MEMO OF MEETING ON 2/27/84

S. Creeger and C. Fletcher, EAB and R. Perfetti, RCB met with RD representative and FMC Corporation representatives to discuss future registration data requirements for the herbicide FMC 57020 for preplant (soil incorporated) or post emergence (surface applied) use on soybeans. The application rate is 0.5 to 1.5 lb a. i./A.

FMC presented 14C rotational crop data and sought EAB guidance on the next step for registration. The data showed oat straw planted 10 months after application contained measurable levels of 14C. Other crops showed little or no 14C activity. EAB stated that the data would support a 10 month crop rotation restriction on the label provided the residues in the dried oat straw were identified as undistinguishable or were shown to be incorporated into natural plant constituents. If parent 14C residues are present then they must be shown to be present at a level less than the limit of detection when using the cold method of analysis. EAB noted that the data would not support grazing of immature crops. (FMC commented that a 10 month rotation restriction would be acceptable.)

FMC asked about the protocol submitted on the special field leaching study. EAB commented that the protocol had not yet been routed for review. However, based on quick overview EAB requested FMC to submit a more complete protocol. EAB asked questions about details of the protocol:

<table>
<thead>
<tr>
<th>EAB Question</th>
<th>FMC Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specify location</td>
<td>Maryland Eastern Shore</td>
</tr>
<tr>
<td>Field size</td>
<td>One-half acre</td>
</tr>
<tr>
<td>Herbicide soil incorporated</td>
<td>Will conduct both broadcast and incorporated study</td>
</tr>
<tr>
<td>Prefer soil with &lt;1% OM</td>
<td>Soil will be at least &lt;2% OM</td>
</tr>
<tr>
<td>Irrigation should simulate major rainstorm</td>
<td>Irrigation will include &quot;major rainfall event&quot;</td>
</tr>
</tbody>
</table>

EAB made other comments: If residues found at 4 feet, soil must be sampled deeper. FMC should sample soil in 1 foot increments and should submit hydrology data of area and estimate rainfall for area (EAB will verify data). FMC should
specify soil textural class for the 1 foot increments. Also, soil should be analyzed for parent compound and Metabolite A found in the anaerobic soil metabolism study. If residues are found, additional studies in other locations may be required.

FMC commented that study will run for 60 days.

Concerning the field dissipation studies reviewed earlier, rainfall data and soil characterization must be submitted.

Clinton Fletcher
Review Section No. 1

STRUCTURES

\[
\begin{align*}
\text{FMC 57020} & \quad \text{Water sol.: 1,100 ppm} \\
\text{Metabolite A} & \\
\end{align*}
\]
February 13, 1984

Mr. Robert J. Taylor
Product Manager 25
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Room 245, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Taylor:

Subject: FMC 57020 Herbicide

We wish to have a conference-meeting with Dr. Samuel M. Creeger, Environmental Assessment Branch, and Dr. Robert S. Quick, Residue Chemistry Branch, in order to review the results of our radio-labeled crop rotational studies with FMC 57020. Our objective is to obtain Agency guidance concerning the need for residue field trials and rotational (inadvertent) crop tolerances for FMC 57020.

I'd appreciate it if you would arrange the meeting for us with Drs. Creeger and Quick. Mr. Ronald F. Cook, Residue Analysis Manager, and Dr. Robert A. Robinson, Metabolism Manager, will accompany me. Acceptable dates for us are Monday, February 27, Tuesday, February 28, or Thursday, March 1 at 10:00 am or 1:00 pm. Please let me know which date and time would be most convenient for you. You can reach me at (215) 299-6503.

Thank you in advance for your assistance in setting up this conference-meeting.

Sincerely yours,

J. J. Lauber
Manager, Product Registration

cc: D. B. Carlson
    R. F. Cook
    J. R. Graham
    J. F. McCarthy
    R. A. Robinson
FMC 57020 HERBICIDE

