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Opinion

of the Scientific Committee on Food

on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials

(expressed on 4 December 2002)

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Terms of reference

The current EU system of estimating exposure of a consumer to a substance migrating from packaging into foodstuffs is based on the assumption that a consumer can ingest up to a maximum of 1 kg of fatty foodstuffs per day, even when the fatty foodstuffs is a pure fatty substance such as a vegetable oil.

In this system, the potential for migration of a substance from a material into fatty foodstuffs is estimated by the use of olive oil as a medium simulating the maximum extraction capacity of any of the packaged fatty foodstuffs (liquid or solid).

The Committee is requested to address the following issues:

1. Can a consumption of 200 g fat/person/day be considered a realistic maximum intake for consumers, taking into account the results of a fat intake study (1)?

2. If the answer to question 1 is yes, could the Committee accept an adjustment to the present convention by introducing a "fat (consumption) reduction factor" (FRF) into the estimation of the exposure to a migrant in fatty food?

3. If the answer to question 1 is yes, could the Committee accept an adjustment to the present convention by introducing a FRF when the estimation of exposure is made on the basis of migration tests using a fatty food simulant?

In answering the questions under 2. and 3., the Committee is requested to note that

a) the present assumptions were developed in the early 1960's before the SCF was established and they were introduced by the Commission;
b) these assumptions have been subsequently adopted by the SCF when it formulated its requests for toxicological data and when it established for the substances in the SCF_ List 3 a concentration limit for the migrant in foodstuffs.

1. BACKGROUND

INTRODUCTION

European trade organisations, aware that the current system for the safety assessment of chemicals migrating from food contact materials overestimates the exposure to fat-soluble migrants, requested the introduction of an additional reduction factor which takes into account that a person cannot eat as much as 1 kg of fat/day.

The Commission services, before submitting the request to the Committee, have instituted a task force composed of experts in migration to consider the request. The conclusions drawn by the task force are described below.

1.1. CURRENT SYSTEM

1.1.1 In the early 1960's, it was decided that the safety assessment of chemicals used in food contact materials would make the assumption that a person of 60 kg will eat daily during his lifetime, up to 1 kg of foodstuffs in contact with a surface of 6 dm² of the same type of plastic packaging, containing the migrant substance at the maximum value compatible with the established specific migration limit (SML). Hence, for a substance having a TDI [(1)], the SML was established as follows :

migration ≤ SML (mg/kg food) = TDI (mg/kg/bw) x 60 (kg/bw) x 1 kg food

1.1.2. Another assumption was that each of this 1 kg of foodstuff could have an "aqueous","acidic", "alcoholic" or "fatty" character and could be simulated by 1 kg of food simulant (respectively "water", "3% acetic acid", "10% ethanol" and "olive oil or other fat simulants") (see also 1.1.5). In this system, the total dose of migrant absorbed per day can only be derived from 1 kg of food in contact with the plastic and that this kg is composed either of 1 kg of fatty food or 1 kg of one of the other types of food, but never by the sum of the various types of food.

Summarising the assumptions of the current system, they are the following:

- no material use factor (plastic, paper & board, glass, metal, etc.)
- same plastic packaging material type (= no plastic use factor)
- 100% market share for the migrants under review
- life-time exposure day by day
- all packaging materials release the migrants at the maximum value

1.1.3 A material is considered suitable for packaging any type of food if the migration in each of the four simulants is below the SML. If the migration into a given food exceeds the SML, the material is considered unsuitable for this corresponding class of food.

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[1] For reasons of clarity this summary uses as an example a substance for which a TDI has been established. However, relatively few food contact substances have been assigned a full TDI. Rather, restrictions are frequently derived from reduced toxicity dossiers, leading directly to fixed migration limits e.g. R=0.05 or R=5mg/kg food or food simulant. The principles explained above using a substance with a TDI as an example, apply also to substances with fixed migration restrictions.

