

The Director General

Maisons-Alfort, 14 October 2015

OPINION

of the French Agency for Food, Environmental and Occupational Health & Safety

relating to consumer information on prevention of foodborne microbiological risks

ANSES undertakes independent and pluralistic scientific expert assessments.

ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.

It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are made public.

This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 14 October 2015 shall prevail.

On 2 May 2012, ANSES received a formal request from the Directorate General for Food (DGAL) for an Opinion on consumption recommendation statements on food labelling to prevent biological hazards.

1. BACKGROUND AND PURPOSE OF THE REQUEST

According to European regulations on food hygiene, the strategy for managing food safety risks is based mainly on prevention of contamination at the primary production stage, and control of hazards at each stage of the food chain.

Nevertheless, around one third of the foodborne disease outbreaks reported in France occur in the family environment (varying between 26 and 39% per year). Some of these cases are associated with improper food-handling practices at home, such as inappropriate storage, insufficient cooking of foods or cross-contamination. Therefore, specific information aimed at consumers could also help reduce the risk of certain foodborne diseases.

Risk managers need to be able to make a substantiated choice from among all their possible communication strategies, in relation to certain food health risks and also potential constraints for the sectors in question. For example, discussions began in 2010 on the benefits and feasibility of a label statement discouraging the consumption of honey by infants under 12 months of age (see the request letter in Annex 1). Following discussions with the different stakeholders in this matter, the authorities decided not to make specific labelling of honey pots mandatory, since the added value of this provision compared to other possible information measures (information via health professionals, for example) has not been demonstrated.

The DGAL's request contained the following questions:

- Which methodology should be applied to define, in terms of prioritisation and proportional to the risk, the measures aimed at each of the parties involved (food sector operators, health professionals, consumers), and how should they be combined to achieve optimal efficiency of the health control scheme in terms of benefits to public health, while remaining proportionate to any constraints for the sector concerned?

- Can the Agency draw up a list of hazard-food combinations of priority to public health for which mandatory specific labelling (reference to the hazard or advice and precautions on use for vulnerable populations) would be likely to significantly improve consumer protection, after having examined the other options regarding information targeted at the groups concerned?

In agreement with the supervisory authorities, the questions were reformulated and it was agreed that ANSES should examine the following points:

1. Identification of hazard-food combinations (or hazard-food-vulnerable population combinations) for which better consumer information may have an impact on risk reduction (compared to upstream control measures).
 - 1.1. Prioritisation of the hazard-food combinations according to the impact of preventive measures that can be applied by consumers.
 - 1.2. Quantitative assessment of the health impact on the representative hazard-food combinations of consumers applying preventive measures.
2. Identification of conditions and criteria of effectiveness for the various information measures that could be applied for the combinations identified.
 - 2.1. Inventory of possible information measures on the food risks.
 - 2.2. Conditions and criteria of effectiveness for these measures.
3. Identification of conditions and criteria of efficiency for the various information measures: case study on a hazard-food combination.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

ANSES entrusted examination of this request to the Expert Committee (CES) on Assessment of the biological risks in foods (BIORISK). The Agency also mandated the Working Group (WG) on "Consumer information on biological risks related to foods" for this expert appraisal. The methodological and scientific aspects of this group's work were regularly submitted to the CES. It was adopted by the CES BIORISK at its meeting on 2 July 2015.

The expert appraisal was carried out in two phases. An initial report was published on 9 May 2014. The Working Group's preliminary investigations identified:

- the hazard-food combinations for which a change in consumer practices could result in a reduction in risks;
- the main communication tools available to inform consumers about the microbiological risks;
- the indicators enabling the effectiveness of the information measures to be assessed.

The present report focuses on the following questions:

- Identification of conditions and criteria of effectiveness and efficiency for a communication measure on the prevention of biological risks;
- Quantitative assessment of the health impact of a communication campaign on the preventive measures that can be applied by consumers.

Given the context of the request, the WG also examined the case of prevention of infant botulism associated with honey, in order to recommend information strategies for this risk.