FEBRUARY 27, 1984

AGENDA

1. INTRODUCTION - REGISTRATION STATUS OF FMC 57020; PROPOSED LABEL

2. REVIEW OF SOYBEAN RESIDUE STUDIES

3. REVIEW OF RADIO-LABELED CROP ROTATION DATA WITH FMC 57020

4. DISCUSSION OF INADVERTENT RESIDUE CHEMISTRY PROGRAM

5. DISCUSSION OF FMC PROTOCOL CONCERNING A FIELD MOBILITY STUDY WITH FMC 57020

FMC PARTICIPANTS: MR. RONALD F. COOK, RESIDUE ANALYSIS MANAGER

DR. ROBERT A. ROBINSON, METABOLISM MANAGER

DR. JACK LAUBER, REGISTRATION MANAGER
FMC 57020 HERBICIDE

CROP REGISTRATION OBJECTIVES

INITIAL:  SOYBEANS

FUTURE:  TOBACCO
         POTATOES
         COTTON

R124A1
DD30
FMC 57020 HERBICIDE

SOYBEANS

0 EXPERIMENTAL USE PERMIT (279-EUP-93)

1983: 800 ACRES, 2,400 LB. A.I., 29 STATES
1984: 935 ACRES, 2,805 LB. A.I., 29 STATES

0 EXPERIMENTAL USE PERMIT/TEMPORARY TOLERANCE (PENDING)

1985: 70,000 ACRES, 70,000 LB. A.I., 29 STATES

0 REGISTRATION APPLICATION/TOLERANCE PETITION

TO BE SUBMITTED: AUGUST, 1984
FMC 57020 HERBICIDE
SOYBEAN USE DIRECTIONS (PROPOSED)

- FMC 57020 4EC OR 6EC HERBICIDE
- 0.5 TO 1.25 (PERHAPS 1.50) LBS AI/ACRE
- BROADCAST APPLICATION (PRE-EMERGENCE OR PREPLANT) - MAIN USE
- BAND APPLICATION
- ALONE OR IN COMBINATION WITH METRIBUZIN OR LINURON (TANK MIX)
FMC 57020 HERBICIDE

CHEMICAL NAME: 2-(2-CHLOROPHENYL) METHYL-4,
4-DIMETHYL-3-ISOXAZOLIDINONE

STRUCTURAL FORMULA:
FMC 57020

TOTAL $^{14}$C RESIDUES

(PPM EQUIVALENT TO PARENT CHEMICAL)

IN SOYBEAN PLANTS FROM FIELD TREATMENT

<table>
<thead>
<tr>
<th></th>
<th>2 LB</th>
<th></th>
<th>3 LB</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$^{14}$C LABEL</td>
<td></td>
<td>$^{14}$C LABEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CARBONYL</td>
<td>RING</td>
<td>CARBONYL</td>
<td>RING</td>
</tr>
<tr>
<td>30 DAY</td>
<td>3.51</td>
<td>2.38</td>
<td>3.59</td>
<td>3.72</td>
</tr>
<tr>
<td>60 DAY</td>
<td>0.74</td>
<td>0.70</td>
<td>1.40</td>
<td>1.40</td>
</tr>
<tr>
<td>BEAN</td>
<td>0.10</td>
<td>0.10</td>
<td>0.15</td>
<td>0.23</td>
</tr>
</tbody>
</table>
## FMC 57020

**DISTRIBUTION OF $^{14}$C RESIDUES FROM SOYBEANS**

<table>
<thead>
<tr>
<th></th>
<th>2 LB AI/A</th>
<th></th>
<th>3 LB AI/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RING-$^{14}$C</td>
<td>CARBONYL-$^{14}$C</td>
<td>RING-$^{14}$C</td>
</tr>
<tr>
<td>FRACTION</td>
<td>%</td>
<td>PPM</td>
<td>%</td>
</tr>
<tr>
<td>FAT/FATTY ACIDS</td>
<td>9.6</td>
<td>0.011</td>
<td>10.6</td>
</tr>
<tr>
<td>FMC 57020</td>
<td>0.4</td>
<td>&lt;0.001</td>
<td>1.4</td>
</tr>
<tr>
<td>METABOLITES</td>
<td>47.7</td>
<td>0.052</td>
<td>27.8</td>
</tr>
<tr>
<td>POLAR RESIDUES</td>
<td>14.7</td>
<td>0.016</td>
<td>38.4</td>
</tr>
<tr>
<td>BOUND RESIDUES</td>
<td>27.6</td>
<td>0.030</td>
<td>21.8</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100.0</td>
<td>0.110</td>
<td>100.0</td>
</tr>
</tbody>
</table>

