EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

Opinion of the Scientific Committee for Animal Nutrition on the use of titanium dioxide-coated mica in feedingstuffs for salmon and trout

(adopted on 20 February 2003)

1. BACKGROUND

A request for authorising titanium dioxide-coated mica under the following conditions as a colouring matter for salmon and trout feed has been submitted.

Feed colouring matter

Additive	Chemical formula, description	Species or category of animal	Maximum Age	Minimum content	Maximum content
				mg/kg complete feedingstuff	
Titanium dioxide-coated mica	TiO_2 – $KAl_2(AlSiO_{10})(OH)_2$	Salmon Trout	- -	- -	5 000 5 000

2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to answer the following questions:

2.1. Product titanium dioxide-coated mica (TiO_2 – KAl_2 $(AlSiO_{10})(OH)_2$ is claimed to improve the visibility of fish feed to allow the fish to more easily detect the presence of feed pellets and the farmer to determine the moment when fish are satiated. Is the efficacy of this product demonstrated, when used in the feedingstuffs of salmon and trout under the conditions laid down in the background?

2.2. Does the use of titanium dioxide-coated mica not impair the characteristics of target animals' products?

2.3. On the basis of the toxicological data provided by the company, is the use of titanium dioxide-coated mica safe:
- for salmon and trout?
- for the user (workers' exposure)?
- for the consumer, taking into account total dietary exposure?

In assessing the safety of the product for the consumer, the Committee should in particular address the metabolic fate of titanium dioxide-coated mica in salmons and trouts and the possible presence of residues in animal tissues, and their qualitative and quantitative composition

2.4. What are the nature and the persistence of the excreted products derived from titanium dioxide-coated mica? Can these products be prejudicial to the environment?

3. OPINION OF THE COMMITTEE

3.1. Product identity

The product TCM, an off-white powdered titanium dioxide-coated mica (TiO_2 – KAl_2 $(AlSiO_{10})(OH)_2$, consists of 2 permitted food additives, 70-80 % platelets of (i) Mica (potassium aluminium silicate, E 555), which is approved as miscellaneous food additive under European Council Directive 95/2/EC, coated with 13-23 % (ii) titanium dioxide (E 171), which is approved as food colour under European Council Directive 94/36/EC, and mixed with water (7 %).

TCM is produced by precipitating hydrous titanium dioxide (from titanium oxychloride + sodium hydroxide) onto sized mica particles and then sintering to fuse titanium dioxide in crystal structure onto the surface.
After cooling, 7 % water is added to prevent dust formation.

Mica and titanium dioxide are insoluble in water and strong acids and are stable to temperature in excess of 900°C. The mean particle size of the product is approximately 35 µm and bulk density 14 g/100 cm^3.

Table 1: Typical composition of TCM (major constituents, % of DM)

Aluminium	4.0	Potassium	1.9	Iron	0.28
Sodium	0.16	Silicon	0.20	Titanium	0.1

TCM contains less than 40 ppm trace metal impurities (As: < 1.0 ppm, Sb: < 2.0 ppm, Pb: 14.0 ppm, Mo: 10.0 ppm, Hg: < 1.0 ppm, Se: < 2.0 ppm, Cr: 6.0 ppm, Cd: < 0.05 ppm). Product specification is less than 15 ppm lead. No data on other potential impurities, such as dioxins or PCBs, are provided.

TCM is intended to be added to feedingstuffs for fish (to pellets prior to bagging) at levels between 3 and 5 g/kg. TCM should adhere to the oily surface of fish feed pellets and is said to improve the visibility of the product. The coating is said to be stable during storage, transportation and use.

TCM was tested for interactions with some micronutrients in fish feed. After storage for 6 weeks at 40°C and 75 % humidity, no significant differences in the concentrations of vitamin E, astaxanthin and TBARS (thiobarbituric acid-reactive substances) were found between untreated and TCM containing feed.

TCM is also applied to lipsticks (8-15 %), toothpaste (0.2-1 %), seed coatings (1.5-3 %) and plastic sausage packaging (2.5-5 %).

3.2. Efficacy

The ability of both fish and the farm personnel who feed the fish to detect pellets in water depends on several factors including stocking density, light intensity, clarity of water and the contrast of pellets against the background. There is documented evidence that predator fish are attracted by the shininess or brightness of feed.

Luminance levels of TCM-coated and control pellets were measured against a black background by different methods. The contrast levels were increased by 4.3 and 5.3 %, respectively, when the pellets were TCM-coated. These findings are interpreted as a better visibility of TCM-coated pellets judged by the farm personnel. A test (number of test persons unknown) was conducted on a commercial salmon farm. Control pellets could be viewed from the above water surface at a maximum depth of 2.2 m, TCM-pellets a maximum depth of 3.1 m. This study can be accepted as a confirmation of the physical tests.

Comparable studies were undertaken to measure the underwater visibility in a large indoor water pool (2.5 m deep, 10 m diameter) by camera at different light intensity. Under low light level the distance for which the pellets could be recorded was 2.9 times farther for the TCM-coated pellets at 0.4 m depth and approximately 2 times at 1.5 m depth.