1.1.4 The current EU regulatory system can be summarised as follows for fatty food in terms of consumer exposure[(1)]:

$$E_{(fat)} < D_{(fat)} \qquad (1)$$

Where:
$E_{(fat)}$ = Exposure to the substance A that has migrated into a fatty food
$D_{(fat)}$ = Dose toxicologically tolerated for the substance A.

By applying the current assumptions, the formula in (1) becomes:

$$M_{fatty\ food} \times 1 \leq SML \times 1 = TDI \times 60$$

Where:
$M_{fatty\ food}$ = Migration (= concentration) of the substance in fatty foodstuff expressed in mg/kg
1 = Quantity of fatty food assumed to be in contact daily with plastic conventionally equal to 1 kg.
TDI = Tolerable Daily Intake expressed as mg/kg/bw
60 = Assumed body weight of a person
SML = Specific migration limit expressed as mg (of migrating substance)/kg of foodstuffs

When the exposure of a migrant is estimated in the fatty food simulant (=olive oil) and not in the fatty foodstuff itself, the formula (1) becomes:

$$M_{olive\ oil} \times 1 \leq (TDI \times 60) < SML \times 1$$

Where:

$M_{olive\ oil}$ = Migration (= concentration) of the substance into olive oil expressed in mg/kg
1 = Daily quantity of olive oil assumed to be in contact with plastic, conventionally equal to 1 kg.

1.1.5. The same system and assumptions are valid for the other types of foodstuffs conventionally subdivided in "aqueous" "acid" and "alcoholic" foodstuffs. Therefore the EU system in total can be summarised as follows:

$$M_{fatty\ food} \times 1 \leq (TDI \times 60) < SML \times 1$$
$$M_{aqueous\ food} \times 1 \leq (TDI \times 60) < SML \times 1$$
$$M_{alcoholic\ food} \times 1 \leq (TDI \times 60) < SML \times 1$$
$$M_{acidic\ food} \times 1 \leq (TDI \times 60) < SML \times 1$$

1.1.6. Even if the current system does not consider the contribution of the various concentrations found in the foodstuffs to the total exposure of a person, this system was considered very conservative by the majority of the experts as the plastics are composed mainly of lipophilic substances. The migration of these components into foodstuffs other than fatty foodstuffs may be considered negligible. Therefore the substitution of 1 kg of fatty foodstuffs by one kg of oil is a great overestimation and provides a large margin of safety (see a comparison of the migration values into fatty foodstuffs and into fat simulant in annex 2) for most substances.

1.2. PROPOSAL FROM EUROPEAN PROFESSIONAL ORGANISATIONS

1.2.1 FIRST CASE: Correction of the *specific* migration values obtained into *foodstuffs* themselves (FRF)

The industry proposes to introduce for the verification of the compliance with the SML in foods the *FRF* [(2)], which takes into account that a man can not ingest daily and for all his life more than 200 grams of fat (see annex 1). The FRF is so defined as:

FRF = (Mass fraction fat in food (g fat/kg of food))/ 200

In conclusion the migration (M) value to be compared with the SML (M_{corr}) is the experimental value obtained by testing for migration into the food (M_{exp}) divided by the FRF for that food.

$M_{corr} = M_{exp}/FRF$

The FRF values are conventionally limited to lie between 1 and 5. This means that there will be no correction at all for the foodstuffs having less than, or equal to 20% of fat (FRF = 1). In fact in this last case the quantity of foodstuffs to be eaten would be more than 1 kg and this fact is excluded by the initial convention.

