

## SCIENTIFIC OPINION

### Statement on further elaboration of the consumption figure of 400 g shellfish meat on the basis of new consumption data<sup>1</sup>

#### EFSA Panel on Contaminants in the Food Chain (CONTAM)<sup>2, 3</sup>

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#### ABSTRACT

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) has prepared a series of opinions since 2007 on various marine biotoxins, including emerging toxins, to assess the current European Union (EU) limits with regard to human health and methods of analysis as established in the EU legislation. In order to protect high consumers against acute effects of marine biotoxins, the CONTAM Panel identified 400 g of shellfish meat as an appropriate estimate of a large portion size consumed in Europe to be used in the risk assessments. This portion size was then applied to all the scientific opinions on marine biotoxins. Recently EFSA has received new data from Belgium, France, Portugal and Spain on the shellfish portion sizes consumed. In addition, new consumption data have been submitted to EFSA for inclusion in the Comprehensive European food consumption database (Comprehensive Database). Based on the assessment of the new data provided to EFSA and the information included in the EFSA Comprehensive Database, the CONTAM Panel concluded that the earlier established estimate of the consumption figure of 400 g shellfish meat is appropriate for protecting high consumers against acute effects of marine biotoxins.

#### KEY WORDS

Marine biotoxins, shellfish, consumption, large portion size, human health, risk assessment

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## **SUMMARY**

In July 2006 the European Commission (EC) requested the European Food Safety Authority (EFSA) to provide a scientific opinion to assess the current European Union (EU) limits with regard to human health and methods of analysis for various marine biotoxins as established in the EU legislation, including new emerging toxins.

In response, EFSA's Panel on Contaminants in the Food Chain (CONTAM Panel) has developed and adopted a series of scientific opinions related to marine biotoxins: okadaic acid (OA) and analogues, azaspiracid (AZA)-group toxins, yessotoxin (YTX)-group toxins, saxitoxin (STX)-group toxins, pectenotoxin (PTX)-group toxins, domoic acid (DA), palytoxin (PITX)-group toxins, ciguatoxin (CTX)-group toxins, cyclic imines (CIs) and brevetoxin (BTX)-group toxins. In addition, a statement on the influence of processing on the levels of lipophilic marine biotoxins in bivalve molluscs and a summary opinion on the currently regulated marine biotoxins have been issued.

At the time of writing of the first opinion, consumption data on shellfish types across the EU were limited and therefore EFSA requested member states (MSs) to provide information on consumption of relevant shellfish types. Based on the data provided by five MSs, the CONTAM Panel identified 400 g of shellfish meat as an appropriate estimate of a large portion size consumed in Europe to be used in its risk assessments in order to protect high consumers against acute effects of marine biotoxins. This portion size was then applied to all other scientific opinions on marine biotoxins. Recently EC has received new data from Belgium, France, Portugal and Spain on the shellfish portion sizes consumed and therefore asked EFSA to assess the new consumption data submitted by the MSs on shellfish portion size in order to evaluate whether the CONTAM Panel's established estimate of the consumption figure of 400 g shellfish meat is appropriate for protecting high consumers against acute effects of marine biotoxins. The CONTAM Panel considered these new data and also the data present now in the EFSA Comprehensive European food consumption database (Comprehensive Database).

Based on the information present in the EFSA Comprehensive Database, the CONTAM Panel estimated that the proportions of consuming days exceeding 100 g shellfish were 0.5-3 % (Spain), 9 % (Ireland), 13 % (Italy), 14 % (Finland), 18 % (Germany), 19 % (UK), 24 % (France) and 48 % (Belgium), while the proportions of consuming days exceeding 200 g shellfish were 2 % (Italy), 2.5 % (France), 4 % (Ireland), 7 % (UK), 11 % (Belgium) and 15 % (Germany).

The CONTAM Panel considered the 95<sup>th</sup> percentile as a realistic estimate of the large portion size to protect high consumers against acute effects of marine biotoxins in shellfish. Revised consumption data for "consumers only" submitted by France indicate a 95<sup>th</sup> percentile of consumption of bivalve molluscs of 300 g. This value supports the earlier established estimate of a large portion size of 400 g shellfish meat. Evaluation of the EFSA Comprehensive European food consumption database (Comprehensive Database) shows a highest 95<sup>th</sup> percentile portion size for shellfish meat of 251 g with an upper confidence limit of 500 g. Also these data do not warrant a revision of the earlier established estimate of a large portion size. Therefore the CONTAM Panel concluded that the earlier estimate of a large portion size of 400 g shellfish meat is appropriate for protecting high consumers against acute effects of marine biotoxins.

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## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>4</sup> establishes maximum levels for marine biotoxins in live bivalve molluscs.

Commission Regulation (EC) No 2074/2005<sup>5</sup> of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004<sup>6</sup> of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004<sup>7</sup> of the European Parliament and of the Council and Regulation (EC) No 882/2004<sup>8</sup> of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004<sup>9</sup> of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 establishes the recognised testing methods for detecting marine biotoxins.

