Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to

the introduction of a Fat (consumption) Reduction Factor for infants and children

(Question No EFSA-Q-2003-070)

Adopted on 5 October 2004

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food has been asked whether or not a special fat (consumption) reduction factor for infants and children needs to be applied when testing food contact materials for compliance with specific migration limits of lipophilic substances migrating into foods.

The current system for the estimation of the exposure of the consumer to substances released by food packaging is based on the assumption that a consumer ingests daily 1 kilogram (kg) of packaged food which contains the migrated substance at the maximum concentration permitted in food, known as the specific migration limit (SML). The SML for a substance is set in legislation such that the theoretical exposure from eating 1 kg of affected food each day would not result in consumers exceeding the tolerable daily intake value or any other toxicologically-based limit value.

The fat (consumption) reduction factor (FRF) is to be introduced for fatty foods with more than 20% fat, because it has been demonstrated that consumption of fat is much less than 1 kg / day. The total daily fat consumption by European adults does not exceed 200 grams (g) of fat per person per day, equivalent to 3.3 g fat / kg bw / day for a 60 kg adult. Because fat consumption

by infants and children is expected to be higher than that of adults on a body weight basis, this raised the question *"Does the adoption of the FRF imply a need for a different factor for infants and children?"*.

Infants and children have a higher fat intake than adults on a body weight basis, ranging from 6.5 - 3.8 g fat / kg bw / day, considering the energy requirements of infants and children from 6 months to 10 years of age. While this might imply the need for a lower FRF for infants and children, in practice the FRF will not be applicable to a number of the foods they consume.

In the case of milk, ready-to-feed infant formulae and pre-packaged baby foods, the FRF is not applicable because these foods all contain less than 20% fat. In the case of dry powdered formulae or liquid concentrates, even if the standard FRF for adults were to be applied to the dry powder or concentrate to assess compliance of the packaged product with any SML, the large dilution with water to make it ready-to-feed would ensure that the concentration in the product as consumed by the infant would be far below the respective SML. Therefore the Panel concluded that, in practice, no special FRF is needed for infants in relation to consumption of milk, infant formulae or pre-packaged baby foods.

With respect to other foods, infants and children do have a higher intake of energy, on a body weight basis, than adults and the fraction of this energy that is derived from fats is also higher. It may range, for high fat diets, from 4.4 g fat/ kg bw/ day for a 12-month infant down to 3.8 g fat/ kg bw/ day for a 10-year-old child. These figures are not markedly different from the maximum fat consumption of 3.3 g / kg bw / day for adults that was used as a basis for the introduction of the FRF. Consequently, the Panel is of the opinion that the higher consumption of fat on a body weight basis from these other foods by infants and children, compared to that of adults, is modest, and that no special FRF is needed for infants and children for any foods.

KEY WORDS

chemical migration; materials and articles; fat consumption; FRF; fat reduction factor; exposure; specific migration limits; infants; children.

1. Background

The current system for the estimation of the exposure of the consumer to substances released by food packaging is based on the assumption that a consumer ingests daily 1 kilogram of

packaged food which contains the migrated substance at the maximum concentration permitted in food, the specific migration limit (SML). The SML for a substance is set in legislation such that the theoretical exposure from eating one kilogram of affected food each day would not result in consumers exceeding the tolerable daily intake value or any other toxicologically-based limit value.

Recently the Scientific Committee on Food (SCF) adopted an opinion [SCF, 2002] which permits the correction of the migration value with a Fat (consumption) Reduction Factor (FRF). The migration value is the measured concentration in the food of the substance released from the food packaging, as determined in the laboratory. The FRF is a reduction factor which takes into account that, for nutritional reasons, a person cannot ingest daily 1 kg of fat and that the maximum amount of fat that can be ingested daily is not more than 200 grams. As an example, if a fatty food contains 50% of fat, only 400 grams of this fatty food can be ingested and not one kilogram, which is the theoretical value used to establish SML values. Therefore, the migration value determined experimentally by testing the food should be divided by a reduction factor (FRF) of 2.5 (i.e.1000/400). In general, the value of the FRF will be variable from 1 to 5 according to the percentage of fat in the fatty food.

During the discussion within the SCF, some experts stressed the need to examine the consequences of the introduction of this new reduction factor for the exposure of children. Because of their lower body weight, exposure of infants and children to substances in food, including substances migrating from food contact materials, is expected to be generally higher than the exposure of adults, when expressed on a per kilogram body weight basis. The same question was raised by some Member States and in a "Nordic workshop on Assessment of proposal for a new EU-model for intake assessment and control of migration from food contact materials and articles" organised by the Nordic countries (Denmark, Sweden etc), [Nordic Workshop (Copenhagen, November 2002)]

2. Terms of reference

The Commission asks the EFSA to issue an opinion on the following question:

"Does the adoption of the FRF (= Fat (consumption) Reduction Factor) imply a need for a different factor for infants and children?"

ASSESSMENT

In order to address this question, it is first necessary to examine the scope of the proposed introduction of the FRF to see whether the FRF would be applicable, in principle, to foods consumed by infants and children.

Scope of the proposed introduction of the FRF

As proposed, the use of the FRF will be restricted to certain cases only:

- it will be applicable only to foods with a fat content greater than 20% on a mass fraction basis;
- the maximum numerical value of the FRF will be 5, for a pure food fat or oil
- it will be applicable only to selected substances, that may migrate into fatty foods but that have negligible migration into non-fatty foods;
- it will not be applicable to those hazardous substances which are classified in SCF List 4 and for which there should be no detectable migration into foodstuffs.

