

DIETARY ASSESSMENT

PROPOSAL P150

FOR RECOMMENDING A JOINT DRAFT GENERAL STANDARD FOR FOOD ADDITIVES

In the P150 Full Assessment report, dietary exposure assessments were undertaken on 175 additives (69 groups of additives) with an acceptable daily intake (ADI). Additives with no ADI were assessed as being of no risk to human health on the basis that the ADI was 'not specified'. Of the 69 additive groups, 40 additive groups were assessed as being of no risk assuming the exclusive use of the additive in foods at maximum permitted levels (MPLs). Information was requested from the food industry on the actual use in the food supply of the remaining 29 additive groups. Based on this information, only 5 additive groups (sulphites, nitrites, cyclamates, saccharin and propylene glycol) were considered as potential causes for concern because potential dietary exposure exceeded the reference health standard (ADI). The Authority proposed risk management options for these additive groups, including the restriction of permissions for use.

The dietary exposure assessments presented in the P150 Full Assessment Report were derived from the 1983/1985 National Dietary Survey (NDS) data because more recent data from the 1995 National Nutrition Survey (NNS) were not available at the time of assessment. The Authority has now repeated dietary exposure assessments of the 29 additive groups of initial concern based on the 1995 NNS data, using the same assumptions about additive levels as in previous assessments. These results are presented below.

Summary of results

In general, the decisions made by the Authority based on the 1983/85 survey data are validated by the revised dietary exposure assessments. However, estimated dietary exposures for additives used predominantly in soft drinks have tended to increase because the level of consumption and number of consumers of soft drinks have increased in the period from 1983 to 1995. Estimated dietary exposures for intense sweeteners have tended to decrease because unlike the 1983/85 NDS, the 1995 NNS data distinguishes between low joule and normal counterpart foods, such that models estimating dietary exposure to intense sweeteners include consumers of low joule foods only. These estimates are therefore more realistic and in most cases reflect the results reported in the Authority's 1994 survey on intense sweetener consumption (NFA 1995). Detailed results are at Table 1.

Risk management options

The additive groups sulphites, nitrites, cyclamates, saccharin and propylene glycol, were identified in the P150 Full Assessment report as cause for concern because actual dietary exposures had the potential to exceed the ADI for either adults or schoolchildren. These additive groups, remain cause for concern following risk assessment procedures based on the 1995 NNS data. Risk minimisation options for these additives have already been proposed by the Authority and essentially do not change. The explanatory notes provided in the P150 Full Assessment report will not be repeated here. Changes due to the revised dietary exposure estimates as a result of using the 1995 NNS data only are noted.

For **sulphites**, there were minimal changes in results derived from the 1983/85 NDS compared with the 1995 NNS, with the ADI being exceeded by mean and high consumers (Table 1). The increased consumption of soft drinks did not have a large impact on dietary exposure estimates because other food categories also make major contributions to estimated dietary exposure, for example, dried fruit. It is recognised that sulphites are generally not present in the final product at the same high concentration levels as added initially, however, the food industry is encouraged to use good manufacturing practice (GMP) levels at all times. Where suitable alternative methods of preservation exist, the industry is encouraged to replace sulphur dioxide and sulphites. Appropriate labelling would help to alert individuals, who cannot tolerate sulphites, of their use in specific food products (refer to P161 Specific Labelling Statements for labelling provisions).

For **nitrites**, estimated dietary exposures derived from the 1995 NNS data are higher than those derived from the 1983/85 data (Table 1). There appears to be an overall increase in processed comminuted meat consumption for children aged 2-19 years reported in the 1995 NNS, compared with the amount reported for schoolchildren aged 10-15 years in the 1985 survey (mean consumption for all respondents for all processed comminuted meats, except sausages, was 17 g/day 1995 NNS, 12 g/day 1985 NDS, the highest 95th percentile consumption for each group was 125 g/day 1995 NNS, 120 g/day 1985 NDS). As a result the proposed restricted permissions for use in specific processed meats have been retained.

For **cyclamates**, estimated dietary exposures derived from the 1995 NNS data are lower than previous estimates derived from the 1983/85 data because the revised dietary model assigned a cyclamate level to low joule foods only (Table 1). Despite this improved estimate, there is still potential for a high consumer of soft drinks containing cyclamates to exceed the ADI. Therefore, the proposal to restrict permissions for soft drinks and fruit juice products and to delete permissions for tabletop sweeteners will be retained, permission for use will not be extended to spoon-for-spoon products. As suggested in the Full Assessment Report, the food and beverage industry are encouraged to phase out extensive use of this additive in the future, particularly in cordials, soft drinks and fruit juice drinks.

For **saccharin**, as for cyclamates, estimated dietary exposures derived from the 1995 NNS data are lower than previous estimates derived from the 1983/85 data because the revised dietary model assigned a saccharin level to low joule foods only (Table 1). However, some individual consumers of saccharin based table top sweeteners may exceed the ADI. The proposal not to extend P150 permissions to spoon-for-spoon products is retained. As suggested in the Full Assessment Report,

one option to reduce the potential risk of exceeding the ADI from excessive consumption of tabletop saccharin sweeteners is the use of voluntary warning on labels about the potential risks associated with excess consumption.

