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OPINION

of the French Food Safety Agency (AFSSA) on models for setting maximum vitamin and mineral levels in fortified foods and food supplements

THE DIRECTOR GENERAL

On 13 May 2009 the French Food Safety Agency (AFSSA) received a request from the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) to assess the models for setting maximum vitamin and mineral levels in fortified foods and food supplements, in the context of Regulation (EC) No.1925/2006 on the addition of vitamins, minerals and of certain other substances to foods.

Context and work objectives

European Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals to foods came into force on 1 July 2007[1]. It provides for the fixing of maximum fortification levels at Community level. In this regard, AFSSA was requested on 11 September 2007 to assess the scientific data available for setting maximum vitamin and mineral levels in food. AFSSA proposed a probabilistic assessment method for testing the safety of the maximum levels, in food supplements and the base diet including fortified foods, obtained by different mathematical models (Flynn et al., 2003; Rasmussen et al., 2006; Richardson, 2007; Domke, 2004a; Domke, 2004b), combined in different scenarios. This method, derived from the approach developed earlier by AFSSA for fortified foods only (AFSSA, 2001), allows the determination of whether the maximum levels established independently for fortified foods and food supplements lead to a risk of exceeding the tolerable upper intake levels for vitamins and minerals when they are introduced into the simulation tool at the same time.
This work gave rise to the opinion of 13 October 2008 (2007-SA-0315) in which AFSSA indicated that two of the scenarios tested were found to be more protective in public health terms. One comprises maximum fortification limits from the DFVR model (Rasmussen et al., 2006) and maximum levels in food supplements set by the French regulations; the other combines the maximum fortification levels and maximum levels in food supplements from the Bfr model (Domke, 2004a; Domke, 2004b). However, the maximum supplementation (fortification and food supplements) proposed by the Bfr (Domke, 2004a; Domke, 2004b) does not avoid the risks of exceeding the UL for each of the nutrients in question (Opinion 2007-SA-0315).

This work (Opinion 2007-SA-0315) was then presented at meetings held at the end of 2008 with the Member States at the European Commission.
At the December 2008 meeting, the European Commission recommended the adoption of two models for setting two series of maximum levels independently: one for fortified foods (expressed for 100 kcal) according to the new Flynn model (Flynn, 2008) and the other for food supplements (expressed in daily intake) based on the model developed by the ERNA[2] (Richardson, 2007). However, in view in particular of the results previously obtained by AFSSA and with the aim of taking account of changes in consumption in the coming years, the European Commission proposed to integrate some "safety factors" in the parameters of the models adopted.

AFSSA received a request on 17 December 2008 to test the maximum supplementation levels (fortification and food supplements) obtained by these two models, by varying the following parameters: the nutritional intake at the 95th percentile via base diet and food supplements $((CI+SI)_{95})$, the energy intake at the 95th percentile via foods fortified with this nutrient (EFF_{95}) as well as the nutritional intake at the 97.5th percentile via base diet and fortified foods (MHI). This work gave rise to the opinion of 28 January 2009 (2008-SA-0398) and allowed the

[1] Regulation (CE) No. 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins, minerals and of certain other substances to foods. JO L 404 of 30.12.2006:26.38
[2] European Responsible Nutrition Alliance

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assessment of the compatibility of the models chosen with regard to the intakes and the risk of exceeding the tolerable upper intake levels for the French population and concluded that the consumer was insufficiently protected.

On the basis of this opinion, the French authorities informed the European Commission of their reservations regarding the insufficient level of protection induced by these management measures. Consequently, it now appears indispensable to improve the level of consumer protection and to carry out a third series of simulations applying new values to the parameters $(CI+SI)_{95}$, EFF_{95} and MHI for the models chosen by the Commission. This was the purpose of this request, which uses its simulation tool to test several new options.

Methods

Data used: the INCA2 2006-2007 consumption study and the CIQUAL[3] food composition study 2008

The second National Individual Study of Food Consumption (INCA2) was conducted from 2006 to 2007. It was carried out on 3 separate occasions over more than a year in order to take account of seasonal variations in diet. It involved a representative sample of 4,079 participants aged between 3 and 79 years (including 2,624 adults aged 18-79 and 1,455 children aged 3-17) living in mainland France. The participants were selected using a three-stage cluster sampling technique stratified on region and size of urban area. The random selection of households was made from the 1999 national population census and records of new housing built between 1999 and 2004.

