AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

Maisons-Alfort, 17 August 2009

OPINION

of the French Food Safety Agency on proposals to improve the histamine surveillance plan

THE DIRECTOR GENERAL

Context of the request

On 7 October 2008, the Directorate General for Food (DGAL) submitted a request for scientific and technical support to the French Food Safety Agency (AFSSA) regarding proposals to improve the histamine surveillance plan.

1 - Background

1-1 Epidemiological background

During the 24 April 2008 meeting at the DGAL headquarters, the French Institute for Public Health Surveillance (InVS) reported an increase in the number of histamine food poisoning outbreaks and cases in France. Outbreaks increased in number from 20 in 2000-2002 to 59 in 2006 (out of a total of approximately 600 food poisoning outbreaks). The number of food poisoning cases per year related to these outbreaks also rose from around 100 to around 200 cases (17).

This increase in the number of cases has not been explained to date. Various hypotheses were put forth during the 24 April meeting at the DGAL:

- product changes (more distant suppliers, different species, etc.),
- suspected changes in consumption habits.

Other hypotheses, such as decreased underreporting, are also plausible.

1-2 Surveillance plan

The request for scientific and technical support states that "*every year, the DGAL sets up a plan to monitor the presence of histamine in fishery products. The objective of this plan is to assess and monitor consumer exposure to this risk from production to consumption of fish species with a particular risk of histamine formation. This monitoring complies with Chapter II of Annex III to the (EC) Regulation No. 854/2004 that stipulates specific rules for the organisation of official controls on products of animal origin intended for human consumption.*"

2 - Questions

AFSSA was asked to provide scientific and technical support on six questions. The first two concerned the number and distribution of samples for the 2009 histamine surveillance plan. A response to these two questions (2) was drawn up by the relevant AFSSA departments and sent to the DGAL in November 2008.

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This opinion addresses the last four questions (III to VI) so that the 2010 histamine surveillance plan may be implemented.

Question III: Should the histamine surveillance plan be limited to the fish species listed in the (EC) Regulation No. 2073/2005 which are associated with high amounts of histidine?

Question IV: The surveillance plan is based on sampling by category and sub-category as defined below. Should this sampling strategy be revised? How representative are these categories in terms of their histamine risk?

Question V: When should the histamine surveillance plan be carried out so that it corresponds to a worst-case risk assessment for consumers?

Question VI: A new geographic distribution based on population density and summer tourist populations has been proposed. Is this distribution satisfactory?

3 - Method of assessment

AFSSA, after consulting with the Scientific panel on microbiology on 15 July 2009, is issuing the following opinion. This opinion is based on the data from previous surveillance plans that were enclosed with the request for scientific and technical support and on the information that is available in the scientific literature (see references).

4 - Answers

4-1. Question III: Should the histamine surveillance plan be limited to the fish species listed in the (EC) Regulation No. 2073/2005 which are associated with high amounts of histidine?

4-1.1. List of currently sampled species

Annex I to the modified (EC) Regulation No. 2073/2005 of 15 November 2005 on the *microbiological criteria for foodstuffs* proposes a list of families of fish species associated with high amounts of histidine and therefore having a particular risk of histamine formation.

The following fish families are on this list: Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae.

Sampling performed for the histamine surveillance plan that the DGAL organises every year is based on the above-listed families, and includes the Istiophoridae and Xiphiidae.

4-1.2. Comparison with other sources

The list of fish families associated with high amounts of histidine in the regulation was compared with other fish families associated with histamine risk identified in scientific review articles (2, 3, 5, 7, 8, 10, 12, 13, 22, 26, 28, 30), in recommendations made by other countries (1, 6) and by the European RASFF (Rapid Alert System for Food and Feed, 25). This comparison was used to draw up the list of families (and species within these families) that is presented in Table 1.

Table 1. List of fish species associated with chemical hazards related to histamine (the families listed in the (EC) Regulation No. 2073/2005 are shaded)

Family	Species	English and French names
Arripidae	*Arripis trutta*	Australian salmon (loup de mer)
Ammodytidae	*Ammodytes tobianus*	Lesser sand eel (lançon)
Belonidae	*Belone belone*	Garfish (orphie, aiguille)
Carangidae	*Seriola dumerili (Risso)* *Seriola lalandii*	Greater amberjack (sériole, limon)
	Caranx sp.	Caranx (carangue)
	Trachurus sp	Trachurus (chinchard)
Coryphaenidae	*Coryphaena hippirus*	Mahi-mahi (coryphène, mahimahi)
Clupeidae	*Sardinella sirm*	Sprat (anchois de Norvège, sprat)
	Amblygaster sirm	Spotted sardinella (sardinelle tachetée)
	Sardinops sp.	Pilchard (pilchard)
	Sardina pilchardus	European pilchard (sardine)
	Clupea harengus	Atlantic herring (hareng)
	Sprattus spp	Sprat (sprat)
	Harrengula spp	Scaled sardine (sardine)
	Alosa pseudoharengus	Alewife (gaspareau)
	Spratelloides gracilis	Silver-stripe round herring (sprat)
Engraulidae	*Anchoa* spp *Anchoviella* spp *Engraulis* spp *Cetengraulis mysticetus* *Stolephorus* spp	Anchovy (anchois)
Gempylidae	*Lepidocybium flavobrunneum*	Escolar (escolar)
	Rivetus pretiosus	Oilfish
Istiophoridae	*Makaira (Tetrapterus) Audax (Poey)*	Spearfish (marlin)
	Istiophorus spp	Sailfish (voilier)
Lutjanidae	*Aphareus spp* *Aprium virescens* *Pristipomoides spp*	Snapper (vivaneau (thazard, mékoua (New Caledonia), job (Reunion))
Pomatomidae	*Pomatomus saltatrix*	Bluefish (tassergal, poisson-serre)
Sciaenidae	*Seriphus politus*	Queenfish (courbine reine)
Scomberesocidae	*Cololabis saira*	Pacific saury (balaou japonais, scombérésoce, samana)
Scombridae	*Auxis thazard*	Frigate tuna (auxide, bonitou)
	Acanthocybium solandri	Wahoo (thazard noir)
	Euthynnus alleratur	Little tuna (thonine)
	Katsowonus pelamis	Skipjack tuna (listao, bonite à ventre rayée)
	Sarda sarda	Atlantic bonito (bonite à dos rayé, bonite, sarde)
	Scomber japonicus	Chub mackerel (maquereau espagnol)
	S. scombrus	Atlantic mackerel (maquereau)
	Scomberomorus cavalla	King mackerel (thazard barré, sierra)
	S. maculatus	Spanish mackerel (thazard tâcheté)
	S. regalis	Painted mackerel (thazard franc)