---

*PPM EQUIVALENT TO PARENT COMPOUND*
### FMC 57020

**SOYBEAN METABOLITE DISTRIBUTION**

<table>
<thead>
<tr>
<th></th>
<th>2 LB</th>
<th></th>
<th>3 LB</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>PPM</td>
<td>%</td>
<td>PPM</td>
</tr>
<tr>
<td>OCB ALCOHOL</td>
<td>5.2</td>
<td>0.003</td>
<td>12.1</td>
<td>0.015</td>
</tr>
<tr>
<td>HYDROXY OCB ALCOHOLS&lt;sup&gt;2/&lt;/sup&gt;</td>
<td>19.0</td>
<td>0.013</td>
<td>10.8</td>
<td>0.015</td>
</tr>
<tr>
<td>OCB ACID</td>
<td>0.8</td>
<td>&lt;0.001</td>
<td>1.3</td>
<td>0.002</td>
</tr>
<tr>
<td>UNIDENTIFIED METABOLITES&lt;sup&gt;(4)&lt;/sup&gt;</td>
<td>2.8</td>
<td>0.003&lt;sup&gt;3/&lt;/sup&gt;</td>
<td>2.1</td>
<td>0.004&lt;sup&gt;3/&lt;/sup&gt;</td>
</tr>
<tr>
<td>REMAINING RESIDUE</td>
<td>19.9</td>
<td>0.022&lt;sup&gt;3/&lt;/sup&gt;</td>
<td>21.7</td>
<td>0.046&lt;sup&gt;3/&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>47.7</td>
<td></td>
<td>48.0</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1/</sup> EtAC SOLUBLE FRACTION (AFTER ACID HYDROLYSIS)

<sup>2/</sup> INCLUDES THREE POSSIBLE MONOHYDROXYLATED ALCOHOLS. A FOURTH ISOMER (5-HYDROXY OCB) WAS ELIMINATED BY CHROMATOGRAPHY

<sup>3/</sup> AS FMC 57020 EQUIVALENT
FMC 57020
SOYBEAN METABOLISM SUMMARY

- TOTAL $^{14}C$ RESIDUES IN IMMATURE PLANTS 2-10 PPM (PARENT EQUIV.) BUT ONLY $\sim 0.2$ PPM IN MATURE BEANS.
  MAJORITY OF RESIDUES BOUND OR POLAR PRODUCTS.

- IMMATURE PLANTS CONTAIN PARENT COMPOUND AND SIX
  SIGNIFICANT ($\geq 10\%$) METABOLITES. CLEAVAGE OF
  MOLECULE INDICATED (NOT OBSERVED IN RAT).

- NO SIGNIFICANT LEVELS OF PARENT CHEMICAL INDICATED
  IN SOYBEANS ($\sim 1$ PPB),

- SUBSTANTIAL AMOUNTS OF SOYBEAN $^{14}C$ RESIDUE INCORPORATED
  INTO BOUND AND POLAR (WATER SOLUBLE) RESIDUES
  ($0.03 - 0.07$ PPM).

- SOME UBIQUITOUS INCORPORATION OF $^{14}C$ INTO NATURAL
  PRODUCTS ($\sim 0.01$ PPM).

- LOW BUT DETECTABLE LEVELS OF O-CHLOROBENZYL ALCOHOL
  AND HYDROXYLATED O-CHLOROBENZYL ALCOHOLS ($<0.01 - 0.01$
  PPM) DETECTED IN SOYBEANS FROM 2 LB AI/A TREATMENT.
FMC 57020
RESIDUE RESULTS

<0.01 PPM FMC 57020
(NO DETECTABLE RESIDUE)

MATURE SOYBEANS
(111-152 DAY PHI)

22 FIELD TRIALS
(11 PRE-PLANT INCORPORATED
& 11 PRE-EMERGENT)

9 STATES
(AR, IL, IN, MD, NC, NE,
NJ, MO, VA)

2 LB AI/A BROADCAST TREATMENT
FMC 57020
SOYBEAN PROCESSING STUDY

APPLICATION
- AT PLANTING
- BROADCAST PRE-EMERGENCE
- 3 LB AI/A

SAMPLED
- MATURE BEANS @ 139 DAYS

ANALYSES
- UNPROCESSED BEANS
- SOYBEAN HULLS
- SOYBEAN MEAL
- SOYBEAN OIL
- SOYBEAN SOAPSTOCK

<0.01 PPM FMC 57020
(NO DETECTABLE RESIDUE)
FMC 57020

CONCLUSION

SOYBEAN REGISTRATION WILL BE FOR BEANS ONLY WITH LABEL RESTRICTION AGAINST FEEDING FORAGE AND FODDER.

TOLERANCE ON BEANS WILL BE NEGLIGIBLE TOLERANCE FOR PARENT COMPOUND BASED ON METHOD SENSITIVITY (0.05 PPM).

