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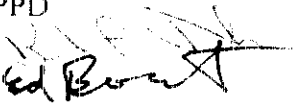
April 5, 2001

Memorandum

Subject: Review of Public Interest Document for CryIF Protected Corn

To: Michael Mendelsohn, RAL, BPPD

Thru: Bob Torla, Economist, BPPD

From: Ed Brandt, Economist, BPPD 

This review includes documents submitted by Pioneer Hi-Bred International, Inc. and DOW Agro Sciences on 2-16-2000 and 1-23-2001. Also included is the Environmental Assessment of Corn line 1507 prepared by APHIS (undated).

Criteria for approval

The criteria for a determination as to whether registration of a pesticide chemical is in the public interest are set forth in a Federal Register notice dated 3-5-1986 volume 51, No.43 (OPP-32500; FRL-2977-2) Conditional Registration of New Pesticides. Thus, there is a presumption that registration of a pesticide chemical is in the public interest if one of the following criteria is met: (i) the use is for a minor crop; (ii) the use is a replacement for another pesticide that is of continuing concern to the Agency; (iii) the use is one for which an emergency exemption under FIFRA Section 18 has been granted for lack of an alternative pest control method, or (iiii) the use is against a pest of public health significance. Notwithstanding whether a registration of a pesticide chemical may be presumed to be in the public interest, EPA may determine that such a registration is in the public interest on the basis of the following criteria: (i) there is a need for the new chemical that is not being met by currently registered pesticides; (ii) the new pesticide is comparatively less risky to health or the environment than currently registered pesticides; or (iii) the benefits (including economic benefits) from the use of the new active ingredient exceed those of alternative registered pesticides and other available non chemical techniques.

Summary of Finding

The registered alternatives commonly used to treat the target pest complex protected by CryIF are restricted use for the most part. They have precautionary label statements such as extremely toxic to fish and aquatic organisms, wildlife and require protective clothing for workers. The specific organophosphate and pyrethroid pesticides likely to be replaced are ranked in the top 15 of all pesticides with respect to reported incidents of mortality to non target wildlife. Many of these products also control corn root worm, which is the most significant pest of corn and is frequently treated along with the target pest complex of CryIF. Compared to other Bt corn products, growers are likely to choose CryIF protected corn due to better product performance and broader spectrum of control. CryIF protected corn is also expected to be economical on some unprotected fields and provide insurance against the risk of crop loss and the need to replant. But without root worm protection, the use of CryIF to reduce conventional pesticide use

is limited.

At product maturity, grower benefits of Cry1F protected corn are estimated to be between \$28 to \$81 million per year on 7.3 to 12.5 million acres of field corn. The range depends upon the technology fee, from \$7.50 to \$13.13/acre. Grower benefits are not a prediction since it does not include the effects of other technological innovations or competitor reactions on the pricing of pest control products. It does not include the effects of stacked genes offering multiple benefits, new competitive products, or the effects of increased competition in the corn insecticide market. Increased competition should offer growers more choice and lower the cost of pest control. The benefits are the incremental improvement to grower profits compared to current practice. All costs are eventually passed along to consumers in the long run, but this review did not deal with the complex topic of the dynamics of when that will occur.

APHIS Environmental Assessment

EPA agrees with the following conclusions from the environmental assessment conducted by APHIS.

“The EA addressed the potential for impacts to the human environment that might be incurred from an APHIS determination....”

“APHIS believes that cultivation of Bt Cry1F corn line has the potential to further reduce insecticide applications targeted not only for the European corn borer and other corn borers, but for cutworm and armyworms as well, provided these insecticides are not also being applied to control the corn root worm. Because many of these insecticides are more toxic to humans and non target organisms...a reduction in their use should provide benefits to the environment as well as to humans, particularly farm workers and their children who are at a higher risk from exposure”

Benefit claims made in PIF documents submitted for review

The registrants believe that Cry1F-protected corn is clearly in the public interest and provide data to support the following claims:

