

**REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION
IN REGARD OF THE POSSIBLE IMPLICATION OF OLAQUINDOX
IN CASES OF PHOTOALLERGIC "PHOTOTOXIC CONTACT-
DERMATITIS"**

DEVELOPED IN PIG-FARMERS

(Opinion expressed: 18 November 1992)

TERMS OF REFERENCE (June 1992):

The SCAN is requested to examine the information shown under "references" and express its opinion on the possible implication of olaquinox in cases of a photoallergic "phototoxic contact-dermatitis" developed in pig-farmers.

BACKGROUND:

Olaquinox (E 851, 2-[N-2'-(hydroxyethyl)carbamoyl-3-methylquinoxaline-N¹,N⁴-dioxide) is included under heading J (Growth Promoters) of annex I to Council Directive 70/524/EEC¹ concerning additives in animal feedingstuffs, as amended by Council Directive 84/587/EEC², according to conditions described below.

- Minimum purity: 98%
- Characteristics of the authorized preparation:
- Olaquinox content: 10%.
- Minimum stability: 24 months
- Medium: calcium carbonate containing 1,5% of glyceryl polyethylene-glycol ricinoleate.

Species or category of animal	Maximum age	Minimum content mg/kg of complete feedingstuff	Maximum content mg/kg of complete feedingstuff	Other provisions
Piglets	4 months 4 months	15 50(2)	50 100(2)	Use prohibited at least 4 weeks before slaughter " Maximum amount of dust emitted during handling as determined by the Stauber Heubach method(1): 0,1µg olaquinox. Indication on the label of the additives, premixtures and feedingstuffs of the safety instructions and warnings designed to protect the health of operatives and in particular to avoid any exposure to the additive, specially by touch and inhalation"

(1) Reference: Fresenius Z. Anal. Chem. (1984) 318:522-4, Springer Verlag 1984

(2) Milk replacers only

¹ O.J. No. L270 (14.12.70) p. 1

² O.J. No. L319 (08.12.84) p. 13

The Committee has expressed its favourable opinion on the use of Olaquinox in feedingstuffs for pigs on 8 July 1981³ and 3 May 1984⁴. Recent information shown under "references" may indicate the possible implication of olaquinox in cases of a photoallergic "phototoxic contact-dermatitis" developed in pig-farmers.

OPINION OF SCAN:

The Committee has examined the information sent by the Commission (see references) in view of the possible implication of Olaquinox in cases of photoallergic "phototoxic contact-dermatitis" developed in pig-farmers. The Committee has examined previously the safety of use of Olaquinox (E-851), under the conditions of use set out in Council Directive 70/524/EEC¹. Its opinions were expressed on 8 July 1981³ and 3 May 1984⁴.

The Committee notices that the use of this molecule (E 851) as governed by Council Directive 70/524/EEC, established a maximum age-limit of up to 4 months, and included the following warnings under the column "other measures":

- "Maximum amount of dust emitted during handling as determined by the Stauber Heubach method: 0,1µg olaquinox";
- "Indication on the label of the additives, premixtures and feedingstuffs of the safety instructions and warnings designed to protect the health of operatives and in particular to avoid any exposure to the additive, specially by touch and inhalation".

Olaquinox has been used for 30 years as a feedingstuffs additive for pigs at weaning, yet there are few clinical cases of photoallergy reported in the literature. The sustained use of this molecule is based on its tested effectiveness as a growth-promoter and on its proven activity against bacteria resistant to other agents.

In view of the present question, the Committee draws the attention of the Commission to the possible risk of inadequate preparation and mixing of these additives. In those cases the applied dose may fall beyond the range as authorised, and occupational toxicity (e.g. phototoxic contact dermatitis) may develop. As a general principle, in order to be able to guarantee the farmer's and animal's safety, there is a need for farmers to be properly equipped and trained in the handling of potentially dangerous substances including feed additives.

The Committee wishes to examine this matter again, once the relevant authorities of Member States have provided the Commission with the necessary elements to answer the following points:

³ Reports of the Scientific Committee for Animal Nutrition. Fourth Series. p.1. Luxembourg: Office for Official Publications of the European Communities. ISBN: 92-825-4101-0

⁴ Reports of the Scientific Committee for Animal Nutrition. Fifth Series. p. 11. Luxembourg: Office for Official Publications of the European Communities. ISBN 92-825-8235-2

1. Did the affected farmers have adequate equipment and installations to guarantee a reduced dust emission and a concentration of Olaquinox in the final feedingstuffs as established in Directive 70/524/EEC?
2. Have the official control authorities knowledge of the existence in their national market of presentations of Olaquinox different from those examined by the SCAN in the dossier provided by the Commission? and if so,
3. Do the official control authorities know if the photocontact dermatitis outlined above has developed from exposure of the affected persons to the substance as authorised (E-851), in particular in respect of its composition and formulation?

References:

DIESING L. & BOMANN W., 1991. Olaquinox (Bayo-n-Ox) Expert opinion on the allergenic, phototoxic and photoallergic potential. (Submitted by Bayer).

Toxicological Pathology of Quinoxaline-di-n-oxide feed additives. *Liber testimonii* Evert Johannes VAN DER MOLEN. Utrecht: Drukkerij Elinkswijk BV (127 pp.).