	S. brasiliensis	Serra Spanish mackerel (thazard moucheté)
	Thunnus alalunga	Albacore (germon, thon blanc)
	T. albacares	Yellowfin tuna (albacore)
	T. obesus	Bigeye tuna (patudo)
	T. thynnus	Northern bluefin tuna (thon rouge)
	T. atlanticus	Blackfin tuna (thon à nageoires noires)
Salmonidae	*Salmo salar, Oncorhynchus sp.*	Atlantic salmon (saumon)
Serranidae	*Epinephelus sp*	Grouper (mérou)
Xiphiidae	*Xiphia gladius*	Swordfish (espadon)

The list of fish species potentially concerned by the histamine hazard is long and it is not possible, in terms of sample size, to monitor all of the families listed in Table 1. The product categories to be sampled must therefore be reviewed and selected beforehand (part 4-2).

4-1.3. Overseas

Species that are fished and those that may be consumed in French overseas *départements* are also listed in Table 1. Consumption data by category used for determining the strategy for sampling among categories and species of fish are not available for these overseas *départements*. We recommend using the same number of samples as in previous years for these *départements*. Samples should be selected from the two to three most frequently consumed species (to be defined by the people taking the sample) listed in Table 1.

4-2. Question IV: The 2009 surveillance plan is based on sampling by category and sub-category. Should this sampling strategy be revised? How representative are these categories in terms of their histamine risk?

4-2.1. 2009 surveillance plan

Thus far, surveillance plans have been based on sampling by category and sub-category, as presented in Table 2.

Table 2. Categories and sub-categories sampled under previous surveillance plans

	Category of fishery product	Sub-category
Production	**Packaged products**	Packaged refrigerated (**analysis on use-by date**) including thawed or frozen raw loins, steaks or fillets, catering products, smoked products, etc.
Delivery to the end consumer	**Refrigerated raw products**	Products sold directly, whole or by the cut
		Packaged self-service products in supermarkets (**analysis on use-by date**)
		Raw products used in food service sector
	Refrigerated packaged processed delicatessen products	Refrigerated delicatessen products (*rillettes*, mousses, etc.) (**analysis on use-by date**)
		Smoked and/or lightly salted fillets or steaks (**analysis on use-by date**)
	Frozen packaged products	All products (processed or not)

The various categories are self-explanatory. The DGAL's recommendations in its guidance note for the implementation of the 2008 surveillance plan do not specify the number of samples to be taken per species. It simply states that tuna must be sampled as a priority for category 3 (sub-category smoked fillets or steaks).

The distribution of the samples that the DGAL took in 2008 between and within the categories is not representative of consumers' exposure to histamine through fishery products. For example, some categories and/or species of fish in a category (e.g. swordfish) are overrepresented in the sampling plan with regard to their consumption.

4-2.2. Proposals for modifying the surveillance plan

Several strategies may be used to formulate a new surveillance plan. Samples may be chosen so that:

- they are strictly representative of the consumed quantity of the various food products that potentially contain the monitored hazard;
- they are based on risk. In this case, there is a greater number of samples for the category (-ies) of food products that are considered to be "at risk". This risk assessment, on which monitoring will be based, can rely on expert opinions (qualitative assessment) or on a risk ranking system (semi-quantitative assessment). The latter approach was recently applied for the implementation of a surveillance plan for *Listeria monocytogenes* in ready-to-eat meat-based products in the United States (15). This sampling strategy is also used to monitor animal diseases, where sampling effort is greater on animals from certain geographic regions or farms (24).

The plan that is proposed below uses a combination of these two strategies (Figure 1).