A weighting was allocated to each participant to ensure that the sample was representative at national level in line with socio-demographic criteria. Moreover, under-reporters (participants who said they consumed less than their requirements) were excluded from the analyses. The sample of non-under-reporting adults included 1,918 people and that of children 1,444.

The INCA2 study gathers all the participants' dietary intakes using food diaries filled in over 7 consecutive days by the participants (food and drink consumed at each meal and between meals). Portion size is estimated from a photo album (SU.VI.MAX, 1994). If they also consumed food supplements, the study participants also filled in a separate food supplement diary during the same week of the study.

Calculating nutritional intakes by simulations

The simulation carried out involves calculating total nutritional intakes from three possible sources (base diet, fortified foods and food supplements) based on detailed and nationally representative consumption data, and by integrating the Maximum Safe Levels calculated for fortified foods (MSL_f) and for Supplements (MSL_s). The assumption made on the market share of fortified foods (among those likely to be fortified) is 25%[4]. For foods considered as fortified, the nutritional intake is calculated with the maximum fortification level.

The simulations carried out concern vitamin D, vitamin B6, vitamin B9 and calcium, nutrients for which there are tolerable upper intake levels set by EFSA.

For each nutrient, the distributions of the total vitamin and mineral intakes (*via* base diet, fortified foods and supplements) are studied according to different scenarios in the adult population and in children independently. The tolerable upper intake levels are then compared to the intake distributions to identify any risks of exceeding them.

The maximum level values for fortified foods ($MSL_{\mathbf{f}}$) as well as the maximal level values for food supplements ($MSL_{\mathbf{s}}$) are calculated according to the Flynn (2008) and Richardson (2007) models explained below respectively:

[3] Food Quality Information Centre
[4] Other hypotheses were also tested (0%, 10%, 50%), but are not presented here.

Setting the maximum levels for fortified foods (Flynn model 2008)

The MSL_f values (expressed for 100 kcal) are calculated as follows:

$$MSL_f=[UL-(CI+SI)_{95}]/[EFF_{95}/100]$$

With **UL:** Tolerable upper intake level
$(CI+SI)_{95}$: 95th percentile intake level from base diet and food supplements
EFF_{95}: Energy intake at the 95th percentile from foods fortified with this nutrient

Irish data were favoured as they take account of a mature market as regards the development of fortified food and food supplement consumption. The European Commission recommended that the MSL_f values be calculated using the values for 3 to 10 year old children in the parameters of the Flynn model(2008). However, the Irish National Children's Food Consumption Survey 2003-2004 (NCFS) concerns children aged 5 to 12 years. In order to meet the simulation conditions required by the European Commission, only the Irish data concerning children aged 5 to 10 years were used. Moreover, within the framework of this request, it was also requested that different MSL_f calculations be carried out by using hypotheses on possible market trends. Accordingly, 3 options were tested[5]:

Option 1: 50% increase in $(CI+SI)_{95,}$ no increase in EFF_{95}

Option 2[6]: 50% increase in $(CI+SI)_{95}$ **and** 100% increase in EFF_{95}

Option 3: 50% increase in $(CI+SI)_{95}$ **and** 150% increase in EFF_{95}

Table 1: MSL_f calculations (in mg or µg/100kcal) from Irish consumption data for 5-10 year old children

Nutrient	UL[a]	$(CI+SI)_{95}$ [c]	EFF_{95}[d]	$(CI+SI)_{95}$ + 50%	EFF_{95}+ 50%	EFF_{95}+ 100%	EFF_{95}+ 150%	**MSL_f - option 1**	**MSL_f - option 2**	**MSL_f - option 3**
Vitamin D	25	6,8	95	10,2	142,5	190	237,5	**16**	**8**	**6**
Vitamin B6	7	3,4	206,7	5,1	310,1	413,4	516,8	**0,9**	**0,5**	**0,4**
Vitamin B9	300	419	190,9	628,5	286,4	381,8	477,3	**0**[e]	**0**[e]	**0**[e]
Calcium[b]	2500	1408	183,2	2112	274,8	366,4	458	**212**	**106**	**85**