STANDARD SOYBEAN PROCESSING STUDY IS NOT REQUIRED FOR FULL REGISTRATION.

COW AND POULTRY METABOLISM AND FEEDING STUDIES ARE NOT REQUIRED FOR FULL REGISTRATION.
FMC 57020
RADIOLABELED CROP ROTATION STUDY

STUDY PROTOCOL

- OUTDOOR TESTS CONDUCTED AT FMC RESEARCH FARM, CHAMPAIGN, IL.

- CARBONYL- AND RING-\(^{14}\)C FMC 57020 FORMULATED (4 EC) AND APPLIED AT 2 LB AI/A (PPI).

\[
\begin{align*}
\text{CH}_3 & - \text{N} - \text{CH}_2 - \text{Cl} \\
\text{CH}_3 & - \text{Cl}
\end{align*}
\]

CARBONYL-\(^{14}\)C FMC 57020

\[
\begin{align*}
\text{CH}_3 & - \text{N} - \text{CH}_2 - \text{Cl} \\
\text{CH}_3 & - \text{Cl}
\end{align*}
\]

RING-\(^{14}\)C FMC 57020

*DENOTES POSITION OF \(^{14}\)C LABEL

- CHEMICALS APPLIED TO 1 X 10 FT TEST PLOTS (6/82), SOYBEANS PLANTED.

- SOYBEANS HARVESTED (10/82).

- ROTATIONAL CROPS PLANTED (4/83).
STUDY PROTOCOL (CONT'D)

- ROTATIONAL CROPS SAMPLED

  CORN  10/83
  OATS  8/83
  CABBAGE  8/83
  SUGAR BEET  10/83

- SOIL SAMPLED (0-6", 6-12")
  - APPLICATION (6/82)
  - SOYBEAN HARVEST (10/82)
  - ROTATIONAL CROP PLANTING (4/83)
  - SUGAR BEET HARVEST (10/83)

- ROTATIONAL CROPS ASSAYED BY COMBUSTION ASSAY FOR TOTAL $^{14}$C RESIDUES.

- MATURE RAC's SUBJECTED TO EXTRACTION/DIGESTION AND SOLVENT PARTITION.

- SOILS ASSAYED BY SOLVENT EXTRACTION. PARENT CHEMICAL ANALYZED BY CHROMATOGRAPHY.
SOIL EXTRATION PROCEDURE

SOIL

1. Methanol/Water
2. Methylene Chloride

METHYLENE CHLORIDE

AQUEOUS

NON-EXTRACTABLE

Methanol Soxhlet

METHANOL

BOUND RESIDUE

HPLC

TLC

107

18
<table>
<thead>
<tr>
<th>TIME (MONTHS)</th>
<th>CARBONYL-$^{14}$C</th>
<th>RING-$^{14}$C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>FMC 57020</td>
<td>1.01</td>
<td>0.25</td>
</tr>
<tr>
<td>DEGRADATES AQUEOUS</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>DEGRADATES BOUND</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1.09</td>
<td>0.41</td>
</tr>
<tr>
<td>TIME (MONTHS)</td>
<td>CARBONYL-$^{14}$C</td>
<td>RING-$^{14}$C</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------</td>
<td>--------------</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>FMC 57020</td>
<td>0.07</td>
<td>0.14</td>
</tr>
<tr>
<td>DEGRADATES</td>
<td>ND</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>AQUEOUS</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>BOUND (NON-EXTRACTABLE)</td>
<td>0.02</td>
<td>0.05</td>
</tr>
<tr>
<td>TOTAL</td>
<td>0.09</td>
<td>0.19</td>
</tr>
</tbody>
</table>
FMC 57020
RADIOLABELED CROP ROTATION STUDY
CROP EXTRACTION/DIGESTION SCHEME

CROP
  1. Hexane
  2. Filter...