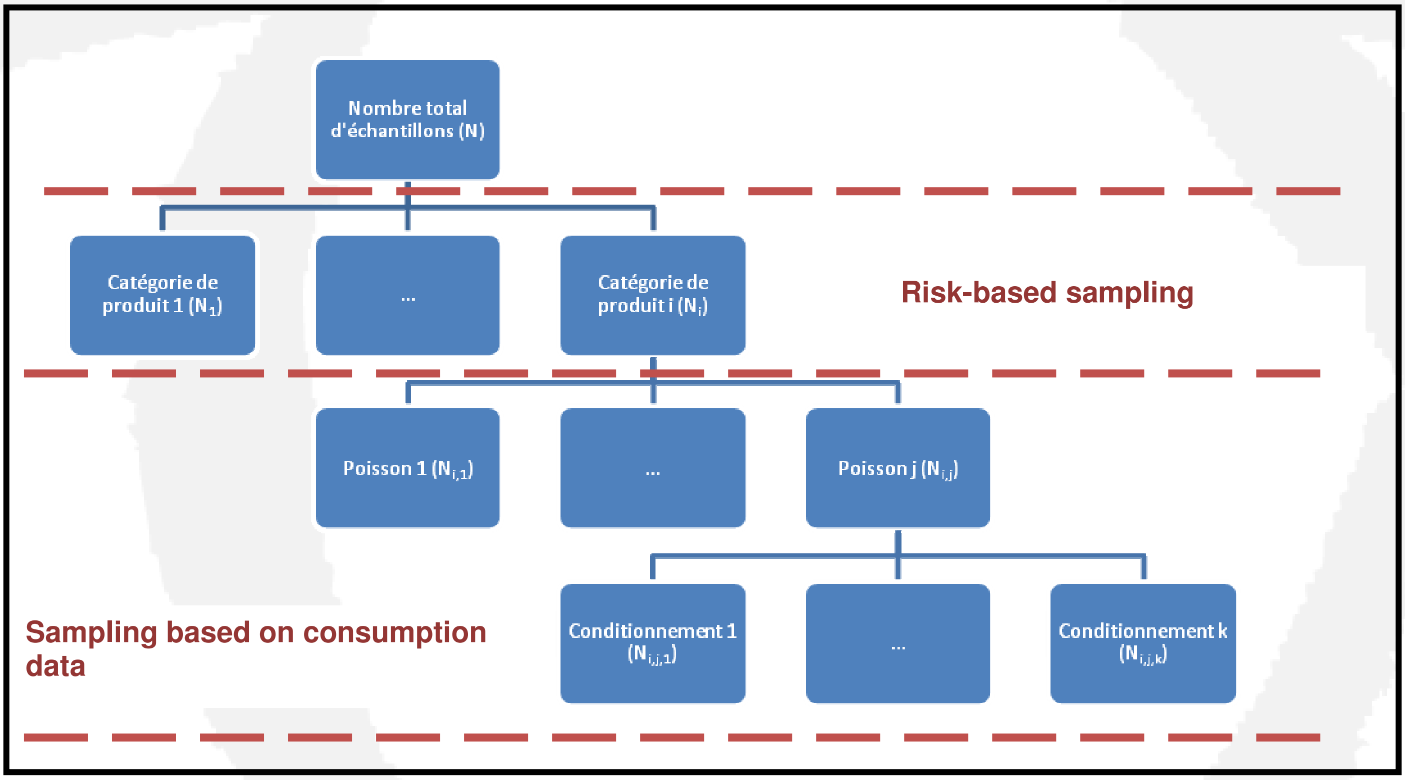


Figure 1. Sampling strategy for the histamine surveillance plan.

Nombre total d'échantillons (N)	Total number of samples (N)
Catégorie de produit 1 (N_1)	Product category 1 (N_1)
Catégorie de produit i (N_i)	Product category i (N_i)
Poisson 1 ($N_{i,\,1}$)	Fish product 1 ($N_{i,1}$)
Poisson j ($N_{i,\,j}$)	Fish product j ($N_{i,j}$)
Conditionnement 1 ($N_{i,j,1}$)	Product form 1 ($N_{i,j,1}$)
Conditionnement 1 ($N_{i,j,k}$)	Product form k ($N_{i,j,1}$)

Six main product categories were considered for the proposed 2009-2010 plan:

- Refrigerated raw products;
- Refrigerated processed products;
- Refrigerated delicatessen products,
- Tinned products;
- Deep-frozen fresh fish;
- Fresh salmon.

The first five categories were already included in previous histamine surveillance plans. A new category has been proposed: fresh salmon. Salmon may be responsible for cases of histamine poisoning (28). Although salmon is more seldom involved in this type of poisoning than other species, it warrants special attention due to the high amounts that are consumed.

Salmon does not fall under the category of refrigerated raw products (which includes tuna, mackerel, anchovies, etc.) since, as was stated above, it stands out from species that are commonly recognised as being involved in histamine poisoning due to the amount of histidine they contain. Salmon contains a lesser amount and therefore the likelihood that histamine will develop is lower (9, 14, 18, 21).

In addition, smoked salmon is not included in any of these categories. The conditions under which it is manufactured do not lead to histamine concentrations that are harmful for human health (18).

For each of these categories, a risk ranking was defined using the semi-quantitative risk assessment tool developed by Ross & Sumner (27) called Risk Ranger (see Appendix 1). This tool has been used to rank the hazards associated with seafood products in Australia (29) and by the FAO to assess histamine-related risks in fish (30).

4-2.2.1 Calculation of risk rankings for the various categories

This calculation is based on answers to 11 questions (listed in Appendix 1).

Concerning the hazard severity (question 1), the criterion (weighted in the Risk Ranger tool) was chosen to match the one attributed to this hazard by the FAO (30).

Risk rankings were calculated for the six product categories in question. Calculations were made for the French general population (questions 2 and 5). Data on consumption of the various categories (questions 3 and 4) were provided using Ofimer 2007 data on amounts of products consumed in France (23).

In response to the question on the probability that the raw product is contaminated (question six), the FAO (30) hypothesised that only 1% of the products in question contain bacterial species capable of producing histamine. Moreover, according to the FAO, contamination of these bacterial species is also considered to be low (10 CFU/cm^2). These hypotheses on low prevalence and contamination levels appear to be reasonable in light of the available literature. Bacterial species capable of producing histamine are not always contained in fish (4, 11, 20) and they represent only a minority (in terms of number) of the bacterial flora in these fish. Furthermore, contamination levels may be extremely low (approx. 10 cfu/cm^2) in fish fillets before storage (10, 19, 20). Two contamination probabilities were tested: 1 and 10%.

As for the influence that the production process has (question 7) on bacterial growth, the official hypothesis is that production operations do not cause the number of bacteria to increase (30).

The Risk Ranger tool takes the frequency of cross-contamination into account (question 8). Fish that come in contact during storage may transmit bacterial flora that potentially produce histamine. The FAO estimates this frequency to be 10% (30). Percentages of 0 and 10% were tested for all of the fish categories with the exception of tinned foods for which recontamination after opening is estimated to be 1%.

Question 9 concerns the effectiveness of the food storage system in terms of controlling growth. It is considered that for tinned products (lack of flora) and deep-frozen products (no growth at freezing temperatures), no growth occurs. For the other categories, a 1 $\log_{10}$ increase in the bacterial flora related to the production of histamine is possible during cold storage.

