

FINDING OF NO SIGNIFICANT IMPACT

FAP 2196

for

1,3-Butanediol for Swine

American Cyanamid
Princeton, NJ

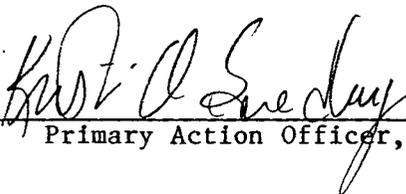
The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

1,3-butanediol (1,3-butylene glycol) would be added to the feed of swine at concentrations not to exceed 10% of air-dry feed (9% of dry matter) as a source of energy. The majority of the compound is metabolized by swine for energy, with the carbon from the chemical released into the air as carbon dioxide or incorporated into the bodies of the swine.

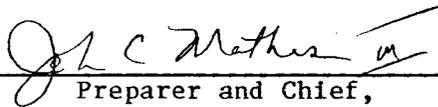
In support of their petition, the firm submitted in October 1985 a claim for conditional exemption (under previous 21 CFR 25.1(f)(1)(iv)) from the requirement to prepare an environmental impact analysis report (attached). This was deemed acceptable for two reasons: 1) the Center had instructed the firm on the environmental submission prior to the effective date of the revised Part 25 and 2) the conditional exemption being claimed is substantively the same as the requirement under the revised Part 25.31a(b)(5). 1,3-butanediol is a naturally occurring substance that qualifies for abbreviated environmental assessment under the current environmental regulations and for conditional exemption under the previous Part 25. Additional information on the potential environmental impacts at the site of manufacture of 1,3-butanediol can be found in a GRAS petition, No. 7G0332, filed on November 23, 1987, which contains an environmental assessment.

We have reviewed the firm's environmental submission and, when taken together with the other information available to the agency and with information on the metabolism of the compound contained elsewhere in the petition, have determined that the submission is adequate.

8-17-88
Date


Primary Action Officer, HFV-226

8-17
Date


Preparer and Chief,
Environmental Sciences Staff, HFV-162

Attachment