Moreover, the industry proposes that the FRF should be applied under the following conditions:

a) not for the substances of SCF List 4 (substances which should not be detectable in food)
b) the application of the FRF should not lead to a specific migration exceeding the overall migration limit (OML)

1.2.2. SECOND CASE: Correction of the specific migration values obtained in simulant D (olive oil or equivalents)(DRF)

The industry proposed to introduce for the verification of the compliance of the SML in fatty simulants ("D" simulant) e.g. in olive oil, the so-called *Simulant D Reduction*

2 In the European professional organisations l document the abbreviation used was FTRF.

Factor (DRF)[3] assumed to be equal to 5. According to industry it is not correct to replace in migration testing 1 kg of fatty foodstuffs composed by semisolids and solids foodstuffs having in the majority of the cases a limited % of fat by 1 kg of olive oil, which is liquid and contains 100% of fat. By so doing the exposure of the consumer is largely overestimated because the realistic maximum intake by the consumers has been shown to be up to 200 grams of fat (i.e. olive oil). Therefore a reduction factor of 5 is requested to correct the experimental values of the migration. This new factor will replace, in the industry proposal, the reduction factors (RF) provided in Directive 85/572/EEC, which were introduced to take into account the different values obtained in fatty food and in fatty food simulants ($M_{fat)}$.

In conclusion the industry requested that migration value to be compared with the SML (M_{corr}) in the enforcement of the legislation is the value obtained by applying the following formula:

$$M_{corr} = (M_{fat}/DRF) = (M_{fat} \times 0.2).= M_{fat}/5$$

This correction does not take into account any contribution to the exposure that may come from migration into the non-fatty simulants. Therefore the industry proposes to add to 1/5 of the migration into simulant D the highest of the three migration values in 1 kg of the other simulants (A, B and C):

Therefore the corrected migration into food simulants is calculated by applying the following formula:

$$M_{corr} = (M_{max} \text{ in simulants A or B or C}) + (M_{sim.D}/DRF)$$

$$M_{corr} = (M_{max} \text{ in simulants A or B or C}) + (M_{sim.D} \times 0.2)$$

1.3. ANALYSIS BY THE COMMISSION TASK FORCE OF THE TWO PROPOSALS

1.3.1. FIRST CASE: Correction of the *specific* migration[4] values obtained in *foodstuffs* themselves.

The Commission task force recognises that the exposure from fatty foodstuffs derives only from the 200 grams of fat dispersed in the fatty foodstuffs and, therefore this quantity of fat is a limiting factor in the ingestion of fatty foodstuffs. But inserting this correction in a system where the contribution to the exposure derived from the other aqueous sources is not considered adequately (1 kg of aqueous beverage is not a conservative value) may increase exposure. Therefore it proposes that this correction can be acceptable only if the substance does not migrate into non-fatty foodstuffs. In this respect the Commission task force proposes that these substances are identified on the basis of the value of their migration into non-fatty simulants which should not exceed 1/10 of their SML. If this value is not available it can be replaced by either the

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3 In the industrial document the abbreviation used was TMRF = Type (Specific) Migration Reduction Factor.

4 It has to be noted that the FRF and DRF do not apply to overall migration as well as QM (Maximal quantity in finished material) values.

solubility in the non-fatty simulants which should be less than 10% of the SML or by the log Po/w which should be no less than 3[(5).]

Moreover the Commission task force agrees on the other conditions proposed by the industry for the application of the FRF.

a) it is applied only to substances which cannot migrate into non-fatty foodstuffs.

b) it is not applied to substances of SCF List 4 (substances which should not be detectable in food simulants)

c) the application of the FRF shall not lead to a specific migration exceeding the OML

1.3.2 Second case: Correction of the specific migration values[5] obtained in food simulants.

The correction proposed by industry $M_{corr}= M_{sim.D}/5$ is not generally acceptable. However the Commission task force agreed that a new reduction factor related to the % of fat present in the foodstuffs (FRF) could be introduced provided that the following conditions are respected:

d) the specific migration (SM) into simulant D is less than 80% of the initial content of the substance in the plastic material or article .

c) the total reduction factor (TRF) should not exceed 5

The Commission task force recognised that replacing 1 kg of fatty food by 1 kg of fat (olive oil) overestimates the exposure from fatty foodstuffs taking into account that a realistic maximum intake for consumers is up to 200 grams of fat. However it stressed the existence of certain specific situations such as the contact at high temperatures or with thin films where the migration is almost complete and then the assumption of the industrial proposal that the exposure is proportional to the quantity of the oil is not longer valid. For example, the substance migrating in 200 grams of olive oil could be just the same as the quantity migrating in 1 kg of oil if the migration is quite extensive and it is regulated only by the solubility of the migrant in the oil.