For question 10, it is necessary to indicate the growth that would be needed to reach the level of bacteria associated with amounts of histamine that are harmful for human health. This level is estimated to be 10^8 bacteria/g. The growth needed to reach this level is estimated (10, 30) to be 10^6-10^7 bacteria/g for all the categories with the exception of fresh salmon, where a more significant increase in the bacterial flora (10^7-10^8 bacteria/g) would be needed. This difference is due to the low amount of histidine in fresh salmon.

The input data and results (scores and estimated number of cases per year) are given in Table 3. Two results are given per category, corresponding to a “lower” estimate (lowest prevalence level, no recontamination, maximum bacterial growth to reach the level associated with a high concentration of histamine) and an “upper” estimate (higher prevalence level, high recontamination prevalence, minimum bacterial growth to reach the level associated with a high concentration of histamine).

Table 3. Responses to questions and scores obtained in the semi-quantitative assessment of risks related to histamine in various categories of fish.

	Fresh fish with high histidine concentrations	Fresh salmon	Tinned fish	Deep-frozen fresh fish with high histidine concentrations	Refrigerated processed fish	Refrigerated delicatessen products	References
Q1: Hazard severity	"Mild"						(30)
Q2: Susceptibility of the population	General population						
Q3: Product consumption frequency	Once a month	96[a]	Once a month	215[a]	Once a month	158[a]	(23)
Q4: Proportion of population consuming the product	25%	75%	75%	5%	25%	25%	(23)
Q5: Size of consuming population	63,967,000						(16)
Q6: Probability that a serving of raw product is contaminated	1 -10%						(4, 10, 19, 20, 30)
Q7: Effect of processing	No Effect						(30)
Q8: Potential for recontamination	0-10%	0-10%	0-1%	0-10%	0-10%	0-10%	(30)
Q9: Effectiveness of the post-processing control system	x10	x10	No growth	No growth	x10	x10	(30, 31)

Q10: Increase in the post-processing contamination level needed to cause illness.	10^6-10^7	10^7-10^8	10^6-10^7	10^6-10^7	10^6-10^7	10^6-10^7	(10, 30)
Q11: Effect of meal preparation			No effect				(30, 31)
Score[b]	**25-37**	**20-31**	**23-28**	**11-22**	**22-33**	**21-33**	
Number of cases per year	**2-192**	**0.2-18**	**0.6-6**	**0.005-0.5**	**0.5-48**	**0.4-37**	

[a] interval (in days) between 2 points of consumption.

[b] A score that increases by six units corresponds to a tenfold risk increase.

[c] Out of all smoked products, only cold-smoked products were considered.

4-2.2.2 Calculation of the number of samples per category

Note: when a score increases by six units, this means the risk is ten times higher (27). The risk associated with a category of fish in relation to the category of refrigerated raw products (RR_i) may be calculated using the scores obtained for each category ($score_i$):

$$RR_i = 10^{\left(\frac{1}{6}(score_i - score_{pf})\right)}$$

Or to produce the same result, by using the estimated number of cases per product category (Cas_i):

$$RR_i = \frac{Cas_i}{\sum_i Cas_i}$$

We propose that the number of samples for a category i (N_i) be inversely proportional to RR_i:

$$N_i = N_{TOT} \frac{RR_i}{\sum_i RR_i}$$

Table 4. Distribution of samples in the various product categories

Category	**Risk Ranger risk ranking**	**Number of annual food poisoning cases**	**Relative risk (RR_i)***	**Number of samples for the 6 categories (N_i for an N_{TOT}=600)**	**Number of samples for the 4 main categories (N_i for an N_{TOT}=600)**
Deep-frozen fresh fish (tuna, sardines, mackerel, anchovies, etc.)	22	0.5	0.003	1	-
Tinned fish (tuna, sardines, mackerel, etc.)	28	6	0.031	12	-
Fresh salmon	31	18	0.094	36	37
Refrigerated delicatessen products	33	37	0.193	74	75
Refrigerated processed fish	33	48	0.250	96	98
Fresh fish (tuna, sardines, mackerel, anchovies, etc.)	37	192	1	382	391

* *Relative to the risk associated with fresh fish with high histidine concentrations*

The (estimated) risks associated with the consumption of tinned and deep-frozen fish appear marginal compared to the risk associated with fresh fish with high histidine concentrations. The calculated number of samples for these two categories is therefore small. We recommend excluding these two categories of fish from the sampling plan.

4-2.2.3 Calculation of the number of samples in each category

We recommend weighting the sample size for a category i (N_i) by an factor proportional to the consumed quantity of each fish product (Q_j) in a given category ($\sum Q_j$).

$$N_{ij} = N_i \frac{Q_i}{\sum_i Q_i}$$

When there are different forms (k) of a fish product (j) in a given product category (i), the sub-sample size N_{ij} is as follows:

$$N_{ijk} = N_{ij} \frac{Q_{ij}}{\sum_j Q_{ij}}$$

Table 5. Distribution of samples for the various categories

Category (i)	Place of Consumption	Fish product (j)	Form (k)	Amount consumed (tonnes) Q_j	Q_{ij}	N_{ij}	N_{ijk}	Amount purchased in supermarkets (%)	Fishmonger	Supermarket
Fresh fish	Home	Tuna		3835		91		66	31	60
			whole		399		9		3	6
			cut		3370		77		26	51
			packaged		216		5		1	4
		Mackerel		4836		114		57.6	48	66
		Sardine		4940		117		68.1	37	80
			whole		4263		101		32	69
			cut		605		14		5	10
			packaged		260		6		2	4
	Elsewhere	Tuna		2929		69				
			whole		1543		36			
			cut		1386		33			
				Sub-total 1		**391**				
Fresh salmon	Home	Fresh salmon		26098		23		84	4	19
			whole		3760					
			cut		22136					
			packaged		6242					
	Elsewhere	Fresh salmon		16468		14				
			whole		8985					
			cut		7483					

			Sub-total 2	**37**
Refrigerated processed fish	Home	Smoked herring	4509	59
		Smoked mackerel	295	-
		Salted dried herring	726	-
		Marinated herring	1676	22
		Marinated anchovies	291	-
		Semi-preserved anchovies	1292	17
			Sub-total 3	**98**
Refrigerated catering products			**Sub-total 4**	**75**
			Total	**600**

4-3. Question V: When should the histamine surveillance plan be carried out so that it corresponds to a worst-case risk assessment for consumers?