The WG's expert appraisal drew on:

- Articles selected during the literature search for the first report on the theme of the impact on consumption behaviour of information aiming to reduce food microbiological risks. As the body of

literature was limited, the question was broadened to include other types of risk (e.g. nutrition, or prevention of cardiovascular diseases);

- The documenting, through hearings and questionnaires, of available information measures and assessments on the prevention of microbiological risks in food conducted by different institutional players, associations and private organisations;
- Quantitative risk assessment (QRA) models, for estimating the impact on risk reduction of changes in consumer behaviour induced by multimedia communication campaigns.

The following hazard/food combinations were selected in the light of their health impact (determined in the first report) and the availability of data for conducting QRAs:

- Shiga toxin-producing *Escherichia coli* (STEC)/minced beef;
- *Listeria monocytogenes*/ready-to-eat foods able to support the growth of *L. monocytogenes* (for example, smoked salmon);
- *Campylobacter*/poultry meat (e.g. chicken).

3. ANALYSIS AND CONCLUSIONS OF THE CES

3.1. Conditions and criteria of effectiveness for a communication campaign on the measures to prevent microbiological risks

➤ ***Identification of the determinants of the behaviours involved in culinary practices presenting a risk***

Public health actions in the field of health education seek to modify behaviour; the type of behavioural model on which they are based is therefore vital for ensuring their effectiveness. The Working Group built a behavioural model combining the variables from different psycho-social models in order to overcome the limitations of each one (Theory of Planned Behaviour (TPB), Theory of Interpersonal Behaviour (TIB), COM-B model¹) (see Figure 1).

The determinants integrated in the proposed model are: attitudes, subjective norms, behavioural control, knowledge, past behaviour, habits, moral values, emotional beliefs, opportunities, capacities and socio-demographic characteristics.

¹ COM-B for Capacity, Opportunity, Motivation and Behaviour

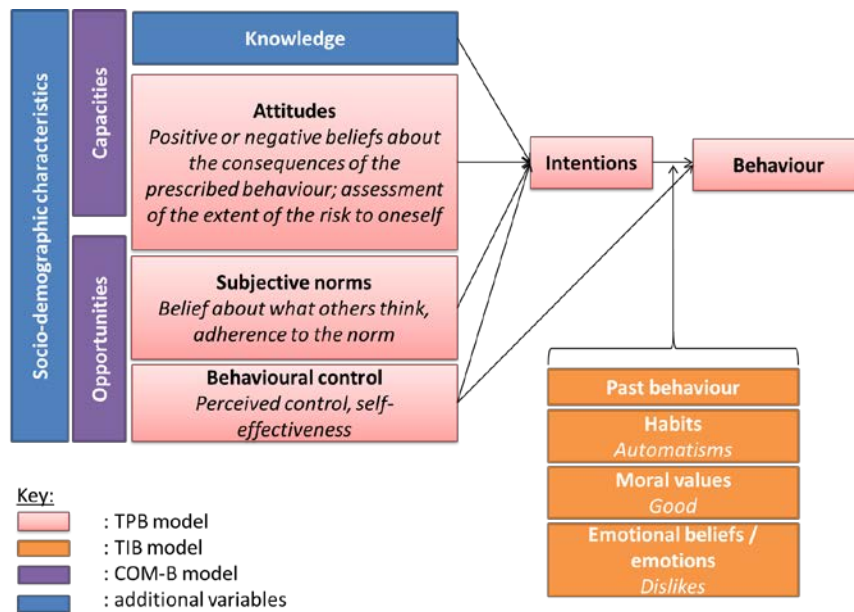


Figure 1: Proposed model of the behaviours involved in culinary practices presenting a risk

An analysis of the contributions of each of the model's determinants, using data from the literature, revealed that behavioural control has the greatest influence overall. This determinant refers both to the belief that behaviour is effective (perceived control) and to the perceived ability to adopt correct behaviour (self-effectiveness: believing oneself to be "*capable*" of performing an action). Opportunities (the conditions that make the behaviour possible, such as having soap and hot water available for washing hands) appear as a necessary determinant for enabling changes in behaviour.