[a] EFSA-SCF UL value in 4-10 year old children for vitamin D (SCF, 2002) and 4-6 year old children for vitamins B6 and B9 (SCF, 2000)
[b] NO UL set by the SCF for calcium for children; value used: the one proposed by the OM for children aged 1-18 years, identical to that for adults.
[c] Irish nutritional intake data for children aged 5-10 years from the National Children's Food Consumption Survey 2003-2004
[d] Values based on the Irish data, provided to the DG SANCO working party on 07/04/09.
[e] The nutritional intake at the 95th percentile via base diet and food supplements alone exceeds the tolerable upper intake level for the nutrient in question. The calculation gives a negative MSL_f value; we will therefore use a value of zero.

Setting the maximum levels for food supplements (Flynn model 2008, Richardson 2007)

The MSL_s values (expressed as daily intake) are calculated as follows:

$$MSL_s(vit)=UL-MHI*150\%$$
$$MSL_s(min)=UL-[(MHI*110\%)+IW]$$

With **UL**: Tolerable upper intake level
MHI: Nutritional intake at the 97.5th percentile from base diet and fortified foods
IW: Nutritional intake at the 97.5th percentile from water

[5] The option of a 50% increase in $(CI+SI)_{95,}$ and EFF_{95} was already tested in the previous simulations and is not repeated here.

[6] Option 2 explicitly corresponds to the hypothesis whereby the nutritional intakes at the 95th percentile via base diet and food supplements would increase by half at the same time as the energy intake at the 95th percentile via foods fortified with this nutrient were multiplied by 2.

The MSL_s values are calculated separately for adults and children. This is because food supplements are intended specifically for either adults or children.
On the basis of realistic vitamin and mineral intakes from fortified foods in France (15% of total intake) and in line with the changes in the vitamin and mineral levels in foods expected by the Irish authorities, it is proposed to test hypotheses for an increase in nutritional intakes at the 97.5th percentile from base diet and fortified foods from 50 to 300% for vitamins and from 10 to 50 % for minerals.
Accordingly, the following hypotheses were tested:

- For vitamins:
  - Option a: 50% increase in MHI (basic Richardson hypothesis)
  - Option b: 100% increase in MHI
  - Option c: 200% increase in MHI
  - Option d: 300% increase in MHI
- For minerals:
  - Option e: 10% increase in MHI (basic Richardson hypothesis)
  - Option f: 30% increase in MHI
  - Option g: 50% increase in MHI

Table 2: MSL_s calculations (in daily intake) from Irish consumption data.

		UL[a]	MHI[c]	IW:	MHI+ 50% [e]	MHI+ 100%[e]	MHI+ 200%[e]	MHI+ 300%	**MSLs option a**	**MSLs option b**	**MSLs option c**	**MSLs option d**
ADULTS	Vitamin D	50	11.2	-	16.8	22.4	33.6	44.8	**33**	**28**	**16**	**5**
	Vitamin B6	25	5.9	-	8.9	11.8	17.7	23.6	**16**	**13**	**7**	**1.4**
	Vitamin B9	1000	595	-	892.5	1190	1785	2380	**108**	**0**[d]	**0**[d]	**0**[d]
	Calcium	2500	1774	300	1951	2306	2661		**249**	**0**[d]	**0**[d]	**-**
CHILDREN	Vitamin D	25	4.5	-	6.75	9	13.5	18	**18**	**16**	**12**	**7**
	Vitamin B6	7	3.4	-	5.1	6.8	10.2	13.6	**1.9**	**0**	**0**	**0**
	Vitamin B9	300	428	-	642	856	1284	1712	**0**	**0**	**0**	**0**
	Calcium[b]	2500	1532	300	1685	1992	2298		**515**	**0**	**0**	**-**

[a] EFSA-SCF values for adults for vitamins D, B6, B9 and calcium; EFSA-SCF values for children aged 4-10 years for vitamin D (SCF, 2002) and for children aged 4-6 years for vitamins B6 and B9 (SCF, 2000)
[b] NO UL set by the SCF for calcium for children; value used: the one proposed by the OM for children aged 1-18 years, identical to that for adults.
[c] Adult values: men aged 18-64 years – "North/South Ireland Food Consumption Survey, 1997-1999"; children's value : 5-10 years "National Children's Food Consumption Survey, 2003-2004"
[d] The calculation gives a negative value; we will therefore use a value of zero.
[e] Respectively MHI+10%, MHI+30%, MHI+50% for calcium.

