



## Ministero della Salute

DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI  
ALIMENTI E LA NUTRIZIONE

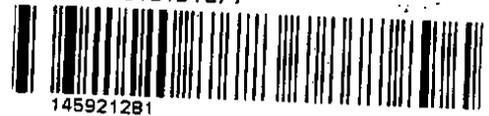
Ufficio VI DGISAN  
Viale Giorgio Ribotta, 5 - 00144 Roma

Ministero della Salute

DGISAN

0035303-P-15/09/2014

I. G. b. d/7



145921281

Agli Assessorati alla Sanità -  
**Regioni e Province Autonome**  
Loro sedi

All'Istituto Superiore di Sanità  
Viale Regina Elena, 299  
00161 Roma

Agli Istituti Zooprofilattici  
**Sperimentali**  
Loro sedi

Alla **Federchimica**  
Via Giovanni da Procida, 11  
20149 Milano

Alla **Federalimentare**  
Viale Pasteur, 10  
00144 Roma

Alla **Federdistribuzione**  
Via Albricci 8  
20122 Milano

Alla **CNA**  
Piazza Armellini 9/a  
00162 Roma

Alla **Confcommercio**  
Piazza Belli 2  
00147 Roma

Alla **Un'Italia**  
Via Torino 146  
00184 Roma

Alla **UnionAlimentari**  
Via della Colonna Antonina 52  
00186 Roma

All'Ufficio VIII DGSAF

Agli Uffici II, III, IV, V, VIII  
DGISAN

### OGGETTO:

Proposta di "Guidance document on the carry-over principle" di cui all'articolo 18 del Regolamento (CE) n. 1333/2008 relativo agli additivi alimentari.

In sede di riunione del Comitato esperti "additivi alimentari" del 4 settembre 2014 la Commissione ha presentato, per la prima volta, una proposta per l'applicazione del **principio del trasferimento** di cui all'articolo 18 del Regolamento (CE) n. 1333/2008 (allegato 1).

Come è noto tale articolo disciplina, fra l'altro, i casi in cui un additivo alimentare non espressamente autorizzato in un **alimento composto** è ivi riscontrabile, ad una verifica analitica, in quanto trasferito da uno degli ingredienti ove lo stesso additivo alimentare è legalmente consentito.

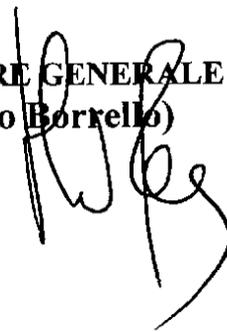
La bozza di documento allegata, volta a fornire un'applicazione uniforme del principio del trasferimento, dovrà essere oggetto di consultazione con gli *stakeholders* dell'Unione europea, per cui nel frattempo si ritiene opportuno acquisire eventuali osservazioni e commenti da parte delle associazioni nazionali e degli organi deputati al controllo ufficiale degli alimenti.

Infatti il documento in questione, presentato sotto forma di linea guida e quindi non legalmente vincolante per le Autorità di controllo, potrà essere comunque uno strumento utile per la verifica della conformità alla norma vigente.

Pertanto si invitano le Associazioni e le Autorità in indirizzo ad esaminare il testo, ancora in fase embrionale, fornendo se possibile anche alcuni esempi pratici atti a descrivere le difficoltà, riscontrate durante le attività di controllo e di autocontrollo, nell'accertamento del rispetto delle condizioni d'impiego degli additivi alimentari.

Nel ringraziare per la collaborazione si resta in attesa di cortese riscontro.

IL DIRETTORE GENERALE  
(Dott. Silvio Borrello)



## Guidance document on the carry-over principle

### DRAFT

*This guidance document describing the carry-over principle laid down in Article 18 of Regulation (EC) No 1333/2008 on food additives was elaborated by Commission services after consultation with the Member States' experts on food additives and the relevant stakeholders.*

*This guidance can be useful for Member State control authorities and food industry to assure correct implementation of the food additives legislation and in particular whether the presence of a food additive in a foodstuff complies with the EU regulation.*

*The guidance document does not represent the official position of the Commission and does not intend to produce legally binding effects.*

*Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.*

### 1. Introduction

Regulation (EC) No 1333/2008 on food additives lays down that only food additives included in the Union list, in its Annex II, may be used in foods under the conditions of use specified therein.

The presence of food additives in foodstuffs not specified in Annex II may however be accepted by virtue of the carry-over principle which is laid down in Article 18 of Regulation (EC) No 1333/2008.