Experience seems to show that there is a clear increase during warm periods (unpublished results from 1987 to June 2003 reported by the central laboratory for veterinary services in Rungis), with temperature being independent of the notion of season.

However, the European alert system's data show that the distribution of histamine alerts is homogenous throughout the year with no seasonal variation (see Figure 2). The implementation period from 1 May to 15 September used in the surveillance plan is probably too limited.

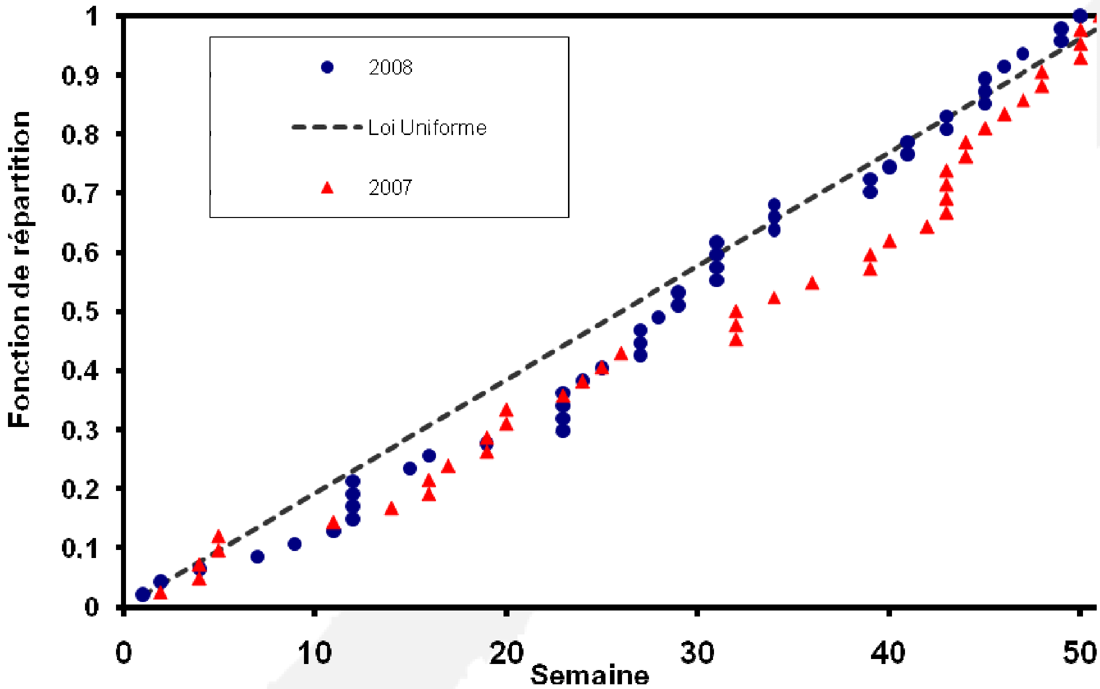


Figure 2. Distribution of histamine alerts over time (Rapid Alert System for Food and Feed, RASFF).

fonction de répartion	[cumulative] distribution function
semaine	week
Loi uniforme	[theoretical] linear relationship

InVS data (Figure 3) also show that histamine food poisoning outbreaks are observed all year round with no significant seasonal effect.

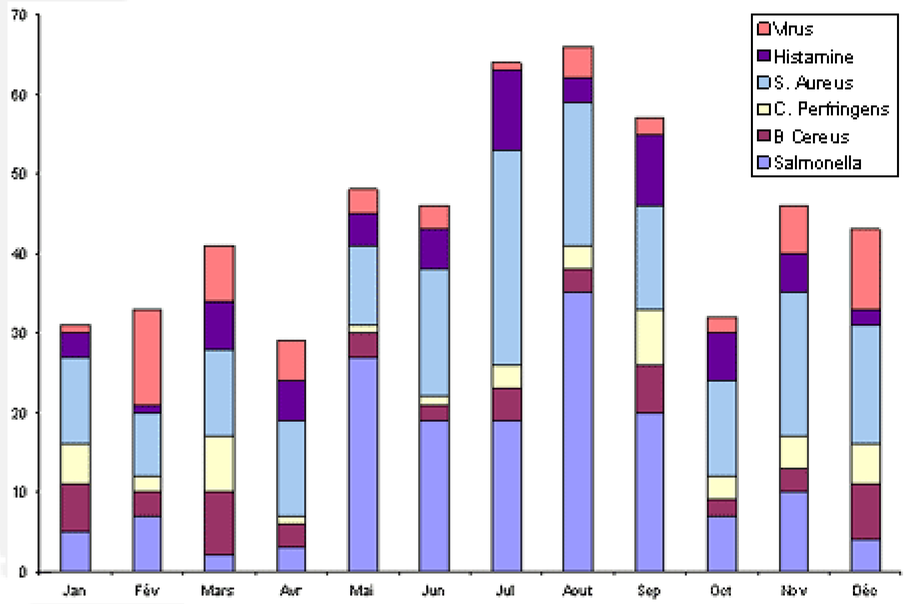


Figure 3. Number of food poisoning outbreaks declared in 2006 by month of exposure, for the primary confirmed or suspected responsible germs. Source: InVS (17).