In July 2006 the Commission requested EFSA to provide a scientific opinion to assess the current European Union (EU) limits with regard to human health and methods of analysis for various marine biotoxins as established in the EU legislation, including new emerging toxins.

In response, EFSA's Panel on Contaminants in the Food Chain (CONTAM Panel) has adopted a series of scientific opinions related to marine biotoxins: okadaic acid (OA) and analogues, azaspiracid (AZA)-group toxins, yessotoxin (YTX)-group toxins, saxitoxin (STX)-group toxins, pectenotoxin (PTX)-group toxins, domoic acid (DA) and palytoxin (PITX)-group toxins. In addition a statement on the influence of processing on the levels of lipophilic marine biotoxins in bivalve molluscs and a summary opinion on the currently regulated toxins have been issued.

For its first scientific opinion on okadaic acid and analogues, the CONTAM Panel identified 400 g of shellfish meat as an appropriate estimate of a large portion size consumed in Europe in order to protect human health against acute effects of marine biotoxins. This portion size was then applied to all other scientific opinions on marine biotoxins.

Recently the European Commission has received new data from certain Member States on the shellfish portion sizes consumed and forwarded these data to EFSA.

## TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Art. 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks EFSA to assess the new consumption data submitted by Member States on shellfish portion size in order to evaluate if the CONTAM Panel's established estimate on the consumption figure of 400 g shellfish meat is the appropriate estimate for protecting human health against acute effects of marine biotoxins. EFSA is asked to revise, if appropriate, its previous scientific opinions related to marine biotoxins.

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<sup>4</sup> OJ L 226, 25.6.2004, p. 22-82.

<sup>5</sup> OJ L 338, 22.12.2005, p. 27-59.

<sup>6</sup> OJ L 139, 30.4.2004, p. 55-205.

<sup>7</sup> OJ L 139, 30.4.2004, p. 206-320.

<sup>8</sup> OJ L 165, 30.4.2004, p. 1-141.

<sup>9</sup> OJ L 139, 30.4.2004, p. 1-54.

## EVALUATION

### 1. Introduction

In July 2006 the European Commission (EC) requested the European Food Safety Authority (EFSA) to provide a scientific opinion to assess the current European Union (EU) limits with regard to human health and methods of analysis for various marine biotoxins as established in the EU legislation, including new emerging toxins.

In response, EFSA's Panel on Contaminants in the Food Chain (CONTAM Panel) has developed and adopted a series of scientific opinions related to marine biotoxins: okadaic acid (OA) and analogues (EFSA, 2008a), azaspiracid (AZA)-group toxins (EFSA, 2008b), yessotoxin (YTX)-group toxins (EFSA, 2008c), saxitoxin (STX)-group toxins (EFSA, 2009a), pectenotoxin (PTX)-group toxins (EFSA, 2009b), domoic acid (DA) (EFSA, 2009c), palytoxin (PITX)-group toxins (EFSA, 2009d), ciguatoxin (CTX)-group toxins (EFSA, 2010a), cyclic imines (CIs) (EFSA, 2010b) and brevetoxin (BTX)-group toxins (EFSA, 2010c). In addition, a statement on the influence of processing on the levels of lipophilic marine biotoxins in bivalve molluscs (EFSA, 2009e) and a summary opinion on the currently regulated marine biotoxins (EFSA, 2009f) have been issued.

At the time of writing of the first opinion (EFSA, 2008a), consumption data on shellfish types across the EU were limited and therefore EFSA requested member states (MSs) to provide information on consumption of relevant shellfish types. Based on the data provided by five MSs, the CONTAM Panel identified 400 g of shellfish meat as an appropriate estimate of a large portion size consumed in Europe to be used in its risk assessments in order to protect high consumers against acute effects of marine biotoxins. This portion size was then applied to all other scientific opinions on marine biotoxins. Recently EC has received new data from Belgium, France, Portugal and Spain on the portion sizes of consumed shellfish and therefore asked EFSA to assess the new consumption data submitted by the four MSs in order to evaluate if the CONTAM Panel's established estimate of the consumption figure of 400 g shellfish meat is appropriate for protecting human health against acute effects of marine biotoxins.

To enable detailed exposure assessment, EFSA has now developed a Comprehensive European food consumption database (Comprehensive Database) which replaces the previous EFSA Concise European food consumption database (Concise Database).<sup>10</sup> The EFSA Comprehensive Database comprises food consumption data from 20 different MSs resulting from their most recent national dietary surveys on the adult population. The EFSA Comprehensive Database includes individual consumption figures at the eating occasion level. As of July 2010 this database has not yet been officially released and critical evaluation of the data is still ongoing. Nevertheless, preliminary statistics on consumption of single shellfish types are presented in this statement.

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<sup>10</sup> The EFSA Concise European food consumption database (Concise Database), with data on average daily consumption of foods per person sourced in the adult population of 17 different member states, Iceland and Norway, has been fully operational since February 2008. It is the first European database with dietary information from the majority of European Union member states.