For **propylene glycol**, the Full Assessment Report assumed that the major use was in fruit salads. However, the main use of the additive is on surface treated fruit and vegetables. If it is assumed that all foods in the 4.1.2 Surface treated fruits and vegetables category contain propylene glycol, estimated dietary exposures for both mean and high consumers of the additive exceed the ADI (Table 1). Revised estimates derived from the 1983/85 NDS data assuming use in 4.1.2 Surface treated fruits and vegetables indicate similar results. However, propylene glycol is currently permitted on waxed citrus fruit only. Dietary exposures are therefore overestimated because the 4.1.2 category also includes apples and pears. In addition, information from the food industry indicates that the additive is only used on a small proportion of citrus fruits available for sale. In reality, it is therefore unlikely that the ADI would be exceeded. However, the additive is placed on the list for monitoring because potential dietary exposures exceed the ADI. The Authority proposes to restrict permission for use of propylene glycol to 4.1.2 Surface treated fruits and vegetables, citrus fruits only.

Monitoring program

In a limited number of cases, the level of concern about the potential risk of the dietary exposure to an additive or additive group is such that the Authority intends to establish an ongoing monitoring program to assess the impact of proposed changes to the additive food standard on the food supply, on estimated dietary exposure and risk to human health.

Additives recommended for monitoring include the five additive groups discussed above plus other additive groups where the theoretical estimated dietary exposure exceeded the ADI or where there was potential for an expansion of the number of food categories where the additive is actually used without changes in permissions as proposed in P150. For colours, those with estimated dietary exposure above 200% ADI are included on the list, assuming that in reality it is extremely unlikely that over one fifth of each food categories permitted to use the colour would do so. Therefore, theoretical estimates of < 200 % ADI are assumed not to be cause for concern.

Additives to be placed on the initial list for monitoring include:

- sulphites
- nitrites
- cyclamates
- saccharin
- acesulphame-K
- alitame
- propylene glycol
- benzoates
- annatto
- amaranth
- sunset yellow
- brilliant black
- brown HT

Acesulphame-K and alitame have been placed on the monitoring list because estimates of dietary exposure derived from the 1995 NNS are based on actual use levels in a restricted number of food categories. If the actual use of these additives increased according to permissions given in P150, there is potential for the ADI of each additive to be exceeded.

Benzoates have been placed on the monitoring list because estimates of dietary exposure derived from the 1995 NNS indicate a potential increase in estimated dietary exposures, with high consumers of foods containing benzoates at risk of exceeding the ADI. The increase in estimated dietary exposure is due to an increase in soft drink consumption (mean consumption all respondents was 248 g/day 1995 NNS, 83 g/day 1983 NDS). However, dietary exposure to benzoates is likely to be over-estimated because dietary models do not take into account the fact that some soft drinks, for example lemonade or vacuum-packed juice products, do not normally contain preservatives.

Annatto has been placed on the monitoring list because estimates of dietary exposure derived from the 1995 NNS indicate a potential for the ADI to be exceeded. However, in reality, it is considered unlikely that the ADI will be exceeded because annatto is only used in the proportion of the food categories where it is permitted that require an orange/red colour. Dietary models derived from the 1995 NNS data take into account the fact that annatto is used only in a small proportion of ice-creams and less than half of flavoured or fruit yoghurts; dietary exposure estimates are lower than those derived from the 1983/85 data.

Amaranth has been placed in Schedule 1, with a restricted number of permissions (previous models used in the full assessment assumed that amaranth was a Schedule 4 colour). As a result, the estimated dietary exposure to amaranth has decreased compared with that given in the Full Assessment Report. Although it is considered unlikely that the ADI will be exceeded in reality, the theoretical estimated levels justify its inclusion on the monitoring list.

Brilliant black and Brown HT have been placed on the monitoring list because estimates of dietary exposure derived from the 1995 NNS exceeds 200% ADI. However, in reality, it is considered unlikely that the ADI for each additive would be

exceeded because these colours are only used in a small proportion of each food category in which they are permitted where a black or brown colour is required.

Although the estimated dietary exposures for polyglycerol esters of fatty acids, polyglycerol esters of inter-esterified ricinoleic acids have increased compared to estimates derived from the 1983/85 data, it is not considered likely that, in reality, exposure will exceed the ADI for the reasons given in the Full Assessment Report.

The estimated dietary exposures for adipates, sucrose esters of fatty acids and sodium aluminium phosphate show minimal changes in results from 1983/85 data, compared to 1995 data. Therefore, it is not considered likely that, in reality, exposure will exceed the ADI for the reasons given in the Full Assessment Report.

It is envisaged that the Authority will monitor the use of the above additives in food products by means of an Authority questionnaire to the food industry on additive use, administered on a regular basis. The Authority already has an extensive data base on additive use, collated as part of the P150 review. Future changes to product formulation for the above additives as a result of P150 being adopted could therefore be monitored. The impact on these changes on the potential risk to human health will be assessed by the Authority's standard risk assessment procedures, including revision of dietary exposure estimates on a regular basis. Risk management decisions would be taken based on the results of the monitoring program, such that, if necessary, food standards could be amended.

References

National Food Authority (NFA) 1995. Survey of intense sweetener consumption in Australia: Final report, National Food Authority, Canberra, Australia.