TER) AND BOUND (TBR)

14-C RESIDUES AND THE DETERMINATION OF 14-C LINDANE RESIDUES
IN PLANT FRACTIONS BY LSC AND GLC

-14-

			LIN	DANE		
SUBSTRATE	TR	TER	GLC	LSC	TBR	TER + TBR
22 DAY RADISH ROOT	0.056	0.038 88.4%	0.030 69.8%	0.027 62.8%	0.005 11.6%	0.043
22 DAY MUSTARD FOLIAGE	0.021		0.017 113.3%	0.016 106.7%	0.003 20.0%	0.015
90 DAY FIELD CORN ROOTS	0.340	0.307 71.2%	0.165 38.3%	0.165 38.3%	0.124 28.8%	0.431
90 DAY FIELD CORN FOLIAGE	0.064	0.016 28.1%		0.005 8.8%	0.041 71.9%	0.057
90 DAY SWEET CORN FOLIAGE	0.051	0.060 81.1%	0.012 16.2%	0.010 13.5%	0.014 18.9%	0.074
5 MONTH SUGAR BEET ROOTS	0.297	0.175 81.0%	0.090 41.7%	0.092 42.6%		0.216
5 MONTH SUGAR BEET FOLIAGE	0.181	0.174 64.9%	0.035 13.1%	0.039 14.6%	0.094 35.1%	0.268
5 MONTH WHEAT FOLIAGE	2.925	0.136 4.2%	7 7 7 7	0.023 0.7%	3.181 98.4%	3.234
5 MONTH WHEAT GRAIN	0.052	0.000	0.002 1.8%	0.002 1.8%		0.113

NOTE: Percentages are based on the normalized Total Residue (TER + TBR).

## RCB's Discussion/Conclusion re: The Seed Treatment Study

This study indicates that when seeds of leafy vegetables, root crops, and grain crops are treated at registered rates, residues may be found in the plants. This indicates that the various seed treatments reflect a food use requiring tolerances.

Those deficiencies related to seed treatment of sugar beets, radish, spinach, mustard, corn, and wheat given earlier in this review and which were listed in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard remain outstanding.

Since residues greater than 1 ppm resulting from seed treatment were found in root crops and grain crops and this use involves a systemic uptake (not involving foliar metabolism), the 14-C in reserve samples grown from seeds in at least one root crop and one grain crop should be characterized.

cc: RF, SF, Circu, Reviewer-N. Dodd, W. Boodee, Lindane Registration Standard File, TOX, PM#15, A. Rispin RDI: JHO nley: 3/14/88: RDS chmitt: 3/21/88 TS-769: RCB: CM#2: RM810: X1681: N Dodd: Kendrick & Co.: 3/21/88