Results and interpretation

1) In children

For vitamins, 12 scenarios are possible: they combine the maximum levels calculated for food supplements on the basis of the "children" data according to the 4 options selected (a, b, c and d) selected with those calculated for fortified foods according to the 3 options selected (1, 2 and 3). Nevertheless, due to the obtaining of negative values (counted as 0) in certain scenarios, no scenario was tested for vitamin B9.
Concerning vitamin B6, only 6 scenarios were tested.
For calcium, 9 scenarios result from the combination of the 3 options selected for the MSL_s (a, b, c) and the 3 options selected for the MSL_f (1, 2 and 3). However, due to the obtaining of negative values (counted as 0), only six scenarios were tested.

Table 3: Summary for each nutrient of the maximum levels (for fortified foods and supplements) tested according to the different scenarios in children[7]

		Vitamin D (in µg)	Vitamin B6 (in µg)	Vitamin B9 (in µg)	Calcium (in µg)
Scenario 11-1	MSLf-option 1 MSLs children (a and e)	16 18	0.9 1.9	0 0	212 515
Scenario 11-2	MSLf-option 1 MSLs children (b and f)	16 16	0.9 0	0 0	212 0
Scenario 11-3	MSLf-option 1 MSLs children (c and g)	16 12	0.9 0	0 0	212 0
Scenario 11-4	MSLf-option 1 MSLs children (d)	16 7	0.9 0	0 0	
Scenario 12-1	MSLf-option 2 MSLs children (a and e)	8 18	0.5 1.9	0 0	106 515
Scenario 12-2	MSLf-option 2 MSLs children (b and f)	8 16	0.5 0	0 0	106 0
Scenario 12-3	MSLf-option 2 MSLs children (c and g)	8 12	0.5 0	0 0	106 0
Scenario 12-4	MSLf-option 2 MSLs children (d)	8 7	0.5 0	0 0	
Scenario 13-1	MSLf-option 3 MSLs children (a and e)	6 18	0.4 1.9	0 0	85 515
Scenario 13-2	MSLf-option 3 MSLs children (b and f)	6 16	0.4 0	0 0	85 0
Scenario 13-3	MSLf-option 3 MSLs children (c and g)	6 12	0.4 0	0 0	85 0
Scenario 13-4	MSLf-option 3 MSLs children (d)	6 7	0.4 0	0 0	

The tables below present the results obtained in children for vitamin D, vitamin B6 and calcium, according to the different scenarios tested in the hypothesis whereby the proportion of fortified foods for a consumer represented 25% of foods likely to be fortified.

Table 4: Percentile of nutritional intake beyond which the tolerable upper intake level may be exceeded: summary of the result in children for ***vitamin D***

MSL_f / MSL_s	Option 1:	Option 2:	Option 3:
Option a	P5	P40	P60
Option b:	P5	P40	P60
Option c:	P5	P40	P60
Option d:	P5	P40	P60

[7] The numbering of these scenarios follows on from that of the scenarios tested in the simulations reported in the previous AFSSA opinions (2007-SA-0315 and 2008-SA-0398)

Concerning vitamin D, the MSL_s value selected (options a, b, c or d) does not seem to modify the percentile of nutritional intake beyond which the tolerable upper intake level may be exceeded, irrespective of the MSL_f calculation options used (options 1, 2 and 3). Although the change from option 1 to option 3 leads to a reduction in the proportion of people with a risk of exceeding the tolerable upper intake level (from 95% to 40%), it remains high. Thus, irrespective of the scenarios envisaged, fortification is not desirable at the levels tested.