## 2. Human consumption of shellfish

### 2.1. Consumption data submitted by member states to EFSA in 2007 and used in the adopted scientific opinions in 2007-2010

In all the adopted scientific opinions, the CONTAM Panel noted that limited consumption data were available for individual shellfish types across the EU and that the EFSA Concise European food consumption database<sup>10</sup> did not provide sufficient information because there was no differentiation between meal sizes for fish and other seafood. Therefore, EFSA requested the MSs to provide information on shellfish consumption. Data were submitted by France, Germany, Italy, the Netherlands and the United Kingdom (UK) in 2007. A compilation of the data received is presented in Table 1.

The German national food consumption survey performed by a weighing protocol in the late 1980s indicated a mean portion size of 107 g and a 95<sup>th</sup> percentile of 400 g for mussel consumers. The maximum portion size reported in this study was 1500 g. The French CALIPSO study differentiated between mussels and bivalve molluscs. The maximum portions for mussels and bivalve molluscs were 245 g and 415 g, respectively. The mean portion sizes were 22 g and 32 g, and the 95<sup>th</sup> percentile 70 g and 94 g for mussels and bivalve molluscs, respectively. A survey reported by the UK indicated a mean shellfish portion size of 114 g and a maximum of 239 g. The Italian study reported a mean portion size of 83 g and a maximum of 1000 g. A Dutch study reported a mean portion size of 136 g of shellfish, a 95<sup>th</sup> percentile of 465 g and a maximum of 480 g. All these data reflect the target population, because they concern consumers only. It should be noted that the surveys show a large variation in the percentage of the populations consuming shellfish and it is unclear whether the data are related to cooked or uncooked shellfish.

Because marine biotoxins have acute toxic effects, it is important to use a large portion size rather than long term average consumption in dietary exposure calculations, to ensure protection of the health of consumers of shellfish against acute effects. In the studies presented in Table 1, the maximum reported sizes are in the range of 239 to 1500 g. The CONTAM Panel noted the reported largest portion sizes of 1000 g and 1500 g, and considered it likely that the shells were included in these weight estimates. Therefore, the CONTAM Panel considered the 95<sup>th</sup> percentile as a more realistic estimate of the portion size for high consumers. As shown in Table 1 the 95<sup>th</sup> percentile values range from 70 g to 465 g. The CONTAM Panel chose the figure of 400 g, which is at the higher end of the range but below the highest reported value, as a reasonable large portion size to be used in the risk assessment, in order to protect high consumers against acute effects of marine biotoxins. This figure was in good agreement with the report of the Joint FAO/IOC/WHO ad hoc expert consultation on marine biotoxins (FAO/IOC/WHO, 2004), where 380 g was reported as the 97.5<sup>th</sup> percentile largest portion size for consumers only.

**Table 1:** Shellfish eating habits in France, Italy, the Netherlands, the UK and Germany, based on national food consumption surveys submitted to EFSA in 2007.

Country	Study	Number of consumers n (%)	Number of eating occasions for consumers/year	Mean portion weight (g)	P95 (g)	Maximum portion weight (g)	Maximum frequency
France (7 days)	INCA 1999	218/1985 (11 %)	N/A	10			N/A
France (FFQ)	CALIPSO 2004 (bivalve molluscs)	962/997 (96 %)	N/A	32	94	415	N/A
France (FFQ)	CALIPSO 2004 (mussels)	862/997 (86 %)	N/A	22	70	245	N/A
Italy (7 days)	INN-CA 1994-96	212/1981 (11 %)	47	83		1000	4/week
Germany (7 days)	NVS 1985-88	150/23239 (0.6 %)	171	107	400	1500	3/week
UK (7 days)	NDNS 2000-01	212/1631 (13 %)	51	114		239	4/week
The Netherlands (2 days)	DNFCS 1997-98	47/4285 (1.1 %)	39	136	465	480	N/A

FFQ: food frequency questionnaire; 7 days: 7 day dietary record; 2 days: 2 day dietary record; N/A: not available; n: number of consumers; P95: 95<sup>th</sup> percentile.

INCA: Enquête Individuelle et Nationale sur les Consommations Alimentaires (Volatier, 2000).

CALIPSO: Fish and seafood consumption study and biomarker of exposure to trace elements, pollutants and omega 3 (Leblanc et al., 2006).

INN-CA: Nationwide Nutritional Survey of Food Behaviour (Turrini et al., 2001).

NVS: Nationale Verzehrstudie (Adolf et al., 1995).

NDNS: National Diet and Nutrition Survey (Henderson et al., 2002).

DNFCS: Dutch National Food Consumption Survey (Kistemaker et al., 1998).