HEXANE
  Acetonitrile
    ACETONITRILE
    HEXANE

SOLIDS
  1. Acid Reflux
  2. Filter
  3. Methylene Chloride

METHYLENE CHLORIDE
AQUEOUS
BOUND
### FMC 57020
#### Radiolabeled Crop Rotation Study
##### Summary of $^{14}$C Crop Residue Distribution

<table>
<thead>
<tr>
<th>Fraction</th>
<th>$^{14}$C Label</th>
<th>PPM (FMC 57020 Equivalents)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Corn</td>
<td>Oats</td>
<td>Cabbage</td>
<td>Sugar Beets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Silage</td>
<td>Stover</td>
<td>Grain</td>
<td>Straw</td>
<td>Grain</td>
<td>Head</td>
<td>Tops</td>
<td>Roots</td>
</tr>
<tr>
<td>Organosoluble</td>
<td>C</td>
<td>0.002</td>
<td>0.007</td>
<td>0.010</td>
<td>0.016</td>
<td>0.019</td>
<td>0.009</td>
<td>0.011</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>R</td>
<td>0.003</td>
<td>0.008</td>
<td>0.005</td>
<td>0.027</td>
<td>0.037</td>
<td>0.006</td>
<td>0.027</td>
<td>0.008</td>
</tr>
<tr>
<td>Polar (aqueous)</td>
<td>C</td>
<td>0.006</td>
<td>0.006</td>
<td>0.004</td>
<td>0.018</td>
<td>0.030</td>
<td>0.012</td>
<td>0.015</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>R</td>
<td>0.006</td>
<td>0.008</td>
<td>0.010</td>
<td>0.024</td>
<td>0.021</td>
<td>0.011</td>
<td>0.013</td>
<td>0.008</td>
</tr>
<tr>
<td>Bound</td>
<td>C</td>
<td>0.005</td>
<td>0.014</td>
<td>0.002</td>
<td>0.036</td>
<td>0.021</td>
<td>0.011</td>
<td>0.016</td>
<td>0.010</td>
</tr>
<tr>
<td></td>
<td>R</td>
<td>0.007</td>
<td>0.029</td>
<td>0.003</td>
<td>0.068</td>
<td>0.027</td>
<td>0.005</td>
<td>0.023</td>
<td>0.016</td>
</tr>
<tr>
<td>Total</td>
<td>C</td>
<td>0.013</td>
<td>0.028</td>
<td>0.016</td>
<td>0.071</td>
<td>0.070</td>
<td>0.032</td>
<td>0.042</td>
<td>0.021</td>
</tr>
<tr>
<td></td>
<td>R</td>
<td>0.016</td>
<td>0.045</td>
<td>0.019</td>
<td>0.118</td>
<td>0.085</td>
<td>0.022</td>
<td>0.063</td>
<td>0.032</td>
</tr>
</tbody>
</table>

---

C = Carbonyl-$^{14}$C FMC 57020  
R = Ring-$^{14}$C FMC 57020  
Organosoluble = Total $^{14}$C in Hexane, Acetonitrile and Methylene Chloride
FMC 57020
RADIOLABELED CROP ROTATION

RESULTS/DISCUSSION

- Levels of radiocarbon (mostly FMC 57020) persist in soil
- $^{14}$C residues incorporated into rotational crops
- Majority of radiocarbon in rotational crops water soluble and/or bound in plant solids
- FMC seeks guidance on current and future status of rotational crop/inadvertent residue issue
FMC 57020
FIELD MOBILITY STUDY

OBJECTIVE

Determine leachability (vertical mobility) of FMC 57020 through a light textured agricultural soil under irrigated field conditions.

TEST SITE

Study will be conducted at a single loamy sand soil (>70% sand, <2% organic matter) location suitable for agricultural production of soybeans. The site and immediately adjacent areas will have no previous history of treatment with FMC 57020. Soil surface at the study site will be worked up in accordance with standard agricultural practice, but no crop will be planted. Treatment of the plot would be with FMC 57020 4.0 EC at 2 lb ai/A as a surface broadcast application (i.e., pre-emergent). Water will be applied to the plot by irrigation on post treatment days 1, 4, 9, 14, 19, 24, 29, 39, 49 and 59 at a rate of 0.5 in/application. Soil surface will be left undisturbed throughout the test.

SAMPLING

Soil core samples (0-1, 1-2, 2-3 and 3-4 ft) will be taken from the plot on days 0, 2, 5, 10, 15, 20, 25, 30, 40, 50 and 60. A total of 10 cores, randomly selected, will be composited to form the sample for each sampling day. An untreated area will also be sampled at 1 foot increments to 4 ft on days 0, 10, 20, 30 and 60.

ANALYSES

Residue levels of FMC 57020 (parent) and FMC 65317 (anaerobic soil metabolite) will be determined in the composite soil samples.

MISCELLANEOUS

The following supplemental information will be obtained.

- Soil textural classification
- Evapotranspiration rate (Pan evaporation)
- Rainfall data
- Temperature