- Cry1F provides highly efficacious control of key Lepidopteran pests of field corn
- Cry1F provides a broader spectrum of pest control than other Bt corn products
- Cry1F hybrids provide comparable or superior pest control compared to existing Bt corn products for all pests.
- the use of Cry1F is expected to reduce the use of more toxic chemical insecticides
- Cry1F will reduce level of mycotoxin in corn
- Cry1F protein presents a very low risk to monarch butterflies (superior to Event 176)
- Cry1F corn does not contain an antibiotic resistance gene and thus meets the long term criteria established for use in Europe
- Cry1F hybrids are predicted to gain significant market share within the first five years after registration as a result of benefits to growers

The registrants have submitted data to support the economic benefits to growers. This included efficacy trials comparing Cry1F to non Bt hybrids, yield and other agronomic characteristics of Cry1F hybrids against their respective non transgenic counterparts, and economic models to compare the benefits of various insect control strategies under different insect pressures. Data to support claims for mycotoxin reduction were not submitted.

The registrant submitted data indicate that Cry1F protected corn offers excellent control of European corn borer (ECB), southwestern corn borer (SWCB), fall armyworm (FAW), black cutworm (BCW), and suppression for the corn earworm(CEW).

Changing current pest management practices

Growers may adopt Cry1F protected corn in three situations:

- 1) Replace current Bt products
- 2) Replace chemical insecticides
- 3) Protect against the risk of replanting due to loss from unprotected corn

The most popular corn insecticides currently used (1998/99 data) to treat the pest complex controlled by Cry1F protected corn are identified in the Table 1 below. Permethrin and terbufos have been identified in the top 15 pesticides reported in incidents of mortality to non target aquatic organisms (EPA ecological incident monitoring system). Chlorpyrifos has been found in surface water monitoring data, detected in sediment or biota at more than 10 percent of total sites. (USGS, National Water Quality Assessment Program, NAWQA). With the exception of Chlorpyrifos, all insecticide alternatives are restricted use, extremely toxic to wildlife, and require protective clothing for workers, as shown in Table 1.

Table 1. Effects of Insecticide Alternatives to Cry1F

| Common Name | Precautionary Label Language |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------|
| PERMETHRIN | Restricted use, extremely toxic to fish and aquatic organisms, highly toxic to bees, protective clothing for workers |
| CYHALOTHRIN-LAMBDA | Restricted use, extremely toxic to fish and aquatic organisms, highly toxic to bees, protective clothing for workers |
| CHLORPYRIFOS | Toxic to birds and wildlife and extremely toxic to fish and aquatic organisms |
| TEFLUTHRIN | Restricted use, very highly toxic to freshwater and estuarine fish and invertebrates. May pose a hazard to endangered species. |
| TERBUFOS | Restricted use, extremely toxic to fish and wildlife, protective clothing |

Source: Registrant submissions and Crop Data Management Systems
<http://www.cdms.net/manuf/AgLinks.asp>

About 24 million acres of corn are treated with an insecticide, which is 30% of the 80 million planted acres. The Cry1F protected corn targeted pest complex is projected to receive 4 million acres, or one sixth of the total use.

The target pest infestation occurs in the Southeast for fall armyworm, Midwest for black cutworm, and Upper Midwest for the European corn borer. Potential for use reduction occurs when growers can substitute Cry1F protected corn for the conventional pesticides (shown in Table 2). The reference to low, medium and high in the potential for use reduction column refers to the chemical treatments of the target pest compared to the total chemical treatments. Low is for less than 15%, medium between 15% and 30%, and high is above 30%.