## 2.2. Consumption data submitted by Belgium, France, Portugal and Spain to EC/EFSA in 2009

Recently Belgium, France, Portugal and Spain (Galicia) submitted new data on the consumption of shellfish to the EC which were forwarded to EFSA. The quality of these data was evaluated in order to decide if they were suitable to assess whether the CONTAM Panel's established estimate on the consumption figure of 400 g shellfish meat is appropriate. It was noted that the Belgian data are included in the EFSA Comprehensive Database (Table 2). The data provided by Spain were not considered suitable because they were based on average weekly consumption and not on daily consumption, and were for the general Spanish population and not for consumers only. The data from Portugal were also not suitable because they were based on the total production volume of shellfish divided by the size of the population of Portugal. The data provided by France were from the CALIPSO study (Leblanc et al., 2006) and the INCA2 study (AFSSA, 2009a). The consumption data reported in the CALIPSO study (Leblanc et al., 2006) concerned consumers only and were collected by food frequency questionnaires (FFQ) in selected areas in France between October 2004 and December 2004. They had already been included in the previous scientific opinions on marine biotoxins. However, in the latest data submission to EC/EFSA the consumption data from the CALIPSO study (Leblanc et al., 2006) were recalculated by AFSSA (AFSSA, 2009b). The recalculated consumption portion sizes provided by AFSSA show that the 95<sup>th</sup> percentile for the portion size of bivalve molluscs is 300 g (the maximum being 1000 g). This 95<sup>th</sup> percentile is

approximately 3 times higher than the one included in Table 1. For mussels the 95<sup>th</sup> percentile was 80 g (AFSSA, 2009b). The maximum frequency for consuming these portions varied from 3 to 4 times per week for mussels and from 1 to 7 times per week for bivalve molluscs (AFSSA, 2009b). Consequently, the previously reported 95<sup>th</sup> percentiles as included in Table 1 now change into: 80 g (France, mussels), 300 g (France, bivalve molluscs), 400 g (Germany), and 465 g (The Netherlands). The consumption data of the INCA2 study (AFSSA, 2009a) are included in the EFSA Comprehensive Database (Table 2).

### **2.3. Consumption data in EFSA Comprehensive Database**

Twenty MSs have submitted food consumption data to the EFSA Comprehensive Database based on consumption surveys in the general population. These data are considered the most representative for the consumption of shellfish by the general population in Europe. The EFSA Comprehensive Database includes individual consumption figures at the eating occasion level. The database also includes information on consumption of shellfish and/or individual types of shellfish. Hence these consumption data, which include the before mentioned French (INCA 2 study) and Belgian consumption data, were used to assess whether the CONTAM Panel's established estimate of the consumption figure of 400 g shellfish meat is an appropriate figure for the assessment of acute risks following consumption of shellfish.

Information on the time period for collecting the data now included in the EFSA Comprehensive database is presented in Table 2. The consumption data from most of the MSs were collected after 2000. Only the data from Estonia, Ireland, Spain and Sweden were collected earlier than this.



**Table 2:** Dietary surveys included in the EFSA Comprehensive Database.

Member state	Name of the dietary survey	Reference for publication
Austria	Austrian Study on Nutritional Status, ASNS	Elmadfa et al. (2008)
Belgium	Diet National 2004	De Vriese et al. (2005)
Bulgaria	National Survey of Food Intake and Nutritional Status	Petrova and Angelova (2006)
Bulgaria II	NUTRICHILD	Petrova et al. (2009)
Czech Republic	Individual Food Consumption – the National Survey, SISPO4	Ruprich et al. (2006)
Denmark	Danish National Survey of Dietary Habits and Physical Activity	Lyhne et al. (2005)
Estonia	National Diet Survey 1997	Pomerleau et al. (1999)
Finland	National Findiet Study, FINDIET 2007	Paturi et al. (2008)
France	Enquête Individuelle et Nationale sur les Consommations Alimentaires, INCA2	AFSSA (2009a); Lioret et al. (2010); Dubuisson et al. (2010)
Germany	German National Nutrition Survey II, NVS II	MRI (2008); Krems et al. (2006)
Hungary	National Representative Survey	Rodler et al. (2005)
Ireland	North/South Ireland Food Consumption Survey, NSIFCS	Kiely et al. (2001); Harrington et al. (2001)
Italy	Italian National Food Consumption Survey, INRAN-SCAI 2005-06	Leclercq et al. (2009)
Latvia	EFSA_TEST	Šantare et al. (2008)
The Netherlands	Voedselconsumptiepeiling onder jongvolwassenen, VCP 2003	Ocké et al. (2005)
Poland	Food and Nutrition Institute-Food and Agriculture Organization of the United Nations, IZZ-FAO 2000	Sekula et al. (2004) Szponar et al. (2001, 2003)
Slovakia	Slovakia MON 2008	Not available
Slovenia	Targeted research project, CRP 2008	Gabrijelčič Blenkuš et al. (2009)
Spain I	Spanish Food Safety and Nutrition Authority- Spanish Food and Drink Industry Federation, AESAN-Fiab	Requejo et al. (2002)
Spain II	Spanish Food Safety and Nutrition Authority, AESAN	Ortega et al. (2010)
Sweden	National Food Survey, RIKSMATEN 1997-98	Becker and Pearson (2002)
United Kingdom	National Diet and Nutrition Survey, NDNS	Henderson et al. (2002)

The design characteristics of the consumption surveys carried out by the different MSs are presented in Table 3. Four different types of survey methodology can be identified: 7 day food records (carried out in 5 surveys), 3 day food records (3 surveys), one-day 24 hour recalls (6 surveys) and two-day 24 hour dietary recalls (7 surveys). Only Finland, with a 48 hour dietary recall method, does not fit into any of these types of surveys.

