# HISTORICAL PERSPECTIVE AND FUTURE COSTS OF KEEPING KEY COTTON INSECTICIDES IN THE MARKET

**R. J. Braun**
**RJB Consulting**
**West Chester, PA**

## Abstract

Historical "on-going" costs of a typical pyrethroid which has been in the USA market since early 1983 have been examined from available public records. Based upon the submission of more than 800 studies to the EPA after initial registration, the cumulative costs are estimated at between $15 and $20 million. At the same time cost to comply with emerging new regulatory requirements are likely to increase significantly putting increased pressures upon USA Agriculture vis a vis the rest of the world - with lower product options, commodity prices and little hope of overall input cost reductions, despite new products and technology.

## Case Study

When looking at a typical older pyrethroid and related analogues which have been sold in the USA since about 1983, publicly available records indicate industry-wide data submissions to the EPA in excess of 800 individual submissions after first USA sales. No public records are available for accurate assessment of the total on-going costs for older pesticides. It is likely, however, that the "cumulative post registration costs" would fall into the $15 - $20 million range. Most of these costs relate to satisfying environmental and residue requirements as currently specified in 40CFR, part 158 Guidelines.

While individual crop uses (eg. cotton) are not responsible for the total cost of such on-going submissions, each approved crop or end-use is indirectly supporting the "market longevity" of a particular pesticide - not withstanding obvious "ADI bucket" limitations. It is unlikely that basic manufacturers would be able to justify the significant on-going data requirements of an older pesticide with limited crop or other end-uses.

## New Guideline Requirements

The emerging complexities of FQPA-10X safety factor, endocrine disruption, developmental neurotoxicity, life time aggregate exposure issues, etc.. are expected to add "orders of magnitude" to on-going costs and exacerbate the workloads all around. Premature cancellations or voluntary withdrawals of older pesticides would be disruptive and potentially costly to overall agriculture. The emerging new products generally do not reduce input costs due to the need to recover heavy discovery and development costs. The jury is also still out concerning their overall safety and long-term efficacy in view of the emerging new Guideline Requirements and the adaptability of the pest complex.

### Human Testing

FQPA 10X safety factor prompts some pesticide producers to conduct human testing in efforts to prove the relative safety of their products. The following companies have and/or are planning to conduct such studies using volunteers in the US and Europe:

BAYER - AZINPHOS-METHYL at Inveresk Clinical Research Ltd. in Scotland

- METHAMIDOPHOS in Scotland

NOVARTIS - DIAZINON at a private US Laboratory

AMVAC - DICHLORVOS - at an R&D company associated with the University of Manchester (UK)

DOW - CHLORPYRIFOS - seeking approval from a US Laboratory

CHEMINOVA - MALATHION - plans at Inveresk in Scotland

Volunteers receive between $500 to $1500 to participate in the tests which last from about one (1) to three (3) weeks.

Sporadic human testing has been conducted in the past by a number of companies including an EPA sponsored trial during the early 1990's.

While no cost data on such trials are publicly available, it is estimated that such an average human study could easily reach $250,000+.

While current regulations (40CFR26) relating to "Protection of Human Subject" require "written approval of EPA's Human Subjects Review Official" - ORD's Director of the National Center of Environmental Research and Quality Assurance" before any studies are started, the EPA has announced a complete review of human pesticide testing and expect a new policy by February 1999.

### FQPA (10X Safety Factor)

The EPA is also reviewing more "detailed criteria" regarding the application of the 10X safety factor for pesticides and expects to issue a Public Notice in January 1999. This is in response to strong industry and grower concerns regarding consistent application of the safety factor by using best available science and specifically relevant and reliable data for each pesticide under review.

Reprinted from the *Proceedings of the Beltwide Cotton Conference*
Volume 2:865-866 (1999)
National Cotton Council, Memphis TN

**Issues Raised by Dow**

During August 1998, Dow reportedly complained to the EPA that decisions were made on Chlorpyrifos before the EPA had reviewed 20 studies specifically addressing the 10X safety factor. Dow also noted that 104 of 142 studies submitted over the last five (5) years for Chlorpyrifos reregistration and FQPA issues have not yet been reviewed by the EPA. This included a "developmental neurotoxicity" study submitted in May 1998.

**EPA and Related Work Loads**

It is clear that the EPA is caught in the middle between implementing new legislation while dealing with business and public interests. The EPA has announced the formal addition of "developmental neurotoxicity" data to the core data requirements under 40CFR part 158. Public Comment is forecast for the spring of 1999.

The dilemma continues to accelerate. The EPA has not been able to formally establish specific new data requirements due to the complex scientific issues as well as achieving a public/industry consensus. Recent reports indicate that additional funds have been approved for the EPA - at least $10 million late 1997 - with additional allocations surely needed in 1998 and beyond. The multiplier effect will generate additional funding needs by other government agencies (NIH, USDA, publicly supported institutes, etc.) as evidenced by the $2-3 million funding to update "USA market basket" data. I am sure these examples are just the tip of the iceberg.

It is estimated that for some older pesticides which have been in the market for at least 10+years, only about one half of the studies specified by 40CFR, Part 158 still have not been accepted by the EPA. This does not include submitted studies which are not formally specified in 40CFR Part 158 (7/1/97). In the interim, the pesticide manufacturers are scrambling to supply all manner of data to prevent premature restrictions or cancellations of their pesticides. The costs for all parties continue to escalate for existing and new products. While protocols defining how to conduct "developmental neurotoxicity" studies will not be available for some time, it is estimated that costs could easily fall in the $50,000 - $100,000+ range per single study. This excludes the peripheral support costs such as the extensive use of specialized consultants which can easily add $200,000 - $300,000 per "product issue" over a limited time period. It also excludes the legal costs resulting from inevitable legal challenges from Industry and other parties.

**Summary**

The significant "on-going and future costs" to support older pesticides in the USA will put increased pressure upon USA agriculture vis a vis the rest of the world - in terms of higher input costs and fewer product choices while commodity prices remain volatile with the elimination of "safety nets" for the farming sector - leading to further dislocations.

The expectations of new generation products - including transgenics most likely will not reduce overall input costs due to manufacturers' need to recover the heavy development costs and the tradition of holding "per unit" pricing at parity with existing products.

**References**


Breckenridge, C. Novartis. November 13, 1998. Private communication.

EPA and related publicly available data bases.

Federal Register.

40CFR,, Part 158. July 1, 1997 Edition.

Pesticide & Toxic Chemical News. September 24 & October 29, 1998.

Stecklow, S. New FQPA has Pesticide Makers doing Human Testing. WSJ September 28, 1998.