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

A Total Reduction Factor of 5 for di(2-ethylhexyl)adipate used as plasticiser in flexible PVC food packaging films

(Question No EFSA-Q-2003-071)

Adopted on 27 April 2005

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food has been asked by the Commission whether or not, for the substance di(2-ethylhexyl) adipate (DEHA) used as plasticiser in flexible PVC films, a Total Reduction Factor (TRF) of 5 could be used for all food packaging applications.

The current procedure for estimating consumer exposure to substances migrating from food contact materials into food assumes a person consumes 1 kg of packaged food daily. However, in the case of fat, it has been demonstrated that the total daily fat consumption by European adults does not exceed 200 g. To take account of this, migration values into fatty foods are corrected by a Fat (Consumption) Reduction Factor (FRF), variable from 1 to 5.

Migration of substances from food contact materials into fatty foods can be estimated using the fat simulant, olive oil. Olive oil is known to extract higher quantities of migrants than do many fatty foods themselves. To take account of this, migrant values obtained using olive oil (Simulant D) are corrected by applying a reduction factor, known as the DRF, variable from 1 to 5. The Total Reduction Factor (TRF) is obtained by multiplying the DRF by the FRF and with the restriction that its value should not be higher than 5.

The Panel concluded that the studies presented of migration from plasticized PVC films, provided too limited a basis to demonstrate that a Total Reduction Factor (TRF) of 5 could be used for DEHA in all food packaging applications.

The general applicable reduction factors (DRF) set in Directive 85/572/EEC for fish, meat and poultry are currently 3 and 4.

The Panel concluded, however, that in the special cases presented, for fresh meat, poultry and fish with less than 20% fat and intended to be overwrapped on trays using plasticised PVC films and then stored for up to four days under refrigerated conditions, followed by 4 h at 25°C, application of a simulant D reduction factor of 5 could be justified, provided the migration with simulant D is determined after a contact period of 10 days at 20°C.

KEY WORDS

chemical migration; di(2-ethylhexyl)adipate; DEHA; plasticised PVC film; reduction factors; food simulants.
BACKGROUND

The current system for the estimation of exposure of the consumer to substances released by food packaging is based on the assumption that a consumer ingests daily 1 kilo of packaged food, which can be composed of only fatty food. The estimation of exposure requires the determination of the substances released by the packaging into the various foodstuffs. To simplify the analytical determination of the substances released in complex matrices such as those represented by the various types of fatty foods, a kilo of fatty food is replaced by a kilo of pure fat (olive oil) in the migration testing. However, it was shown that olive oil extracts from the packaging materials quantities of substances higher than those extracted by many fatty foods and, therefore the migration in the current system is corrected by the application of a reduction factor (DRF), variable from 1 to 5.

Recently the Scientific Committee on Food (SCF) adopted an opinion which recommended the correction of the migration value by another reduction factor, i.e. Fat (Consumption) Reduction Factor (FRF). Its value takes into account that a person cannot ingest daily more than 200 grams of fat for nutritional reasons. Therefore, for example, if the fatty food contains 50% of fat, only 400 grams of this fatty food can be ingested and, therefore, the migration obtained in 1000 grams of olive oil should be corrected by a reduction factor of 2.5 (=1000/400) as only 200 grams of fat can be ingested daily. In general the value of the FRF will be variable from 1 to 5 according to the % of fat in fatty food. Finally the migration of a substance from a packaging material and then the exposure of the consumer to this migrant is determined not only by its concentration in the food but, in the case of fatty foods, also by the maximum quantity of fat which can be ingested. When a fatty food is replaced by a fatty simulant, the value of migration should be corrected by the two mentioned factors DRF and FRF. Therefore a third factor was introduced called Total Reduction Factor (TRF) which is obtained by multiplying DRF by FRF. The TRF cannot exceed a value of 5.

In accordance with the SCF opinion some conditions should be respected in the application of the FRF (and TRF). The more important for the terms of reference are the following:

(a) The TRF is applicable only to fatty foodstuffs containing more than 20% of fat;
(b) When the fatty food simulant is used, the TRF is applicable if <80% of the initial amount of the substance is migrating.

In a letter transmitted to the Commission, the European Polyvinyl Film Manufacturers Association (EPFMA, 2003a) asked for di(2-ethylhexyl)adipate (DEHA) the possibility to apply a value of 5 for TRF. EPFMA justified its request arguing that:

(i) The migration of DEHA in fatty foodstuffs is proportional to the content of fat in fatty foodstuffs and, therefore, the FRF for DEHA may be applied also when the migration in fatty simulants is higher than 80% of the initial content of the substance in the plastic material or article;
(ii) The migration of DEHA into the fatty simulant is 5 times or more higher than the migration into food containing less than 20% of fat and, therefore for DEHA a DRF of 5 is the more realistic value.