Infant formula, milk and baby foods

Estimates of fat consumption by infants

According to European Recommended Dietary Allowances, the average energy requirement is approximately 100 kcal / kg bw / day for infants aged 6 months to 3 years of age (CEC, 1993). The maximum lipid content established by the European legislation for infant formulae is 6.5 g / 100 kcal, equivalent to 58.5% energy from fat (CEC, 1991). Consequently, meeting all the average energy requirement from a diet of formula containing the maximum permitted fraction of fat, would result in a consumption of 6.5 g fat / kg bw / day. This is double the upper limit of fat consumption of 3.3 g / kg bw / day (i.e. 200 g fat each day for a 60 kg adult) that was used as a basis for the introduction of the FRF.

The above considerations could be taken to indicate that a lower FRF value is required for infants. However, it must be recognised that in order to test compliance with legislation, packaging materials must not release substances in concentrations greater than the respective specific migration limit (SML) into ready-to-eat foods. Hence there is a need to examine the types of foods consumed by infants and children.

Infant formula and milk

Infant formula is sold pre-packaged either as a dry powder, as a liquid concentrate, or as ready-to-feed milk and formula. In the case of milk and ready-to-feed infant formulae, the FRF is not applicable because these foods all contain less than 20% fat. In the case of dry powdered formulae or liquid concentrates, even if the standard FRF for adults were to be applied to the dry powder or concentrate to assess compliance of the packaged product with any SML, the large dilution with water (typically 1:7) to make it ready-to-feed would ensure that the concentration in the product as consumed by the infant would be far below the respective SML.

Pre-packaged baby foods

As they mature, infants consume smaller quantities of formula as their intake of weaning foods increases. Pre-packaged baby foods do not contain more than 20% fat. For example, in a Europe-wide survey of 248 samples of pre-packaged baby foods purchased from 12 countries, the highest fat content was 5.8% [Fantoni and Simoneau, 2003]. Consequently, the FRF would not be applicable for any packaging materials for these foods nor to materials and articles used in the home for preparing and feeding these foods.

Other foods

Some of the foods prepared by the carer for infants and children are prepared from ingredients that contain more than 20% fat. Examples include meals prepared using cheese, meat or poultry that was purchased packaged in plastic films and trays. For these, the FRF would be applied to the packaging. Hence there is a need to examine the quantity of these fatty foods that may be consumed by older infants and children.

Estimates of fat consumption by older infants and children

Infants and children have a higher intake of energy, on a bodyweight basis, than adults and the fraction of this energy that is derived from fats is also higher for infants and children compared to adults. Recommended intake for infants and young children is 35 to 40% of energy from fats versus 25 to 30% for adults [SCF, 1993].

As an example, fat consumption can be calculated for a 12-month-old infant using an energy requirement for such infants of 1000 kcal / day and with 40% of this energy requirement

provided by fat in the diet. Since fat provides 9 kcal / g, the fat consumption would be 44 g / day. For a 10 kg bodyweight child this would be a consumption of 4.4 g fat / kg bw / day. This is higher than the maximum fat consumption of 3.3 g / kg bw / day for an adult that was used as a basis for the introduction of the FRF.

As children get older their energy requirement on a bodyweight basis is lower. Potential fat consumption can be assessed for an example of a child aged 10 years. According to European Recommended Dietary Allowances, at this age an average body weight is 30 kg and an average energy requirement is 68 kcal / kg bw [CEC, 1993]. In order to assess potential consumption for a child with an average energy intake consuming a diet high in fats, it was assumed that 50% of the energy requirement was from fat. This assumption leads to a conservative (but not unrealistic) estimate of 3.8 g fat / kg bw / day. This figure is very similar to the upper limit of fat consumption of 3.3 g / kg bw / day that was used as a basis for the introduction of the FRF.

DISCUSSION AND CONCLUSIONS

The Fat (Consumption) Reduction Factor is to be introduced because it has been demonstrated that total daily fat consumption by European adults does not exceed 200 g fat / person / day. For the conventional 60 kg adult this is 3.3 g fat / kg bw / day. Infants and children have a higher fat intake than adults on a body weight basis, which may range, for high fat diets, from 6.5 - 3.8 g fat / kg bw / day, considering the energy requirements of infants and children from 6 months to 10 years of age. The fact that the experimentally determined migration should be divided by the FRF in order to test compliance with the SML, might imply the need for a lower FRF for infants and children because they may consume more fat on a body weight basis. In practice, however, the FRF will not be applicable to a number of the foods they consume.

In the case of milk, ready-to-feed infant formulae and pre-packaged baby foods, the FRF is not applicable because these foods all contain less than 20% fat. In the case of dry powdered formulae or liquid concentrates, even if the standard FRF for adults were to be applied to the dry powder or concentrate to assess compliance of the packaged product with any SML, the large dilution with water to make it ready-to-feed would ensure that the concentration in the product as consumed by the infant would be far below the respective SML. Therefore, in practice, no special FRF is needed for infants in relation to consumption of milk, infant formulae or pre-packaged baby foods.

With respect to other foods, infants and children do have a higher intake of energy, on a body weight basis, than adults and the fraction of this energy that is derived from fats is also higher. It may range, for high fat diets, from 4.4 g fat/ kg bw/ day for a 12-month infant down to 3.8 g fat/ kg bw/ day for a 10-year-old child. These figures are not markedly different from the maximum fat consumption of 3.3 g / kg bw / day for adults that was used as a basis for the introduction of the FRF. Consequently, the Panel is of the opinion that the higher consumption of fat on a body weight basis from these other foods by infants and children, compared to that of adults, is modest, and that no special FRF is needed for infants and children for any foods.

DOCUMENTS PROVIDED TO EFSA

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