Studies with TCM on trout (*Oncorhynchus mykiss*) were performed in aquaria under artificial low light conditions in both clear and turbid water. One TCM-coated and one control pellet, each suspended from a float, were offered simultaneously. An attack of fish during 2 minutes was recorded and assessed as (preferential) detectability. In this system TCM-coated pellets were 4.1 times better detectable in clear water and 2.3 times more detectable in turbid water than untreated pellets.

In the Member State rapporteur's assessment (September 1999) it is stated that the company is carrying out a feeding trial on the target species and that the study is expected to provide data on any effects of the additive on growth rates, FCR, mortality and on carcass composition. These data have not been submitted to SCAN

The company is of the opinion that TCM is not a zootechnical additive, that growth promotion is not claimed, that therefore studies concerning the effects of TCM on animal production need not to be performed and submitted.

3.3. Influence on the characteristics of the target animals' products

In the company's view TCM is not expected to affect the organoleptic, nutritional, hygienic and technological characteristics or any other qualities of produce from animals fed TCM. No studies on edible tissues have therefore been presented.

Mica and titanium dioxide are considered as chemically inert and therefore not absorbed to a significant amount. Titanium dioxide is worldwide used as marker for digestibility studies in numerous animal species because of its indigestibility (fecal recovery rates between 96 and 99.7 %). Therefore SCAN shares the opinion of the company that TCM will not exert any influence on the characteristics (composition) of trout or salmon products.

3.4. Safety aspects

3.4.1. Safety for the target species

Atlantic salmon (*Salmo salar* L, 4 x 52 per group, 192 g body weight) was fed TCM at the recommended level (0.5 %) for 22 days (20 days on feed). No significant differences were found in growth rate (average 1.401), FCR (average: 0.641 g feed/g biomass gain) or feed intake (average: 1.03 % body weight per day), apparent digestibility of crude protein (average: 89.5 %) and ether extract (83.5 %) between TCM and the control group. No negative effects related to fish health, or feed palatability were seen.

Another feeding trial with about 20,000 Atlantic salmon in two cages per group was presented as preliminary report. However the study was inadequately described and was consequently excluded from consideration.

***Conclusion**:* Safety on the target species could not be assessed, because TCM was tested only at the recommended level and for a too short period.

3.4.2. Toxicological data

Both substances are approved as food additive and no ADI has been set for mica or for titanium dioxide by the SCF. JECFA set an ADI "not specified" for Mica (1986) and noted that there was no need to assign an ADI for titanium dioxide (1970).

3.4.3. Toxicity

TCM was evaluated for acute oral toxicity in rats. The study indicated that the acute oral LD_{50} is greater than the highest level tested (10,000 mg/kg body weight).

A three months subchronic toxicity study was conducted on albino rats fed diets containing 0, 1.0, 3.16 and 10 % TCM. No compound related effects on behaviour, growth, food consumption or mortality were observed. Organs and tissues showed neither consistent gross changes nor histopathological changes that could be attributed to dietary administration of TCM.

A chronic toxicity study with TCM was also conducted for 130 weeks (Bernard et al., 1990). Rats were fed diets containing 0, 1.0, 2.0 or 5.0 % TCM. No consistent or biologically important changes

related to the dose regime were found concerning survival, body weight gain, haematology, clinical chemistry or histopathology.

3.4.4. Metabolism of TCM in fish

47 Atlantic salmon each received control feed and TCM feed for 30 days. Samples of muscle and liver were taken on day 0, 10, 20 and 30 and analysed for aluminium, titanium and barium (as markers for TCM) by ICP atomic absorption spectrophotometry. Limits of detection were 9.0 µg Al, 1.1 µg Ti and 1.1 µg Ba/g wet sample. The results are given in Table 2.

Table 2: Concentration of Al, Ba and Ti in feed, liver (5 samples) and muscle (5 samples) tissue (day 30)

	Al (µg/g)	***Ti (µg/g)***	***Ba (µg/g)***
Control feed	59.3	1. 3	4.5
TCM feed	175.8	49.4	5.0
Control liver	918.9±245.3	31.4±23.7	3.2±0.9
TCM liver	920.9±307.0	24.9±4.2	6.1±4.9
Control muscle	48.6^{a}±7.3	1.5^{a}±0.2	0.7^{a}±0.6
TCM muscle	96.0^{b}±33.1	19.4^{b}±2.2*	2.1^{b}±0.3

* 2nd analysis: 3.8±0.8

Values with different letter superscripts in the same column are significantly different.

The results according to table 2 show significantly higher values of Al, Ti and Ba in the muscle tissue of TCM fed fish. However, no significant differences were found in the liver. All values show high standard deviations.

The company is of the opinion that the differences appear to be due to consistently lower levels of the three elements in the control fish, which is in fact only supported for Ba in the liver. The company continues: “This suggests that some analytical errors affected these results”.