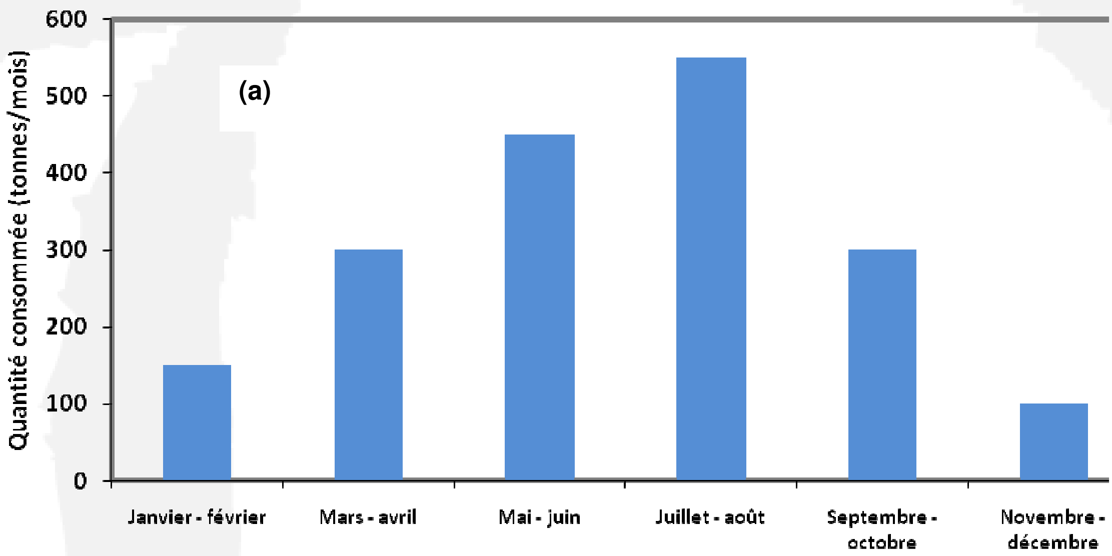
Jan	Jan
Fév	Feb
Mars	Mar
Avr	Apr
Mai	May
Juin	Jun
Jul	Jul
Aout	Aug
Sep	Sep
Oct	Oct
Nov	Nov
Déc	Dec

We therefore recommend implementing the surveillance plan throughout the entire calendar year.

Furthermore, to closely monitor consumer exposure to histamine, the number of samples per time period (t) for the fish product (j) in a given category (i) could be proportional to the amounts consumed during each period of the year (Q_{ijt}):

$$N_{ijt} = N_{ij} \frac{Q_{ijt}}{\sum_t Q_{ijt}}$$

An illustration of this distribution is presented in Figure 4.



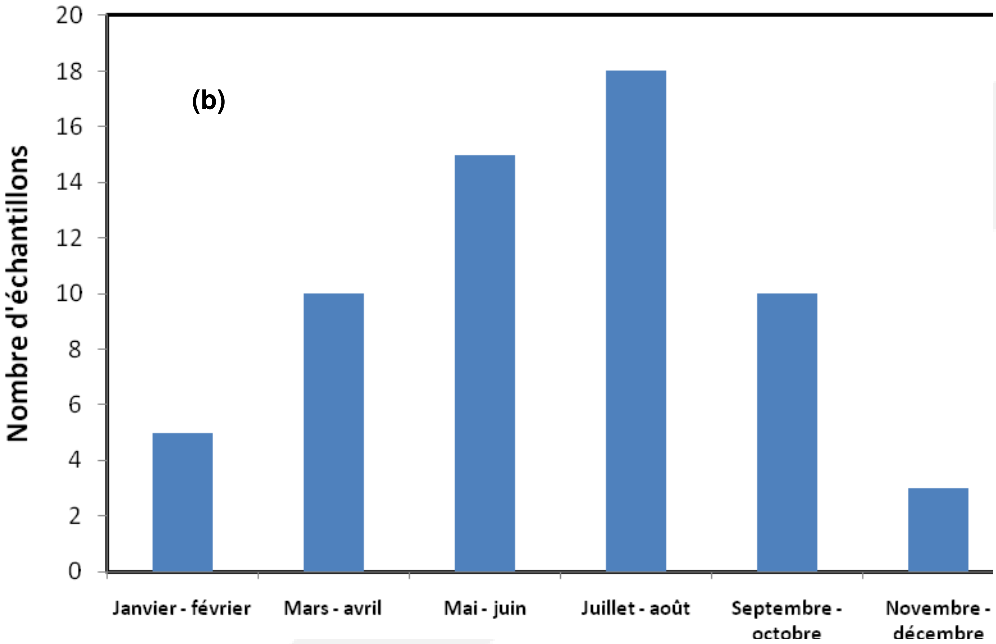


Figure 4. (a) Seasonal variation in fresh tuna consumption in 2007. (According to Ofimer 2007). (b) Proposed numbers of fresh tuna samples to be taken in supermarkets by season.

Quantité consommée (tonnes/mois)	Quantity consumed (tonnes/month)
Janvier-février	January-February
Mars-avril	March-April
Mai-juin	May-June
Juillet-août	July-August
Septembre-octobre	September-October
Novembre-décembre	November-December
Nombre'échantillons	Number of samples

4-4. Question VI: A new geographic distribution of samples has been proposed based on population density and summer tourist movements. Is this distribution satisfactory?

The distribution proposed by the DGAL involves the annual monitoring of the most populated *départements* and those that experience significant changes in population density in the summer (a total of 40 *départements*). The other *départements* are monitored periodically every three years. A total of 60 *départements* are monitored each year (40 continuously + 20 periodically).

These two selection criteria are relevant. They make it possible to annually monitor the exposure of both the most populated *départements* and the *départements* that consume the most fish (these correspond to the *départements* that experience significant changes in population density).

