Opinion on Derivatives of Wood Rosin as Coating Agents for Fresh Citrus Fruits (expressed on 19th September 1997)

Terms of Reference

To evaluate the safety of certain wood rosin derivatives as coating agents for fresh citrus fruits presently not listed in the Directive on Food Additives other than Colours and Sweeteners.

Background

The Directive on Food Additives other than Colours and Sweeteners (1) does not include in its Annex IV among the coating agents listed therein any rosin derivatives as coating agents for fresh citrus fruits. However, these materials have been in use for years in some EU Member States as protective coating agents on citrus fruits to prevent transpiration of moisture with resulting weight loss, to delay fruit ageing and to improve the appearance of the fruits by increasing the shine of the peel. An amendment to this Directive has now been requested to permit the use of certain rosin derivatives as surface treatment of citrus fruits at a rate of application of 50 mg/kg fruit.

Another rosin derivative, Ester Gum 8BG (a glycerol ester of wood rosin), used as an emulsifier and stabiliser in soft drinks, was previously evaluated by the SCF in 1990 (2) and allocated a temporary ADI of 0 - 0.5 mg/kg b.w, provided that the only rosin present is wood rosin and that the results of an adequate 90-day feeding study in rats using a well specified commercial product would be submitted in due course. The same compound was subsequently re-evaluated by JECFA in 1995 (3) and allocated an ADI of 0 - 25 mg/kg b.w.

Information submitted

The Committee was provided with specifications, technological information on use levels and biological data on the following 3 specific rosin derivatives: partially hydrogenated rosin, rosin esterified with pentaerythritol and rosin modified with maleic anhydride and esterified with pentaerythritol (4).

The specifications submitted do not specify wood rosin as the basic rosin, modified for the production of the 3 coating agents put forward for inclusion in the present Directive. However all the biological data submitted relate entirely to modified wood rosins.

For partially hydrogenated wood rosin a 90-day feeding study in Sprague-Dawley rats was submitted. It encompassed 5 test and 2 control groups, each consisting of 10 animals/sex/group and covered the dietary dose levels 0%, 0.01%, 0.05%, 0.2%, 1% and 5% of the test substance suspended in corn oil. All control and test groups were adjusted to a corn oil content of 2.33%, the 5% test group had a dietary corn oil level of 11.7%. The investigations carried out covered the usual parameters except that no clinical chemistry parameters were investigated. Organ weights were determined for 7 major organs and histopathology was performed on 20 different tissues. All animals of the 5% test group had died by day 11 from inanition due to food refusal as a consequence of unpalatability of the diet. Reduced body weight gain and slight increase in relative liver weight were noted at the 1% dose level. The NOAEL was 0.2% (=100 mg/kg b.w.) (5)

In addition a 2-year chronic feeding study in Sprague-Dawley rats was submitted. It used 3 test and 2 control groups, each comprising 30 animals/sex/group. The dietary dose levels tested were 0%, 0.05%, 0.2% and 1% of the test substance suspended in corn oil. All diets including that of the controls were adjusted to a total corn oil level of 2.33%. The investigations carried out covered the usual parameters but did not include any clinical chemistry. Organ weights

were determined for 8 major organs and histopathology examined 24 different tissues. Apart from lower body weights in the 1% test group compared to controls, not accompanied by reduced food consumption, no other significant adverse toxicological effects were noted in any test or control group. The NOAEL was 0.2%(=100 mg/kg b.w.) (6).

Furthermore, a 2-year chronic feeding study in beagle dogs was supplied, which used 2 test groups with 3 animals/sex/group and a control group of 6 animals/sex/group. The dietary dose levels investigated were 0%, 0.05% and 1%. The diet of all groups was adjusted to a corn oil content of 2.33% as the test substance was suspended in corn oil. None of the standard investigations showed any toxicologically significant findings compared to controls. The NOAEL was 1% in the diet (=250 mg/kg b.w.), the highest dose level tested (7).

For the pentaerythritol ester of wood rosin the submission contained the results of acute toxicity tests in rats and guinea-pigs (8,9). The respective LD_{50}s were >20 g/kg b.w. and >18 g/kg b.w.

A 90-day feeding study in Sprague-Dawley rats was also supplied. It used 5 test groups and 2 control groups, each consisting of 10 animals/sex/group and the following dietary dose levels: 0%, 0.01%, 0.05%, 0.2%, 1% and 5%. The test material was suspended in corn oil and each group diet was adjusted to contain 2.33% corn oil except for the 5% group which had 11.7%.

1 rat died in each of the control and test groups up to the 1% dose level, 2 rats died in the 5% dose group. There were no significant adverse toxicological findings in all standard investigations in the test groups compared to the controls. The NOAEL was the highest level tested, i.e. 5% in the diet (=2500 mg/kg b.w.) (10).

In addition the results of a 2-year feeding study in Sprague-Dawley rats were submitted. This study was inadequate in design as it used only one rather low test dose level and 2 control groups, each of 30 animals/sex/group. There were a few unscheduled deaths in the 3 groups due to respiratory disease. No significant adverse toxicological effects were noted in the test group compared to the controls. Tumour incidence and type in the test group were also comparable to those of the controls. The NOAEL was 0.05% (=25 mg/kg b.w.), the only dose level tested (11).