**Table 3:** Methods used in the dietary surveys.

Country	Method	Number of replicates	Survey period	Age range (years)
Austria	24 hour dietary recall	1	May 2005 - February 2006	19 - 64
Belgium	24 hour dietary recall	2	February 2004 - February 2005	14 - 105
Bulgaria	24 hour dietary recall	1	March 2004 - August 2004	16 - 95
Bulgaria II	24 hour dietary recall	2	April 2007 - August 2007	0.1 - 5
Czech Republic	24 hour dietary recall	2	November 2003 - November 2004	16 - 64
Denmark	Food record	7	June 2000 - December 2002	4 - 75
Estonia	24 hour dietary recall	1	March 1997 - September 1997	19 - 65
Finland	48 hour dietary recall	1	January 2007 - March 2007	25 - 74
France	Food record	7	December 2005 - April 2007	3 - 79
Germany	24 hour dietary recall	2	November 2005 - January 2007	14 - 80
Hungary	Food record	3	October 2003 - December 2003	18 - 96
Ireland	Food record	7	October 1997 - October 1999	20 - 65
Italy	Food record	3	October 2005 - December 2006	0.1 - 98
Latvia	24 hour dietary recall	2	June 2008 - November 2008	7 - 66
The Netherlands	24 hour dietary recall	2	October 2003 - December 2003	19 - 30
Poland	24 hour dietary recall	1	September 2000 - November 2000	1 - 96
Slovakia	24 hour dietary recall	1	January 2008 - December 2008	17 - 68
Slovenia	24 hour dietary recall	1	September 2007 - April 2008	18 - 65
Spain I	Food record	3	January 1999 - November 2001	17 - 60
Spain II	24 hour dietary recall	2	January 2009 - September 2009	18 - 60
Sweden	Food record	7	January 1997 - January 1998	17 - 79
United Kingdom	Food record	7	July 2000 - June 2001	19 - 64

Data on consumption of shellfish were included in 14 out of the 22 studies included in the EFSA Comprehensive Database. Table 4 shows the percentage of consumers of different shellfish types for each of these countries. There is a large variation in the percentage of consumers amongst the different MSs. Only in France and Spain does the percentage of consumers of total shellfish exceed 10 % of the population. For Italy the percentage of consumers is 9.4 %, and for all other countries the figure is less than 2.8 %. The column “Total shellfish” in Table 4 refers to consumers of at least one type of shellfish among clams, cockles, mussels, oysters and scallops.<sup>11</sup> Comparing the figures for total shellfish with those for the single shellfish types reveals that in some cases the same consumer reported consumption of more than one type of shellfish. It is also important to note that consumers who consumed shellfish within recipes, even in small quantities, are included among the shellfish consumers. This is because MSs were asked, as much as possible, to disaggregate industrially produced composite foods or home-made dishes, such as a ready-made frozen pizza or a home cooked beef stew, into their main ingredients at a level that can be reported by the consumers e.g. in the case of a sandwich with ham and butter it was requested to distinguish between the three components such as bread, ham and butter.

<sup>11</sup> The term “shellfish” is used to group a broad variety of molluscs, crustaceans and echinoderms. However, the scope of the present statement is limited to bivalve molluscs and therefore in this statement “total shellfish” comprises only clams, cockles, mussels, oysters and scallops.

The total consumption for each shellfish type and for total shellfish was calculated per individual and day taking into consideration only the consuming days. The number of consuming days per country and shellfish types (clams, cockles, mussels, oysters and scallops) together with a reliable estimate of the 95<sup>th</sup> percentile consumption is presented in Table 5. For each country, an estimate of the 95<sup>th</sup> percentile consumption of total shellfish is also reported, comprising the data reported also separately for the different shellfish types (Table 5). The number of shellfish consuming days among all days reported by all the subjects in the survey ranged from 1 day (in Bulgaria) to 635 days (in France) but the highest percentage of consuming days out of the total number of reporting/recall days was calculated for Spain (AESAN-Fiab dietary survey) where total shellfish was consumed at 18.8 % of the record days (Table 5).

Based on the information present in the EFSA Comprehensive Database it was possible to estimate the number of days for which a certain consumption of total shellfish would be exceeded. The proportions of consuming days exceeding 100 g were 0.5 % (Spain I), 3 % (Spain II), 9 % (Ireland), 13 % (Italy), 14 % (Finland), 18 % (Germany), 19 % (UK), 24 % (France) and 48 % (Belgium) while the proportions of consuming days exceeding 200 g were 2 % (Italy), 2.5 % (France), 4 % (Ireland), 7 % (UK), 11 % (Belgium) and 15 % (Germany).

