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Interim Reproduction Study Results with Bolstar and Monitor

Section Head, Environmental Safety

Environmental Safety Files

On September 14, 1977, I met with Dr. Don Lamb of Chemagro on 2 interim reports on the pesticides, Bolstar and Monitor. The purpose of this meeting was to provide protocol and data requirement guidance when avian reproduction studies show effects.

The two studies in question did not give a "no-effect/encl." Both levels produced adverse effects. Chemagro wanted to know what the additional data requirements would be for chemicals that have positive avian peproduction effects.

Dr. Lamb wanted to know our feelings on expanding the avian study to include more levels so as to establish both "no-effect" and "effect" levels. I indicated that we were leaning in that direction and probably would go in that direction in the future. Chemagro will probably initiate such studies to examine further the two pesticides in question.

I also mentioned that the normal "flow" for supporting data is from the simple to the more complex. The "flow" from the positive avian reproduction is to the large pen field study. Dr. Lamb indicated he was aware of this.

I also indicated that avian reproduction impairment in the studies in question would probably exceed the avian risk criteria for an acceptable registration. Likelihood of avian exposure and the levels of exposure are critical decision points when applying the criteria to the results of the laboratory studies. Dr. Lamb hopes to initiate studies to establish residue levels in/on avian food and feed under actual field conditions.

Note to reviewers: Do not accept for registration any submission for Bolstar or Monitor unless each of the submissions contains both bobwhite quail and mallard duck reproduction studies. I don't recall much of the details from the interim reports, but reproductive impairment was noted with Monitor on the quail and with Bolstar on the mallards. The impairment with Monitor is not unexpected since orthene (of which Monitor is a degradate) has also shown avian reproductive impairment.

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