Table 2. Potential for insecticide use reduction on corn

| State | Planted (000's) | Pct treated (000's) | Lbs ai (000's) | Potential for use reduction |
|---------------------------|--------------------|------------------------|-------------------|--------------------------------|
| Illinois | 10,800 | 38 | 1,833 | medium |
| Iowa | 12,100 | 25 | 2,462 | medium |
| Missouri | 2,650 | 38 | 218 | high |
| Nebraska | 8,600 | 39 | 1,295 | low |
| Kentucky | 1,320 | 50 | 22 | high |
| Indiana | 5,800 | 36 | 1,156 | low |
| Ohio | 3,450 | 7 | 98 | medium |
| Minnesota | 7,100 | 11 | 280 | medium |
| Texas | 1,950 | 54 | 458 | low |
| Kansas | 3,150 | 32 | 385 | low |
| Wisconsin | 3,600 | 31 | 473 | low |
| Colorado | 1,230 | 45 | 479 | low |
| South Dakota | 3,600 | 18 | 520 | medium |
| Michigan | 2,200 | 22 | 214 | medium |
| North Carolina | 750 | 35 | 222 | low |
| Total for states surveyed | 68,300 | 30 | 10,115 | |

Source: Agricultural Chemical Usage 1999 Field Crops Summary, NASS, and EPA estimates.

Estimating grower economic benefits

Registrant submitted data are used to estimate grower economic benefits. A Model grower economic analysis is provided for different typical grower pest management situations:

- High risk for Black cutworm, moderate risk for European corn borer
- Moderate risk of Black cutworm and southwestern corn borer
- High risk for fall armyworm.

Information is provided on TC1507 to represent Cry1F. Alternative options include no treatment, preventative and rescue insecticide treatments, replant seed, and other Bt corn hybrids Event 176 (Mycogen) and CBH 351(Advanta).

Table 3. Model Grower Economic Analysis: Returns over variable cost

| Scenario | Best alternative approaches | Maximum advantage/acre |
|--------------------------------------------------------------------|-----------------------------|------------------------|
| High risk for Black cutworm, moderate risk for European corn borer | CBH-351, Rescue | \$23.36 |
| Moderate risk of Black cutworm and southwestern corn borer | CBH-351, Rescue | \$18.06 |
| High risk for fall armyworm. | Event 176, CBH-351 | \$48.46 |

The Monte Carlo simulation model described in the Bt reassessment is used to estimate adoption rate and grower benefits for Cry1F protected corn (see Bt reassessment documents for a description of the methodology). The advantage of Cry1F protected corn over the next best alternative is set at \$25 per acre, a sort of 95% upper limit. This is closer to the cutworm and corn borer situations than the fall armyworm since these cases represent the bulk of chemical treatments. The technology fee is stated to be between \$7.5 to \$13.13/acre. Bt related costs is assumed to be \$10/acre, an estimate also used in Bt reassessment. These costs cover refuge requirements and marketability concerns and apply to situations where Cry1F replaces chemical control or no control.

The simulation model estimates adoption rate to be between 29% and 50% of acres at risk. Acres at risk is estimated to be 25 million acres, based on the states affected and the extent of area infested. Grower benefits could vary by an average of \$3.90/acre to \$6.51/acre. Total annual grower benefits could be between \$28 million to \$81 million per year. The very wide range is due to the wide range of the proposed technology fee, from \$7.50 to \$13.13 per acre.

It should be noted that these annual benefits would occur at product maturity, or 3 to 5 years after commercialization. The analysis does not consider possible stacked products which offer multiple protections and efficiencies, the effect of new competitor products, or the impact of increased competition on overall market equilibrium conditions.

Table 4. Summary of Estimated Grower Benefits for Cry1F

| Technology fee | Cry1F Acres (millions) | Grower Benefits per acre | Aggregate annual benefits (millions \$) |
|----------------|------------------------|--------------------------|-----------------------------------------|
| \$13.13/acre | 7.3 | \$3.90 | \$28 |
| \$7.50/acre | 12.5 | \$6.51 | \$81 |

Based on: 1) 35 million acres at risk for ECB, BCW, SWCB, and FAW; 2) Current pricing for competitive pest control products; and 3) field corn market price/bushel of \$2.25. Note that corn prices are volatile. Lower prices reduces the economic value of pest protection and would lower the acreage of Cry1F.



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R145790

Chemical: *Bacillus thuringiensis* Cry 1F protein and the genetic material necessary for its production (plasmid insert PHI 8999)in corn

PC Code:
006481

HED File Code: 41100 BPPD Benefits

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