A non-parametric method is used to calculate confidence intervals for the 95<sup>th</sup> percentile (Conover, 1971). This method does not assume any given distribution for the data, e.g. (log-) normal distribution. For the calculations of the results presented in Table 5 this method was implemented in the SAS software.<sup>12</sup> The significance level ( $\alpha$ ) is set at 0.05 to determine a 95 % confidence interval. The coverage probability of each non-parametric 95 % confidence interval is also calculated as described in the SAS manual.<sup>12</sup> In statistics, the coverage probability of a confidence interval is the probability that the interval contains the true value of interest (here 95<sup>th</sup> percentile) as presented in Table 5. For a statistical value, like the mean or a percentile of a set of data, the confidence interval aims to contain the “true” value with a given probability. This probability is a nominal value used by the procedure for constructing the confidence intervals and is often set at 95 %. The coverage probability is evaluated after calculating the confidence interval and represents the actual probability that the calculated interval contains the true value. When the number of observations is not large enough, the coverage probability does not attain the nominal value, e.g. 95 %. This is more likely to occur at high percentiles, e.g. 95<sup>th</sup> or 99<sup>th</sup>. Therefore, in this assessment the coverage probability is used to evaluate the uncertainty of the calculated 95<sup>th</sup> percentiles of the portion sizes. The CONTAM Panel decided that in this statement the coverage probability should be at least 95 %.

As presented in Table 5 the calculated 95<sup>th</sup> percentile consumption figures presenting a coverage probability not lower than 95 % were 63 g for mussels and 75 g for total shellfish for Spain, 162 g for total shellfish for Italy, 200 g for scallops in France and 251 g for total shellfish for Belgium. The CONTAM Panel noted that the upper confidence limit of the highest 95<sup>th</sup> percentile of consumption (251 g) is 500 g. Also the data from Germany for total shellfish indicated a high 95<sup>th</sup> percentile of consumption of 338 g, with an upper confidence limit of 525 g (Table 5). The CONTAM Panel noted however, that the coverage probability for this figure was lower than 95 %, and therefore these data were not further used in the assessment.

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<sup>12</sup> For details of the methods used to calculate the 95<sup>th</sup> percentile values, the 95 % confidence intervals and their coverage probability see Base SAS(R) 9.2 Procedures Guide: Statistical Procedures, Third Edition. [http://support.sas.com/documentation/cdl/en/procstat/63104/HTML/default/viewer.htm#/documentation/cdl/en/procstat/63104/HTML/default/procstat\\_univariate\\_sect028.htm](http://support.sas.com/documentation/cdl/en/procstat/63104/HTML/default/viewer.htm#/documentation/cdl/en/procstat/63104/HTML/default/procstat_univariate_sect028.htm).

**Table 4:** Number of consumers by shellfish type and by country.

Country	Number of subjects	Number and percentage consumers of											
		Clams		Cockles		Mussels		Oysters		Scallops		Total shellfish <sup>(a)</sup>	
		n	%	n	%	n	%	n	%	n	%	n	%
Austria	2123		0.0		0.0	2	0.1		0.0		0.0	2	0.1
Belgium	3245		0.0		0.0	73	2.2	9	0.3	12	0.4	91	2.8
Bulgaria	1204		0.0		0.0	3	0.2		0.0		0.0	3	0.2
Germany	13926		0.0		0.0	27	0.2	4	0.0	9	0.1	40	0.3
Estonia	1866		0.0		0.0		0.0	1	0.1		0.0	1	0.1
Spain I	1068	197	18.4	15	1.4	315	29.5		0.0	2	0.2	358	33.5
Spain II	418	22	5.3	2	0.5	46	11.0		0.0	1	0.2	55	13.2
Finland	2038		0.0		0.0	12	0.6		0.0		0.0	12	0.6
France	4079	5	0.1		0.0	232	5.7	137	3.4	176	4.3	492	12.1
United Kingdom	1724	1	0.1	4	0.2	27	1.6	2	0.1	16	0.9	45	2.6
Ireland	958	1	0.1		0.0	15	1.6		0.0	7	0.7	17	1.8
Italy	3323	189	5.7		0.0	147	4.4	1	0.0	2	0.1	312	9.4
The Netherlands	750		0.0		0.0	9	1.2		0.0		0.0	9	1.2
Sweden	1210		0.0		0.0	4	0.3		0.0		0.0	4	0.3

n: number of consumers;

(a): Total shellfish comprises clams, cockles, mussels, oysters and scallops.<sup>11</sup>