In October 2003 and in November 2004 the EPFMA provided further clarification that each request above mentioned under ii applies only to flexible films used to machine-wrap fresh meat, poultry and fish held on trays and then stored chilled (EPFMA, 2003b, 2004). These foods currently have simulant D reduction factors of 3 or 4 specified in Directive 85/572/EEC.
It was their view that the factors of 3 or 4 are too severe and that a factor of 5 can be justified by the migration data available.

**TERMS OF REFERENCE**

The Commission asks the European Food Safety Authority (EFSA) to issue an opinion at the request of EPFMA on the application in all situations of a Total Reduction Factor of 5 in the specific case of di(2-ethylhexyl)adipate used as plasticiser in flexible PVC.

**ASSESSMENT**

**Di(2-ethylhexyl)adipate migration from plasticised PVC films**

The substance in question is DEHA (di(2-ethylhexyl)adipate; PM ref no. 31920) which is used as a plasticiser for thin polyvinylchloride (PVC) films used to wrap foods. These films are in the range typically 8 to 25 micrometers thick and the total plasticiser content, including DEHA, would be in the range 10 to 30% by mass. In the past, DEHA was the sole or the dominant plasticiser used in such films but nowadays it is normally used at lower levels and in combination with other plasticisers.

A Tolerable Daily Intake (TDI) of 0.3 mg/kg bw has been established for DEHA by the SCF and the specific migration limit (SML) for DEHA is 18 mg/kg food or food simulant. There is a large body of literature describing laboratory studies of DEHA migration from plasticised films and several surveys of packaged foods have been reported. There have also been biomarker studies reported for limited population surveys in 4 European Countries. The SCF noted that, despite severe limitations of the biomarker surveys of DEHA intake, the data were nevertheless reassuring (SCF, 2000).

**Reduction factors applied to migration levels**

As described in the background section, the TRF is derived arithmetically from multiplication of the FRF and the DRF. The FRF is linked to the fat content of the food. The DRF has its origins in the relationship between the extractive power of simulant D (olive oil or alternatives) and fatty foods themselves, because the fat simulant normally elicits higher migration and so a conventional reduction factor is used.

**Analysis of this proposal for DEHA migration into foodstuffs**

When considering migration into foodstuffs, the DRF is irrelevant and the TRF is equal numerically to the FRF which in turn is calculated from the mass fraction of fat in the food. The FRF falls in the range 1 to 5 for foods with fat content in the range 20% to 100%, respectively. For foods, application in all situations of a Total Reduction Factor of 5 for di(2-ethylhexyl)adipate used as plasticiser in flexible PVC is not justified.

**Analysis of this proposal for testing DEHA migration using food simulants**

Food simulants are commonly used by the industry and by enforcement authorities to test plastics for chemical migration. Simulants are intended to indicate the likely migration into different classes of foods that those simulants are intended to mimic. The DRF has its origins in
the relationship between the extractive power of olive oil used as a fat stimulant and fatty foods themselves, because the fat stimulant normally elicits higher migration and so reduction factors are used. These reduction factors were derived by the Commission using certain conventions, because there is not an exact and constant numerical relationship between migration into different food items and into food simulants. In the Panel’s work the migration into foodstuffs takes priority over any simulations using model foods (simulants), if data for foodstuffs are available.

EFPMA presented several reports [1-3] but these provided too limited a basis to demonstrate that a Total Reduction Factor (TRF) of 5 could be used for DEHA in all situations.

These reports did however focus especially on migration of DEHA into fresh, chilled meat, poultry and fish. The results were compared with the migration from the same films into the simulant olive oil. The migration results were normalised on an area basis to allow for the different ratios of food or simulant mass used per unit area of film in direct contact. The test conditions used for the foods were storage for four days at 5 to 10°C followed by shorter periods at room temperature (4 h at 25°C) as might occur during transport of the packed food from the shop to the home or after removal from a refrigerator prior to unwrapping and use. The test conditions used with the food simulant were contact of the film with olive oil for 10 days at 20°C, as specified in Directive 82/711/EEC for these food contact applications. In all cases, the migration of DEHA into the olive oil was at least 5 times higher than the migration of DEHA into the food. For example, whereas migration from a typical film into sausages and chicken was 1.7 and 3.0 mg/dm$^2$, respectively, migration into olive oil was 15.5 mg/dm$^2$.

CONCLUSIONS

The Panel concluded that the request to use in all food packaging applications, a Total Reduction Factor of 5 for di(2-ethylhexyl)adipate used as plasticiser in flexible PVC, was not supported by the available evidence.

The generally applicable reduction factors (DRF) set in Directive 85/572/EEC for fish, meat and poultry are currently 3 and 4.

However, the Panel concluded that in the special cases presented, for fresh meat, poultry and fish with less than 20% fat and intended to be overwrapped on trays using plasticised PVC films and then stored for up to and including four days under refrigerated conditions, followed by storage for maximum 4 h at 25°C, application of a simulant D reduction factor of 5 could be justified, provided the migration with simulant D is determined after a contact period of 10 days at 20°C.
REFERENCES


SCIENTIFIC PANEL (AFC) MEMBERS