Table 5: Percentile of nutritional intake beyond which the tolerable upper intake level may be exceeded: summary of the result in children for ***vitamin B6***

MSL_s \ MSL_f	Option 1:	Option 2:	Option 3:
Option a	P90	–	–
Options b=c=d*	P90	–	–

-: no exceeding of the tolerable upper intake level
* the results obtained in options b, c and d are identical

Concerning vitamin B6, irrespective of the MSL_s value selected (option a or b, c, d), MSL_f option does not seem to be sufficiently protective for the consumer. The risk of exceeding the tolerable upper intake level would concern 10% of children.

Concerning vitamin B9, as the MSL_f and MSL_s calculations systematically give negative values (counted as 0), it was not possible to test any of the scenarios since the data show that no fortification can be envisaged.

Table 6: Percentile of nutritional intake beyond which the tolerable upper intake level may be exceeded: summary of the result in children for ***calcium***

MSL_s \ MSL_f	Option 1:	Option 2:	Option 3:
Option e:	P95	–	–
Options f=g	P95	–	–

-: no exceeding of the tolerable upper intake level
* the results obtained in options f and g are identical

Concerning calcium, irrespective of the MSL_s calculation option used (option e or f, g), MSL_f options 2 and 3 seem to be sufficiently protective for the consumer. Concerning option 1, and irrespective of the MSL_s calculation option, 5% of the population of children are at risk of exceeding the tolerable upper intake level, with the result that this option cannot be envisaged.

2) <u>In adults</u>

For vitamins, they combine the maximum levels calculated for food supplements on the basis of the "adult" data according to the 4 options selected (a, b, c and d) with those calculated for fortified foods according to the 3 options selected (1, 2 and 3). Nevertheless, due to the obtaining of negative values (counted as 0) in certain scenarios, no scenario was tested for vitamin B9.

For calcium, 9 scenarios result from the combination of the 3 options selected for the MSL_s (a, b, c) and the 3 options selected for the MSL_f (1, 2 and 3). However, due to the obtaining of negative values (counted as 0), only six scenarios were tested.

Table 7: Summary for each nutrient of the maximum levels (for fortified foods and supplements) tested according to the different scenarios in adults

		Vitamin D (in µg)	Vitamin B6 (in µg)	Vitamin B9 (in µg)	Calcium (in µg)
Scenario 14-1	MSLf-option 1 MSLs adults (a and e)	16 33	0.9 16	0 108	212 249
Scenario 14-2	MSLf-option 1 MSLs adults (b and f)	16 28	0.9 13	0 0	212 0
Scenario 14-3	MSLf-option 1 MSLs adults (c and g)	16 16	0.9 7	0 0	212 0
Scenario 14-4	MSLf-option 1 MSLs adults (d)	16 5	0.9 1.4	0 0	
Scenario 15-1	MSLf-option 2 MSLs adults (a and e)	8 33	0.5 16	0 108	106 249
Scenario 15-2	MSLf-option 2 MSLs adults (b and f)	8 28	0.5 13	0 0	106 0
Scenario 15-3	MSLf-option 2 MSLs adults (c and g)	8 16	0.5 7	0 0	106 0
Scenario 15-4	MSLf-option 2 MSLs adults (d)	8 5	0.5 1.4	0 0	
Scenario 16-1	MSLf-option 3 MSLs adults (a and e)	6 33	0.4 16	0 108	85 249
Scenario 16-2	MSLf-option 3 MSLs adults (b and f)	6 28	0.4 13	0 0	85 0
Scenario 16-3	MSLf-option 3 MSLs adults (c and g)	6 16	0.4 7	0 0	85 0
Scenario 16-4	MSLf-option 3 MSLs adults (d)	6 5	0.4 1.4	0 0	

The tables below present the results obtained in adults for vitamin D, vitamin B6 and calcium, according to the different scenarios tested in the hypothesis whereby the proportion of fortified foods for a consumer represented 25% of foods likely to be fortified.