5 If log Po/w is >3 then the solubility in the non-fatty simulants is expected to be low and the substance, even at equilibrium, will not have migrated to a significant extent from the (non-polar) plastic.

2. CONCLUSIONS

2.1. The Committee, taking into account also the analysis of the situation by the Commission task force, offers the following views on the questions as posed by the Commission in the terms of reference.

2.2 *Question 1*
Can a consumption of 200 g fat/person/day be considered a realistic maximum intake?

Answer 1
Yes. The Committee agrees that the consumption of 200 g fat/person/day can be considered a realistic maximum intake.

2.3. *Question 2*
Could the Committee accept an adjustment to the present convention by introducing a "fat (consumption) reduction factor" (FRF) in the estimation of the exposure to a migrant in fatty food?

Answer 2
Firstly the Committee notes that the introduction of a FRF in the estimation of exposure, would not influence the opinions expressed by the Committee for the substances classified in SCF lists 0, 1, 2 and 4[6]. Only substances classified in list 3 may be affected if the FRF were introduced. The existing restrictions[1] expressed in term of concentration in food have been used by the Committee taking into account the current system and its conservative assumptions. For these SCF_List 3[7] substances the correction due to the introduction in the system of the FRF would be limited because the proposal is to limit the scope of FRF to only lipophilic substances and only to foodstuffs containing more than 20% of fat (see 1.3.1)

Moreover the Committee recognises that the current EU system of the evaluation of the exposure to a migrant from food contact materials is conservative and other upper-bound assumptions are made. For example, the assumption that all the 1 kg food eaten each day is in contact with a plastic that releases the substance at the highest concentration (the SML) permitted. On the other hand, the present system does not take into account possible exposure from other, non-packaging, sources. In total, the introduction of FRF for lipophilic substances and for fatty foods only, would still leave the whole system conservative.

In conclusion the Committee can accept the conclusions reached by the Commission task force (2) and has no objection to the introduction of a "fat (consumption) reduction factor" in the way proposed (1) for estimating exposure to a substance migrating into a fatty food.

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[6] SCF_ list 0 is related to substances which have not any restriction. SCF lists 1 and 2 are related to the substances for which the SCF has established respectively an ADI or TDI. SCF list 4 (substances which should not be detectable in foodstuffs) is not affected by FRF because the FRF does not apply to these substances.

[7] SCF_List 3 list 0 is related to substances for which an ADI or a TDI could not be established, but where the present use could be accepted.

2.4. Question 3

Could the Committee accept an adjustment to the present convention by introducing a FRF when the estimation of exposure is made by testing for migration into a fatty food simulant?

Answer 3

The same considerations mentioned in the second answer apply here also.

It is the Committee's task to recommend concentrations in foodstuffs, and consequent exposure, that are considered to be safe. It is the responsibility of the Commission to ensure that, if a fatty food simulant is used (including conventional or alternative or substitute fat simulants) to test materials for migration, the system used provides a suitable approach to estimate the migration potential from the material into a fatty food. The extrapolation of data obtained from conventional test using simulants to evaluate of migrants in fatty foods involves consideration of the different extraction power between the fatty foodstuffs and the pure fat simulant, the test conditions (e.g. time, temperature, contact area: food mass ratio), the fat content of fatty foods and the consumption of fatty foods. If the Commission decided to introduce the FRF for the fatty simulant, the Committee recommends that the limitations suggested by the Commission task force (2) are considered, to maintain the corrections of exposure close to the current system.

References

1. Final version of CEFIC-FCA document entitled "EU Food Consumption Factor for fat" (Parts I and II)

2. Minutes of the Commission task force EMB 806 final, 7 March 2002.