**Table 5:** 95<sup>th</sup> percentile of consumption reported by shellfish type and by country.

Country	Shellfish types	Consuming days		95 <sup>th</sup> percentile of consumption among consuming days only			
		Number	%	Estimate (g/day)	Lower confidence limit (g/day)	Upper confidence limit (g/day)	Coverage probability (%)
Austria	Mussels	2 <sup>(a)</sup>	0.1	38			
	Total shellfish <sup>(b)</sup>	2 <sup>(a)</sup>	0.1	38			
Belgium	Mussels	73	1.2	250	180	500	97
	Oysters	9 <sup>(a)</sup>	0.1	252			
	Scallops	12	0.2	160	70	160	44
	Total shellfish <sup>(b)</sup>	94	1.5	251	201	500	97
Bulgaria	Mussels	3	0.2	200			
	Total shellfish <sup>(b)</sup>	3	0.2	200			
Germany	Mussels	27	0.1	375	300	525	60
	Oysters	4 <sup>(a)</sup>	0.0	60			
	Scallops	9 <sup>(a)</sup>	0.0	98			
	Total shellfish <sup>(b)</sup>	40	0.1	338	250	525	82
Estonia	Oysters	1 <sup>(a)</sup>	0.1	30			
	Total shellfish <sup>(b)</sup>	1 <sup>(a)</sup>	0.1	30			
Spain I	Clams	209	7.0	50	23	63	96
	Cockles	15	0.5	20	15	20	50
	Mussels	333	11.2	63	44	70	95
	Scallops	2 <sup>(a)</sup>	0.1	63			
	Total shellfish <sup>(b)</sup>	559	18.8	53	44	63	96
Spain II	Clams	22	2.7	20	16	50	58
	Cockles	2 <sup>(a)</sup>	0.2	2			
	Mussels	49	5.9	85	70	100	82
	Scallops	1 <sup>(a)</sup>	0.1	40			
	Total shellfish <sup>(b)</sup>	74	8.9	75	50	100	97
Finland	Mussels	14	0.3	160	44	160	48
	Total shellfish <sup>(b)</sup>	14	0.3	160	44	160	48

Table 5: Continued.

Country	Shellfish type	Consuming days		95 <sup>th</sup> percentile of consumption among consuming days only			
		Number	%	Estimate (g/day)	Lower confidence limit (g/day)	Upper confidence limit (g/day)	Coverage probability (%)
France	Clams	5 <sup>(a)</sup>	0.0	7			
	Mussels	256	0.9	100	80	140	95
	Oysters	184	0.7	135	117	216	95
	Scallops	190	0.7	200	180	270	96
	Total shellfish <sup>(b)</sup>	635	2.3	160	150	180	95
United Kingdom	Clams	1 <sup>(a)</sup>	0.0	63			
	Cockles	7 <sup>(a)</sup>	0.1	214			
	Mussels	27	0.2	200	198	239	60
	Oysters	2 <sup>(a)</sup>	0.0	284			
	Scallops	17	0.1	50 <sup>(c)</sup>	45	50 <sup>(c)</sup>	53
	Total shellfish <sup>(b)</sup>	54	0.4	214	163	284	92
Ireland	Clams	1 <sup>(a)</sup>	0.0	75			
	Mussels	15	0.2	89	75	89	50
	Scallops	7 <sup>(a)</sup>	0.1	251			
	Total shellfish <sup>(b)</sup>	23	0.3	149	89	251	59
Italy	Clams	192	1.9	149	129	162	96
	Mussels	152	1.5	162	121	202	96
	Oysters	1 <sup>(a)</sup>	0.0	65			
	Scallops	2 <sup>(a)</sup>	0.0	30			
	Total shellfish <sup>(b)</sup>	347	3.5	162 <sup>(c)</sup>	129	162 <sup>(c)</sup>	95
The Netherlands	Mussels	9 <sup>(a)</sup>	0.6	91			
	Total shellfish <sup>(b)</sup>	9 <sup>(a)</sup>	0.6	91			
Sweden	Mussels	4 <sup>(a)</sup>	0.0	60			
	Total shellfish <sup>(b)</sup>	4 <sup>(a)</sup>	0.0	60			

(a): The confidence interval and the coverage probability were not calculated when the number of consuming days was below 10; (b): Total shellfish comprises clams, cockles, mussels, oysters and scallops;<sup>11</sup> (c): It is possible that different days present the same quantity of consumption, because when the consumed amounts were reported by the subjects the standard portion sizes were used. This is the reason why the estimate for the 95<sup>th</sup> percentile of consumption can be equal to its upper confidence limit.

### **3. Appropriateness of the consumption figure of 400 g**

The new shellfish consumption data submitted by Spain and Portugal were not suitable to assess the CONTAM Panel's earlier established estimate of the consumption figure of 400 g shellfish meat. The recalculated consumption data submitted to EC/EFSA by France indicate a 95<sup>th</sup> percentile of consumption of mussels of 80 g and of bivalve molluscs of 300 g. Consequently, the previously reported 95<sup>th</sup> percentiles as included in Table 1 now change into: 80 g (France, mussels), 300 g (France, bivalve molluscs), 400 g (Germany), and 465 g (The Netherlands). These figures support the CONTAM Panel's earlier established estimate of a large portion size of 400 g of shellfish meat.

The data on the consumption of shellfish that are included in the EFSA Comprehensive Database show 95<sup>th</sup> percentile for portions sizes ranging from 63-251 g. The upper confidence limit of the highest 95<sup>th</sup> percentile with at least 95 % coverage probability (251 g for total shellfish in Belgium) is 500 g/day. The value of 500 g can be considered as a rather conservative estimate of high consumer shellfish consumption in Europe. Hence the consumption data included in the EFSA Comprehensive Database also do not warrant a revision of the CONTAM Panel's earlier established estimate on the consumption figure of 400 g shellfish meat.