Table 8: Percentile of nutritional intake beyond which the tolerable upper intake level may be exceeded: summary of the result in adults for ***vitamin D***

MSL_f / MSL_s	Option 1:	Option 2:	Option 3:
Option a	P40	P80	P80
Option b:	P40	P80	P90
Option c:	P40	P80	P90
Option d:	P40	P80	P95

Concerning vitamin D, the different MSL_s options selected do not seem to modify the percentile of nutritional intakes beyond which the tolerable upper intake level can be exceeded in MSL_f options 1 and 2. On the other hand, in the case of MSL_f option 3, a reduction is observed in the percentage of people who might exceed the tolerable upper intake level. Thus, option 3 combined with option d gives the percentage of the population that might exceed the lowest tolerable upper intake level. This risk would concern 5% of the adult population. Thus, irrespective of the MSL_s and MSL_f values selected, fortification with vitamin D is not desirable at the levels tested.

*Table 9: Percentile of nutritional intake beyond which the tolerable upper intake level may be exceeded: summary of the result in adults for **vitamin B6***

MSL_f / MSL_s	Option 1:	Option 2:	Option 3:
Option a	P97.5	–	–
Option b:	–	–	–
Option c:	–	–	–
Option d:	–	–	–

-: no exceeding of the tolerable upper intake level

Concerning vitamin B6, only MSL_f option 1 combined with MSL_s option a does not seem sufficiently protective for the consumer; the risk of exceeding the tolerable upper intake level would concern 2.5% of adults.

Concerning vitamin B9, given the fact that the MSL_f and MSL_s calculations give negative values in several cases, the only scenario tested (no fortification and a daily intake level in supplements of 108 µg) seems protective for adults

*Table 10: Percentile of nutritional intake beyond which the tolerable upper intake level may be exceeded: summary of the result in adults for **calcium***

MSL_f / MSL_s	Option 1:	Option 2:	Option 3:
Option e:	P90	–	–
Options f=g*	P90	–	–

-: no exceeding of the tolerable upper intake level
* the results obtained in options f and g are identical

Concerning calcium, irrespective of the MSL_s calculation option used (option e or f, g), MSL_f options 2 and 3 seem to be sufficiently protective for the consumer. Concerning option 1, and irrespective of the MSL_s calculation option, 10% of the adult population are at risk of exceeding the tolerable upper intake level. This option cannot therefore be envisaged.

Conclusion

This study has enabled the simulation of the impact on nutritional intakes of the intake of the maximum vitamin and mineral levels via fortified foods on the one hand and food supplements on the other hand, calculated on the basis of Flynn's (2008) and Richardson's (2007) models. Safety factors are applied to these models on the following parameters: the nutritional intake at the 95th percentile via base diet and food supplements ($(CI+SI)_{95}$), the energy intake at the 95th percentile via foods fortified with this nutrient (EFF_{95}) as well as the nutritional intake at the 97.5th percentile via base diet and fortified foods (MHI).

The results examined in this opinion complete the conclusions of the previous simulations carried out by AFSSA (Opinions of 13/10/08 and 29/01/09) according to which the maximum levels tested, on the basis of the first options defined, were not sufficiently protective for the consumer.

The new options tested as part of this work were globally more protective than those tested previously. However, using the same scenario, the risks of exceeding the tolerable upper intake level (UL) vary from one nutrient to the other.
Thus,

- concerning vitamin B6 and calcium, the MSL_f calculation options 2 and 3 (irrespective of the MSL_s calculation option) are protective, for both the adult population and children;
- in the case of vitamin D, no scenario was sufficiently protective. Indeed, even in the most protective scenario (option 3-d), there remain 5% of adults and 40% of children at risk of exceeding the tolerable upper intake level;
- concerning vitamin B9, a supplementary intake *via* food supplements alone at 108 µg/day seems to be sufficiently protective for adults. In children, according to the Irish data, the models tested propose maximum levels of zero both for fortified foods and food supplements. Accordingly, no fortification scenario may be envisaged.

In total, the differences in the levels of protection are particularly great between options 1, 2 and 3; these differences are related to the levels of energy intake at the 95th percentile via fortified foods (parameter EFF_{95}). The simulations presented in this opinion have enabled critical parameters to be determined for the calculation of maximum levels for fortified foods and for food supplements in order to ensure the protection of the consumer.

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