Measures designed to reduce microbiological risks should therefore act primarily on behavioural control and foster the development of opportunities. These guidelines are often implemented in the health field. For example, some communication campaigns carried out in the framework of the French National Health and Nutrition Programme (PNNS), such as "*Manger Bouger*" ("Eat and Move"), aim to develop confidence in the French in their ability to act, and to facilitate the practical implementation of the recommendations (simple cooking recipes, tips for keeping active on a daily basis).

The analysis also revealed that raising the level of knowledge is not sufficient to cause a change in behaviour: the communication measures designed to inform consumers are necessary in order to provide knowledge, but insufficient to change behaviour and reduce microbiological risks.

➤ **Effectiveness of the different communication strategies in the framework of prevention of foodborne microbiological risks**

The literature search, broadened to encompass the fields of health and nutrition, revealed different communication strategies, which could be adapted for actions in the framework of microbiological risks. The impacts of these actions on changes in consumer behaviour have nevertheless undergone very little quantitative assessment.

- **Multimedia communication campaign:** This is a campaign combining various complementary communication media such as television, Internet, press, radio and billboards. On the basis of meta-analyses, the WG found that a multimedia communication campaign on the prevention of foodborne microbiological risks would contribute to changing the behaviour of 5 to 10% of the population. This data formed the basis of the WG's assumptions regarding modelling to estimate the health impact of changes in behaviour following a multimedia communication campaign.

- **Labelling:** This responds to a concern for transparency and a requirement for information. Labelling is mainly used today to provide nutritional information, and it is difficult to extrapolate the uses and analyses to the issue of microbiological risks. One conclusion is nevertheless clear from the literature analysis: the labelling is primarily read by motivated and interested individuals. Bias associated with label reading/processing may lead to the opposite behaviour from that advocated. In addition, there is currently a trend to increase the information on packaging (nutrition, safety, commercial, animal welfare, environmental impact, etc.), and the consequences on the readability, understanding and use by consumers should be assessed.
- **Educational programmes:** These aim to raise awareness in individuals about general hygiene over the long term and can help reduce social inequalities in health. The analysis of the literature on existing practices in other countries showed that improving knowledge in the framework of school programmes could play a role in the prevention of foodborne microbiological risks. Information relating to general hygiene measures could be considered in existing French programmes on food, such as *La Semaine du Goût* (National Taste Week) or the educational pathway on health.
- **Interpersonal interventions:** These can be defined as a direct relationship without mediation between two individuals, for example a health professional and a patient. The effectiveness of interpersonal interventions depends on the nature of the intervention and the targeted population, and is therefore extremely difficult to assess.
- **Nudges:** These are measures that consist in making slight changes to the individuals' environment in order to guide them towards behaviour that is more beneficial to their health (e.g. provision of thermometers for checking whether meat is sufficiently cooked, positioning wash basins at the entrance to canteens). Nudges can be a way of fostering "opportunities" in the environment of individuals that represent one of the two determinants most likely to change behaviour.

➤ **Targeting of populations**

• **Prioritise interventions intended for the general population or for specific populations?**

When a communication action is preferred, the first step is to decide between communication intended for the general population or a target population.

In the absence of specific studies on microbiological risks, the literature on measures intended to reduce cardiovascular disease was examined.

- The targeted approach is effective because it is specific to a risk factor, and individuals' motivation may then be higher. Nevertheless, it is not always easy to identify the population at risk and individuals are led to make choices that may be different from the norms of the people around them. In addition, the target population may not identify with the population at risk (optimism bias) which can reduce the impact of the communication.
- The universal approach for a general population addresses the root of the problem by eliminating the underlying causes of the disease in the population, and aims to change social norms. Nevertheless, individuals are less motivated to change and the individual health benefits are low.
- In the framework of a policy of social justice, the consequences of these communication choices should be anticipated in terms of social inequalities in health; studies agree in showing that health education campaigns and general population screening tend to increase these inequalities.
- A measure based on proportionate universalism seeks to ensure the fairness of the intervention in developing both universal measures and measures directed specifically at more vulnerable groups (home visits, training, etc.).

