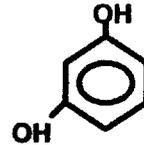
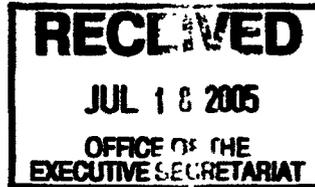


RESORCINOL TASK FORCE



201-15982

Michael O. Leavitt, Administration
United States Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
United States of America



The Old Dairy
Woodend Farm
Cromhall
Wotton-under-Edge
Glos, GL12 8AA
United Kingdom

Tel. -44-1454-269330
Fax. -44-1454-269197

05 JUL 29 AM 10:20

RECEIVED
APPT OFF

Subject: Rationale for the conduct of a multi-generation study on resorcinol

24th June 2005

Dear Administrator Leavitt,

We have been made aware through one of our Task Force members (INDSPEC) of comments submitted by PCRM, among others, about the efficacy of conducting a multi-generation animal study on resorcinol. I am therefore writing in my capacity as manager of the Resorcinol Task Force (RTF) to provide further context and hopefully address the concerns expressed.

In the first instance, others providing comments have noted that there is a genuine gap in the SIDS data requirement in the area of a reprotoxicity study. Although PCRM highlights the fact that other reproductive data is cited in the TERA peer review of March 2003, other sources, notably the Dutch Health Council, have recognised the inadequacy of these earlier studies by Cooksey, Seffner and others, not only in their lack of GLP status, but also in their transparency and reproducibility. This was one of the reasons why the TERA panel defaulted to the NTP Study as its critical reference, even though the critical end-point of thyroid was not specifically covered.

Subsequent to this first TERA review, news spread of the Dose Range Finding Study conducted by RTF in preparation of the current OECD guideline compliant study. This was sufficient to cause the sponsor of the TERA work to reconvene the panel in November 2004 to review this important new work and a report of the outcomes of that review is now available on the TERA website. This would not have been considered either necessary or appropriate if previous studies had been viewed as adequate for the purpose.

All this said, the main rationale for the current study has been in response to developments in Europe. These have related to the recognition of the thyroid as part of the endocrine system for regulatory purposes. Although the hazard assessment of resorcinol has not changed significantly over the last fifty years, the inclusion of a chemical of previously low regulatory concern within a list of potential endocrine disruptors has placed an unsolicited spotlight on resorcinol. Under such circumstances, the precautionary principle requires responsible producers to complete their datasets, particularly in areas such as repro-toxicity where there could be a perceived effect. This regulatory dimension was presented to key EPA staff by the Task Force in June 2003.

It is well known that resorcinol exhibits a mild dose-related reversible effect on the thyroid through a mechanism of thyroperoxidase inhibition. The Resorcinol Task Force, in its decision to proceed with a multi-generational study, is therefore not seeking to dispute the linkage between resorcinol and thyroid activity, but to confirm that such reversible thyroid activity has no impact on generational outcomes. This had not been achieved by any previous study.

Before closing, we would add that Huntingdon Life Sciences had no influence whatsoever on the decision to proceed with the study. Indeed, their involvement with INDSPEC came after the decision to proceed had been taken. This decision was taken with the full knowledge and agreement of the European Commission who had been advised through a report written by WRC-NRF in 2002. This report had highlighted the data-gaps existing for resorcinol and the need to fill them in order to properly assess the risks posed by the chemical.

In conclusion, the Resorcinol Task Force considers that it has acted in a manner completely consistent with its responsibilities and in total harmony with the request of the regulators and the interests of the wider public. However, we would agree with PCRM that it might be helpful to make the European dimension of the project and the further deliberations of the TERA panel available via the EPA website in order that all stakeholders have a better opportunity to understand the context. To this end, we would be happy for you to publish this submission on the HPV Challenge website.

Please do not hesitate to contact me if you require any further clarification of the contents of this letter.

Yours Faithfully,

Paul Ashford – Resorcinol Task Force Manager