The number of samples per geographic area (z) for a fish species (j) in a given category (i) was proportional to the amounts consumed in each geographic region (Q_{ijz}):

$$N_{ijz} = N_{ij} \frac{Q_{ijz}}{\sum_z Q_{ijz}}$$

The N_{ijz} samples will then need to be divided up among the various *départements* that the DGAL proposed in its request.

An illustration of this distribution is presented in Figure 5.

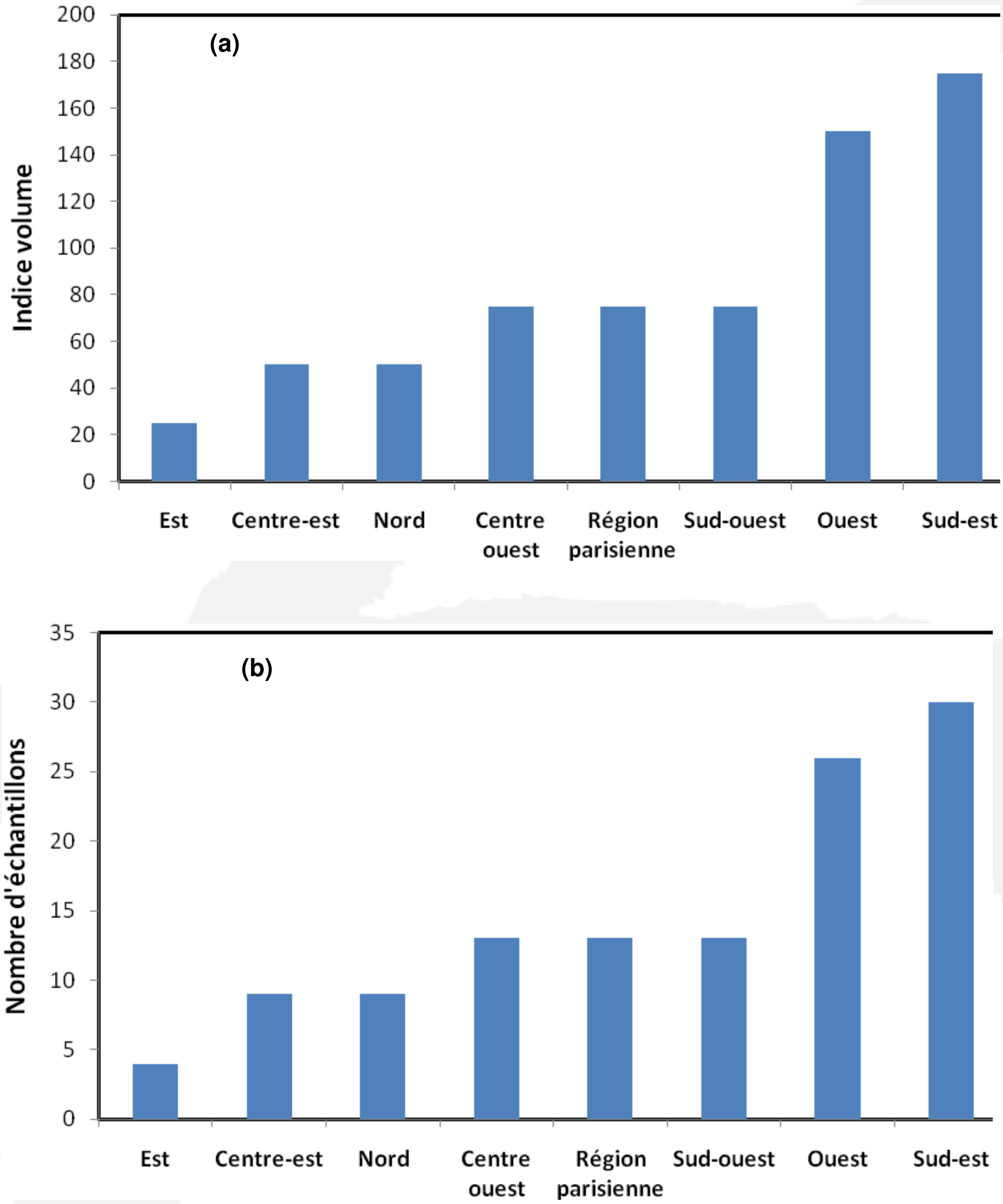


Figure 5. (a) Geographic distribution of sardine consumption in 2007. (According to Ofimer 2007). (b) Proposed spatial distribution of fresh sardine samples.

Indice volume	Volume index
Est	East
Centre-est	Eastern Central
Nord	North

Centre ouest	Western Central
Région parisienne	Paris region
Sud-ouest	South-West
Ouest	West
Sud-est	South-East
Nombre'échantillons	Number of samples

6- Recommendations-conclusions

The sampling distribution based on both risk and consumption data should be the most effective method for assessing consumer exposure. A detailed sampling strategy determined by category, species, consumption during the year and region is summarised in Appendix 2.

It is important to note that complete case histories are essential, even if samples are compliant. However, given the extremely low number of products that exceed the 50 ppm limit, possibilities of comparing differences between compliant and non-compliant samples are minimal, which may also be limiting when attempting to identify significant risk factors.

Assessing consumer exposure risks will be less than optimal until real progress can be made in measuring risks quantitatively with a quantification limit that is as low as possible. When this can be achieved, exposure risk calculations such as those recently published by an Austrian research group (26) will be possible.

As with most food poisoning cases, the number of cases of histamine poisoning are probably underestimated.

To assess risks affecting the French population, in addition to the surveillance plan, several studies should be carried out:

- An epidemiological study to identify, based on reported observations, potential risk factors, and possibly to estimate the frequency of underreporting;
- Acquisition of data on the nature, quantity and behaviour of microbial flora associated with histamine production.