• **Practices, attitudes and characteristics of target populations**

When the targeted approach is preferred, knowledge of the practices, attitudes and characteristics of the target population is a prerequisite for developing a communication measure. In this report, three target populations of interest for the three selected hazard/food combinations were the subject of a literature review:

- **Pregnant women:** they actively seek information during their pregnancy but often consider the dietary information intended for them as a source of confusion and uncertainty, especially concerning the choice of foods to avoid. Health professionals are regarded as one of the main sources of information and trust, but they appear insufficiently informed about foodborne microbiological risks; midwives could play a crucial role through their greater proximity to pregnant women.
- **The elderly:** they represent an increasingly large share of the population and, contrary to popular belief, they are liable to change their behaviour after a communication campaign. They associate food with health but are rarely able to identify the risks related to food. Lastly, home deliveries of meals to the elderly have been little studied in France, both regarding the practices of operators (delivery times, information provided to customers during delivery) and users (time until consumption and meal storage conditions).
- **Parents of young children:** the literature research conducted was unable to identify any studies reporting campaigns or experiments aimed at parents of young children, who do not constitute a specific social group. However, until the age of two, the child's diet is raised at consultations with paediatricians or general practitioners, and parents can thus be targeted by a communication measure during the discussions with the health professionals.

3.2. Simulation of the health impact of a communication campaign on the preventive measures that can be applied by consumers

The communication campaigns to be implemented can focus on:

- the prevention of risks related to a hazard/food combination,
- general hygiene measures to reduce the majority of microbiological risks.

➤ **Communication on the hazard/food combinations**

An assessment of the impact of a communication campaign on risk reduction requires a two-step quantitative approach:

- An assessment of the effectiveness of communication campaigns on changes in consumer behaviour. On the basis of the meta-analyses published, the WG found that a multimedia communication campaign contributes to changing 5% to 10% of behaviour in line with the recommendations.
- A quantitative assessment of the impact on risk reduction of the preventive measures applied by consumers. The measures identified are: cooking, appropriate storage, avoidance, and prevention of cross-contamination.

A quantitative risk assessment (QRA) uses models based on: (i) the knowledge of the food chain described, (ii) characterisation of the hazard studied, i.e. the description of its behaviour in the food, and (iii) the probability of occurrence of the adverse effect (dose-response models). The risk is expressed in the number of cases of disease and DALYs (Disability-Adjusted Life Years). The DALY corresponds to the sum of potential life years lost due to premature mortality and/or productive life years lost due to disability(ies). The DALY was calculated using the ECDC's BCoDE software² for haemolytic uremic syndrome (HUS) and on the basis of estimates by Havelaar *et al.* (2012) for listeriosis and campylobacteriosis (see report).

This approach makes it possible to compare the impacts on health risk reduction induced by communication measures to consumers with actions implemented in the industry sectors by the agro-industrial operators (see Table 1).

² Burden of communicable diseases in Europe (BCoDE)

Table 1: Summary of the results of the simulations of the health impact of a communication campaign and measures implemented by the agro-industrial operators

Hazard/food combination	Measures applicable by consumers	Health impact of a communication campaign ¹	Control measures applicable by the professionals	Health impact of measures applicable by the professionals
STEC/minced beef	Thoroughly cooking minced beef for young children	5 to 10% reduction in risk 24 to 47 DALYs gained	1 Log reduction (factor of 10) in the average concentration of bacteria per mixture	64% reduction in risk
<i>L. monocytogenes</i> /smoked salmon ²	Storage of foods at 4°C	5 to 10% reduction in risk	Reduce the use-by date from 28 to 21 days	50% reduction in risk
	Avoidance by pregnant women of foods presenting a risk	38 to 75 DALYs gained	50% reduction in prevalence on leaving the factory	50% reduction in risk
<i>Campylobacter</i> /chicken	Prevention of cross-contamination when preparing the chicken	1.2 to 9% reduction in risk 270 to 1500 DALYs gained	20% reduction in the current prevalence of contamination of chickens	30% reduction in risk
			1 Log reduction in the concentration on raw chicken carcasses	58% reduction in risk