Furthermore, the results of a 2-year study in beagle dogs were supplied. This study was inadequate because it used only one rather low dose level. The test group consisted of 3 animals/sex/group, the control group of 6 animals/sex/group. There was no mortality and no significant differences were noted between the test and control group in all standard parameters investigated. The NOAEL was 0.05% (=12.5 mg/kg b.w.) the only dose level tested (12).

For the rosin modified with maleic anhydride and esterified with pentaerythritol only an inadequate specification was supplied which did not clarify, whether the basic unmodified rosin was of the wood rosin type. It is therefore not possible to use the 90-day feeding study in Sprague-Dawley rats also submitted for the safety assessment of this particular modified rosin, although the design of this feeding study was reasonably adequate, until the identity of the material tested becomes available (13).

The Committee has received an intake estimate of 0.00075 mg/kg b.w./person/day as the likely worst case from assumed non-standard use of rosin esters on the peel of bitter oranges. This estimate is based on import figures for certain EU countries and assumed consumption of all imported fruit by their total population (14). The Committee considered this to be an unsatisfactory and unrealistic approach. It has now been supplied with intake estimates based on dietary surveys in the U.K. which suggests that the estimated total dietary intake of wood rosins ranges for adults from a mean of 0.04 mg/kg b.w./day to a 97.5 percentile of 0.17 mg/kg b.w./day. The equivalent figures for pre-school children range from a mean of 0.08 mg/kg b.w./day to a 97.5 percentile of 1.16 mg/kg b.w./day. The only significant intake of citrus peel is taken to come from the consumption of orange juice made from comminuted crushed whole oranges and from marmalade (40% fruit) made from bitter oranges.

Conclusion

The question whether the coating materials requested for inclusion in Annex IV of the Directive on Food Additives other than Colours and Sweeteners are in fact produced from appropriately modified wood rosin cannot be verified by the Committee until the revised specifications become available. Meanwhile, the Committee is of the opinion, that

coatings made from partially hydrogenated wood rosin are **temporarily acceptable** as coatings for fresh citrus fruits at an application rate of 50 mg/kg fruit. This decision is based on the available though limited feeding studies in rats and dogs, which indicate a safety margin of 75-500 between likely intakes and the NOAEL. The Committee requires information on reproductive effects, teratogenicity, mutagenicity and an adequate specification defining the source of the rosin within the next three years.

For coatings made from the pentaerythritol ester of wood rosins the Committee considers that these are **temporarily acceptable** for use on fresh citrus fruits at an application rate of 50 mg/kg fruit. This decision is based on the available though inadequate long term studies in the rat and dog and the reasonably adequate 90-day rat study none of which disclose any significant adverse toxicological effects. The acute toxicity is also very low and hydrolysis is unlikely in view of the stable chemical structure of the ester. The safety margin between likely intakes and the NOAEL lies between 10 and 60. However appropriate information on reproductive effects, teratogenicity and mutagenicity is required within the next 3 years and an adequate 2 year oral feeding study in rats is required within 5 years. An adequate specification defining the source of the rosin is also required.

The Committee is unable to evaluate the safety of rosin modified by maleic anhydride and esterified with pentaerythritol because of the grossly inadequate toxicological database and the uncertainty regarding the specification of this modified wood rosin. The Committee therefore considers this modified resin **unacceptable** for food use.

References

1. Directive on Food Additives other than Colours and Sweeteners
2. SCF (1992) Reports of the SCF (26th Series), p 11
3. JECFA (1996) WHO FOOD Additives Series 37, 3-6.
4. Submission by Spanish rosin derivatives producers (1993) to EU Commission
5. IBT Laboratories (1960a) Report to Hercules Powder Co.,Inc. 90-day sub-acute oral toxicity of staybelite resin in rats, dated 12.8.1960.
6. IBT Laboratories (1962a) Report to Hercules Powder Co.,Inc. Two-year chronic oral toxicity of staybelite resin in rats, dated 24.8.1962
7. IBT Laboratories (1962b) Report to Hercules Powder Co.,Inc. Two-year chronic oral toxicity of staybelite resin in dogs, dated 31.7.1962.
8. Smyth,H.F. (1940) Letter from Smyth Laboratories, Philadelphia, to Hercules Powder Co.,Inc., dated 20.11.1940.
9. CCCA/NACGM Submission (1948-1959) Report No. 38.
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11. IBT Laboratories (1962c) Report to Hercules Powder Co.,Inc. Two-year chronic oral toxicity of Pentalyn A resin in rats, dated 24.8.1962.
12. IBT Laboratories (1962d) Report to Hercules Powder Co.,Inc. Two-year chronic oral toxicity of Pentalyn A in dogs, dated 31.7.1962.
13. IBT Laboratories (1960c) Report to Hercules Powder Co.,Inc. 90-day sub-acute oral toxicity of Pentalyn 856 in rats, dated 14.9.1960.
14. Union Resinera Española (1997) Summary report on consumption of fresh citrus fruits and derivatives in EU countries and estimation of the maximum intake of rosin derivatives. Unpublished report dated 21.March 1997 submitted to EU Commission.