7 - References

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8 - Keywords

Histamine, fishery products, food poisoning, surveillance plan, sampling plan

Appendix 1: Presentation of the Risk Ranger semi-quantitative assessment tool

A. Presentation

Ross & Sumner (27) developed a semi-quantitative risk analysis tool called Risk Ranger. The authors describe the tool as being a simple way of:

- comparing food-related risks and classifying/ranking them;
- highlighting factors that contribute to food safety risks;

Risk Ranger is presented as an Excel spreadsheet (Figure A1). It can be used to examine food-borne risks and to identify those that warrant more rigorous assessment.

Risk Ranger generates a structured response and is primarily focused on food production factors, e.g. processing, distribution and meal preparation, which have the greatest impact on food safety risk. It is thus particularly appropriate for risk management strategies.

The software uses the principles of risk assessment, i.e. it factors in the likelihood of exposure to a food-related risk, the prevalence of hazards in a food product when they exist, and the likelihood and severity of the consequences of a particular contamination level and frequency of exposure.

The tool requires that the user choose a qualitative statement and/or supply quantitative data concerning the factors that will affect the risk related to a specific food product and a specific hazard for a specific population, from production to consumption.

The Excel table converts the qualitative data into numerical values and combines them with the quantitative data in a series of mathematical and logical steps that use standard spreadsheet functions.

Risk assessments for product/hazard (pathogen) combinations use a 0-100 scale where zero represents no risk and 100 represents the extreme opposite where each member of the population consumes one meal containing the lethal dose of the hazard every day.

A risk-ranking increase of six approximately corresponds to a tenfold increase in the risk.

B. User interface

The user interface represents a generic "conceptual model" of the factors that contribute to food safety risk.

The model was developed in Microsoft Excel in the form of a spreadsheet, using mathematical and logical functions. A macro (an intrinsic function of MS Excel that can be accessed from the 'Forms' toolbar) was used and allows users to select their choice from a list of options. The software converts this selection into a numerical value.

The user must answer 11 questions, which are related to all the factors that affect the risk from a hazard in a specific food product, including:

* *Severity of the hazard* (affected by the intrinsic characteristics of the pathogen/toxin and the consumer's susceptibility);

* *Likelihood of a disease-causing dose of the pathogen being present in a meal* (depends on: serving size, probability of contamination in the raw product, initial level of contamination, probability of contamination at subsequent stages in the farm-to-fork chain, and changes in the level of the hazard during the journey from farm to fork);

* *Probability of exposure to this risk in a given period of time* (will depend on: how much is consumed per meal by the population of interest, how frequently and the size of the population exposed).

Question 1: Hazard severity.

Question 2: Susceptibility of the population of interest.

Question 3: Frequency of consumption.

Question 4: Proportion of population consuming the product.

Question 5: Size of consuming population.

Question 6: Probability that a serving of raw product is contaminated.

Question 7: Effect of processing.

Question 8: Potential for recontamination after processing.

Question 9: Effectiveness of the post-processing control system.

Question 10: Increase in the post-processing contamination level required to cause an infection or food poisoning.

Question 11: Effect of meal preparation.

Appendix 2: Summary tables

Table A2-1. Space-time distribution of samples

Plan category		Fresh fish																																									
Sampling site		Distribution																																				Catering					
		Supermarket																		Other sources																							
Product		Tuna						Mackerel						Sardine						Tuna						Mackerel						Sardine						Tuna					
Period of the year		1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6
Geographic region	North				2			1	2	1	1					2	3	1					1				2	1						1	2					1	1		
	East			1	2	1			1		1					1	1	1				1	1				1		1						1				1	1	1		1
	Paris region	1	1	2	2	1	1	1	3	2	2	1		1	1	1	4	1	1			1	2	1		1	2	2	1	1				1	2	1		1	1	2	2	2	1
	West	1	2	2	3	1		2	5	4	5	3	2	2	3	3	6	3	1	1	1	1	1	1		2	4	3	3	2	1	1	1	2	3	1		2	2	2	3	1	1
	Western Central		1	1	1	1		1	2	2	1	1		1	1	1	4	1	1					1	1	1	1		1	1	1		1	1	1	1		1	1	1		1	
	South-West	2	2	4	4	2	1	1	3	2	2	2	2		2	2	3	1	1	1	1	2	2	1	1	1	1	2	2	2	1		1	1	1	1		1	3	5	5	2	1
	Eastern Central		1	2	2	1		1				1			1	2	2	1			1	1		1		1				1				1	1	1			1	1	2		
	South-East	1	3	2	2	3	1	1	1	2	1	2	1	1	2	8	7	1	1	1	2	2	2				2	1	1		1	1	2	2	3		2	1	2	4	7	4	

*1: January-February; 2: March-April; 3: May-June; 4: July-August; 5: September-October; 6: November-December

Table A2-2. Space-time distribution of samples (continued)

Plan category		Fresh salmon												Refrigerated processed fish																		Refrigerated delicatessen products					
Sampling site		Distribution						Catering						Distribution																		Distribution					
Species/product														Smoked herring						Marinated herring						Marinated anchovies											
Period of the year		1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6
Geographic region	North	1		1		1		1		1				1	2	1	1	1	1	1		1	1		1	1		1	1		1	2	1		2	2	2
	East		1		1		1				1			1	1	2	1	1	2		1		1	1			1		1	1		1	2	1		2	
	Paris region	1		1		1						1		1	1	1	2	2	1	1	1						1					2	4	2	2		2
	West		1		1		1				1		1	1	1	1	2	1	1					1						1		2	1	3		2	3
	Western Central	1		1		1			1		1			1	1	1	1	1	1	1			1	1	1						1				3	1	1
	South-West		1		1		1	1		1				2	1	1	2	1	1		1	1		1				1		1		2	2	2	2	2	2
	Eastern Central	1		1		1			1					1	2	2	1	1	2														1	2	2		
	South-East				1		1				1	1		1	1	1	1	1	1	1	1	1	1		1	1	1	1	1		1	2		1	1	1	1

*1: January-February; 2: March-April; 3: May-June; 4: July-August; 5: September-October; 6: November-December