This principle raises a lot of questions by Member State control authorities as well as the food business operators, particular to verify whether the presence of an additives in a compound foodstuffs or in a (intermediate) food ingredient is permissible or not. and whether this presence needs to be included in the list of ingredients list.

## 2. The principle (Article 18.1)

- 1) *The presence of a food additive shall be permitted in a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food;*

Compound foods such as pizza's, sandwiches, tarts etc. do not belong to the food in Annex II to Regulation (EC) No 1333/2008. However the different ingredients from which they are composed belong to one or more of the categories of the Annex.. The additives authorised in these ingredients are as a consequence authorised in the compound food taking into account the conditions of use. The level in the compound food should not be higher than what is contributed via the different ingredient(s).

It should be clarified that "a compound food other than as referred to in Annex II" means those listed in Table 1 and 2 in part A of Annex II

Example: Pizza (to be developed...)

- 50 % Bread (E 322 QS; E 450 12000 mg/kg, ..);
- 20 % Sauce
- 15 % Meat
- 15 % Cheese

Final product (....),

→ the use of this additive should be labelled for each ingredient.

### Remarc

It should be clarified that "a compound food other than as referred to in Annex II" means those listed in Table 1 and 2 in part A of Annex II

- 2) *The presence of a food additive shall be permitted in a food to which a food additive, food enzyme or food flavouring has been added, where the food additive:*
- i. *is permitted in the food additive, food enzyme or food flavouring in accordance with this Regulation; and*
  - ii. *has been carried over to the food via the food additive, food enzyme or food flavouring; and*
  - iii. *has no technological function in the final food*

The use of additives in food additives, food enzymes and flavourings is permitted in accordance with Annex III to Regulation (EC) No 1333/2008. Presence in the final food due to this use is permitted even if the additive is not authorised for use in that food.

When provided, the amount carried over in the final food should comply with the maximum in Annex III. When the additive is authorised for use at *quantum satis* in a food additives, food enzymes or flavourings; the level carried over in the final food should not have a technological function unless the additives is authorised in the final food or the "reverse carry-over" applies (see c)).

→ If the additive has no function in the final food, it shall not be required to be included in the list of ingredient, in accordance with Article 20 of Regulation (EU) No 1169/2011.

- 3) *The presence of a food additive shall be permitted in a food which is to be used solely in the preparation of a compound food and provided that the compound food complies with this Regulation.*

This is often referred to as “reverse carry over”.

This provision is in particular important for food ingredients that are sold between business operators. In such a case the use of additive can be permitted in foods (such as intermediary products), in which they would not otherwise be permitted, provided that those foods are to be used solely in the preparation of a compound food that will be conform to the relevant Regulations.

This principle can only apply if the purchaser of the product is clearly informed about the purpose of the ingredient, including instructions of use so that, if needed, the maximum levels in the final food can be respected.

(Question: case of citrates in blood, discussed at WGA 14/03/02 )

Example:

- premixes for bakery ware

### 3. Exceptions:

- 1) The principle of carry over shall not apply to infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children as referred to in Directive 89/398/EEC, except where specifically provided for.
- 2) Where a food additive in a food flavouring, food additive or food enzyme is added to a food and has a technological function in that food, it shall be considered a food additive of that food and not a food additive of the added flavouring, food additive or food enzyme, and must then comply with the conditions of use for that food as provided for.
- 3) List of foods in which the presence of an additive may not be permitted by virtue of the carry over principle: Table 1 in part A to Regulation (EC) No 1333/2008
- 4) List of food in which the presence of a food colour may not be permitted by virtue of the carry over principle: Table 2: in part A to Regulation (EC) No 1333/2008

#### **4. Specific provisions sweeteners and colours**

- 1) the presence of a food additive used as a sweetener shall be permitted in a compound food with no added sugars, in an energy-reduced compound food, in compound dietary foods intended for low-calorie diets, in noncariogenic compound foods, and in a compound food with an increased shelf-life, provided that the sweetener is permitted in one of the ingredients of the compound food.

As a consequence the presence of a sweetener is not permitted in compound food if that compound food does not comply with the specific conditions of use for sweeteners laid down in Article 7 of Regulation (EC) No 1333/2008:

Examples to be provided

- 2) The use of colours can be permitted in an ingredient of a compound even if the compound food contains ingredients that may not be coloured

Example: breadcrumb used for coating on fish fingers, can be coloured.

#### **5. Question and answers**

To be developed