Obviously the document itself shows some errors. In contrast to the value for Al in the liver of TCM fish of table 2 (920.9 µg/g) the mean value for the liver of the TCM treated fish is given in the “Average for single results” with 554.2, recalculation of the 7 single values leads to an average of 691.4.

The liver can be considered as the most sensitive organ in comparison to muscle tissue reflecting the trace element supply of an animal. It may therefore be assumed – also considering the magnitude of the standard deviation – that feeding TCM would not significantly affect aluminium and titanium residues in fish (salmon).

3.4.5. Safety for the user

In workers occupationally exposed to titanium oxide nodular fibrotic pneumoconiosis was observed after several years of exposure (Daum et al, 1977). In a plant producing titanium metal, some indication of a work related mild deterioration in lung function was seen (Garabant et al., 1987). However, EPA (1988) felt that various limitations of the above cited studies were such that the data were inadequate for assessing adverse human health effects associated with titanium dioxide.

Respirable particles (less than 10 μm) amount to 3-6 % of the product. In addition, water is added to TCM (7% of the final product) to reduce dust formation. The respiratory risk would be minimal.

TCM was tested for dermal irritation in rabbits. No toxic signs were noted. All animals' skin appeared normal at the 48-hour observation period and remained normal throughout the 14-day study. The dermal toxicity of TCM was also tested by repeated exposure (15 applications in three weeks an abraded and intact skin, 65 applications for 13 weeks on intact skin). Criteria were general appearance, behaviour, body weight, gross signs of dermal irritation, clinical laboratory studies, and gross and microscopic pathology. No effect attributable to the dermal exposure was evidenced except a slight to moderate skin hyperkeratinisation after repeated administration.

In a 4 weeks eye irritation study in rabbits no significant irritation was observed after 20 applications of TCM.

Conclusion: The exposure risk of workers is expected to be minimal. However, because of the small respirable fraction in TCM and the slight to moderate skin hyperkeratinisation, the product label should contain appropriate provisions for worker protection.

3.4.6. Safety for the consumer

TCM at a level of 5 % in the diet did not produce any toxicologic or carcinogenic effect in rats (Bernard et al., 1990). The authors conclude that dietary exposure to TCM does not pose a significant human health hazard.

The consumption of fish fed TCM treated pellets could increase human uptake of titanium and aluminium but only to a negligibly low amount. In this respect SCAN does not see any necessity to calculate a potential uptake, considering the toxicological data and the fact, that an ADI is not set by SCF or by JECFA.

3.4.7. Environmental impact

Mica is one of the most common rock forming minerals, and is found in most detrital sediments at high concentrations. Titanium dioxide is an extremely common mineral and has an inert environmental chem-

istry. Solubility and bioavailability of the components of TCM are expected to be extremely low. TCM is also not expected to influence significantly the sedimentation rate of wastes beneath salmon or trout cages.

According to the dossier, predicted environmental concentrations (PECs) in sediments under salmon cages are estimated with 14,000-20,000 mg mica/kg and 2,800-4,000 mg titanium dioxide/kg, if TCM would be added to all salmon feed. These PECs are said to be lower than natural background levels. No adverse effects of feeding TCM pellets on marine or freshwater sediment are therefore expected.

SCAN calculates that each ton of TCM treated fish feed will release 3-5 kg TCM (0 % absorption), corresponding to a maximum of 2.4-4.0 kg mica (potassium aluminium silicate) and 0.7-1.2 kg titanium dioxide. Both compounds are chemically inert, they will not influence other marine or freshwater organisms.

4. CONCLUSION

Titanium dioxide coated potassium aluminium silicate (TCM) meets the criteria for a technological feed additive. It is designed to colour the surface of fish pellets in order to improve their visibility for fish and farm operators. The advantage of such a feed additive could be seen in lowering feeding costs by reducing feed wastage.

Better visibility of TCM coated pellets is demonstrated by limited experiments. Large scale experiments on salmon and trout providing proof of this advantage under more practical conditions were not submitted. A definite experimental demonstration of the efficacy under practical conditions is required.

The tolerance test submitted is insufficient because of the lack of overdosing and a too short feeding period. However, unfavourable results are not expected due to the biologically inert nature of TCM.

TCM is a chemically inert material; its components are hardly absorbed by the fish. Therefore no significant residues in fish products are to be expected.

TCM is used in the cosmetic industry and its components in the food industry. Toxicological data available support the assumption that no risk for the consumer would result from the addition of TCM to fish feed even if small amounts should be absorbed by the fish. No ADI is set for mica or for titanium dioxide by the SCF.

Although SCAN considers it unlikely that the raw ingredients in the product would carry dioxin or PCB contamination, this should be confirmed.

In view of the workers' safety studies, appropriate measures to protect workers are recommended.

The impact of feeding TCM on the environment would be low. Considering that all TCM is excreted; the amount fed will therefore entirely contribute to the (natural) sediment.

By feeding TCM, aluminium silicate and titanium dioxide will be deposited beneath the fish cages and accumulate. If such a redistribution should be accepted, a clear demonstration of the benefits of the use of TCM in feed – reducing feed wastage and by this the organic load of water – should be required.

5. REFERENCES

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