Overall the CONTAM Panel concluded that the earlier estimate of a large portion size of 400 g shellfish meat is appropriate for protecting high consumers against acute effects of marine biotoxins.

### **4. Uncertainty**

The earlier identification of 400 g of shellfish meat as a large portion size to be used in the acute risk assessment of marine biotoxins by the CONTAM Panel was based on consumption data provided by five member states. This limited information of shellfish consumption in Europe as well as the limited representative data on shellfish types other than mussels introduced considerable uncertainty. Additional consumption data recently provided by Spain and Portugal were not suitable for assessment of the large portion size. Additional data (CALIPSO study) provided by France narrowed the uncertainty of the 95<sup>th</sup> percentile and therefore decreased the uncertainty in the earlier estimated consumption figure of 400 g.

Additional data provided by Belgium and France (INCA2) were included in the EFSA Comprehensive Database. The evaluation of the data on shellfish consumption submitted by 14 member states to the EFSA Comprehensive Database indicates that these are also mainly based on limited consumption data as well as different methodologies. The confidence intervals show wide ranges of the 95<sup>th</sup> percentiles which are indicative of appreciable uncertainty. If the highest upper confidence limits of the 95<sup>th</sup> percentile of the portion size with at least 95 % coverage probability for each member state are taken as a conservative estimate, then the 400 g portion size is either an overestimation or underestimation depending on the member state. Only in Belgium and Germany does the upper 95 % confidence interval exceed 400 g, and by only approximately 20 %.

## **CONCLUSIONS**

- Because marine biotoxins have acute toxic effects, the Panel on Contaminants in the food chain (CONTAM Panel) considered it is important to use a large portion size rather than a long term average consumption in dietary exposure calculations, to ensure protection of the health also of high consumers.
- The CONTAM Panel estimated that the proportions of consuming days exceeding 100 g shellfish were 0.5-3 % (Spain), 9 % (Ireland), 13 % (Italy), 14 % (Finland), 18 % (Germany), 19 % (UK), 24 % (France) and 48 % (Belgium), and the proportions of consuming days

exceeding 200 g shellfish were 2 % (Italy), 2.5 % (France), 4 % (Ireland), 7 % (UK), 11 % (Belgium) and 15 % (Germany).

- The CONTAM Panel considered the 95<sup>th</sup> percentile as a realistic estimate of the large portion size for high consumers.
- Based on the assessment of the new data provided to EFSA and the information included in the EFSA Comprehensive Database, the CONTAM Panel concluded that the earlier established estimate of the consumption figure of 400 g shellfish meat is appropriate for protecting high consumers against acute effects of marine biotoxins.

## DOCUMENTATION PROVIDED TO EFSA

AFSSA (Agence française de sécurité sanitaire des aliments), 2009b. Portion sizes and daily amounts of bivalve molluscs consumed in the CALIPSO study. 2<sup>nd</sup> October 2009.

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## ABBREVIATIONS

AESAN	Spanish Food and Drink Industry Federation
AESAN-Fiab	Spanish Food and Drink Industry Federation – Spanish dietary survey
AFSSA	Agence française de sécurité sanitaire des aliments
ASNS	Austrian Study on Nutritional Status
AZA	Azaspiracid
BTX	Brevetoxin
CALIPSO	Fish and seafood consumption study and biomarker of exposure to trace elements, pollutants and omega 3
CI	Cyclic imine
CONTAM Panel	Panel on Contaminants in the Food Chain
CRP	Slovenian dietary survey - Targeted research project
CTX	Ciguatoxin
DA	Domoic acid
DNFCS	Dutch National Food Consumption Survey
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FAO/IOC/WHO	Food and Agriculture Organization of the United Nations/ Intergovernmental Oceanographic Commission of UNESCO/World Health Organization
FFQ	Food frequency questionnaire
FINDIET	Finland National FINDIET Study
INCA	Enquête Individuelle et Nationale sur les Consommations Alimentaires
INN-CA	Nationwide Nutritional Survey of Food Behaviour
INRAN-SCAI	Italian National Food Consumption Survey
IZZ-FAO	Food and Nutrition Institute – Poland dietary survey
MON	Slovakian dietary survey
MS	Member state
MRI	Max Rubner-Institut
NDNS	National Diet and Nutrition Survey
NSIFCS	North/South Ireland Food Consumption Survey
NUTRICHILD	Bulgarian dietary survey
NVS	Nationale Verzehrstudie
OA	Okadaic acid
OJ	Official Journal of the European Union
P95	95 <sup>th</sup> percentile
P97.5	97.5 <sup>th</sup> percentile
PITX	Palytoxin
PTX	Pectenotoxin
RIKSMATEN	Swedish national food survey
SISP04	Individual Food Consumption – the National Survey
STX	Saxitoxin
UK	The United Kingdom
VCP	Voedselconsumptiepeiling onder jongvolwassenen
WG	Working group
YTX	Yessotoxin