(1) On the basis of a 5 to 10% change in behaviour for the general population; and 10% to 15% for pregnant women

(2) The *Listeria monocytogenes*/smoked salmon combination was used as a study model, given the lack of a QRA model taking into account all the ready-to-eat foods able to support the growth of *L. monocytogenes*. This typical combination can be regarded as representative of all ready-to-eat foods, because of its storage conditions (storage temperature and shelf life) and its microbiological characteristics (low initial concentration of *Listeria monocytogenes* and growth rate among the average for all other foods).

The conclusions are similar for all three hazard/food combinations, namely:

- Due to the only slight effect on changes in behaviour, a communication campaign on the risks associated with a specific hazard/food combination would have little impact on risk reduction;
- The levers to risk reduction are mainly found in the actions within the industry sectors.

➤ **Communication on general hygiene measures**

The application of general hygiene measures by consumers would have an impact on several hazard/food combinations. In order to assess the impact of a communication campaign focusing on these preventive measures, the following approach was adopted:

- Determine the preventive measures contributing predominantly to risk reduction;
- Simulate the impact on risk reduction of a multimedia communication campaign focusing on these hygiene measures.

The preventive measures not applied (or incompletely applied) by consumers that contribute most to the health burden are the adequate cooking of food (27%), appropriate food storage (17%) and prevention of cross-contamination (17%). Lastly, 14% of the health burden is not attributable to any specific practices (food contamination) and 8% is due solely to consumer susceptibility.

The simulation of a communication campaign on these general hygiene measures shows a 2.8% to 5.6% reduction in the health burden if 5% to 10% of consumers change their behaviour. Adequate cooking, complying with storage conditions and preventing contaminant transfers account for 80% of this reduction. Avoidance of foods presenting a risk by 10 to 15% of vulnerable populations would reduce the risk by 0.8 to 1.2%.

3.3. Assessment of the cost-effectiveness of measures for the prevention of microbiological risks

Risk prevention policies are most often assessed on the basis of a cost-effectiveness analysis (CEA). A CEA aims to determine the measure leading to a (non-monetary) objective while minimising costs or, conversely, while maximising an effect for a given budget.

Data on the costs of measures, whether a multimedia communication campaign or a targeted campaign via health professionals, are limited. The costs of campaigns vary according to numerous criteria (objective, target, chosen media strategy, repetition). Orders of magnitude have been determined from information provided by the National Institute for Prevention and Health Education (INPES). The cost of a multimedia communication campaign for the general public (for example on nutritional guidelines) is of the order of 3 to 5 million euros for three weeks. If this campaign is repeated over three years, the total cost is then 9 to 15 million euros. It was not possible to estimate the cost of a communication campaign implemented via health professionals.

The indicator of effectiveness adopted is the DALY. In a CEA, the measures are assessed by the ratio between the gains in DALYs and the additional costs generated. A cost-effectiveness threshold is generally used to delineate the range of acceptable solutions.

➤ Cost-effectiveness of prevention measures: act on the food supply or on consumer behaviour?

The results of the simulations carried out show that the measures taken in the industry sectors are more effective than the communication campaigns on risk reduction. The cost of the proposed measures was however not assessed in the framework of this expert appraisal due to the lack of available data.

In the case of prevention of contamination by *Campylobacter* in the poultry sector in the Netherlands, the comparison of the effects and the cost-effectiveness of actions implemented at the level of the farm, the production phase and the consumer favours the measures in the industry sectors (Havelaar *et al.*, 2007, Mangen *et al.*, 2007).

➤ Cost-effectiveness of a communication campaign on the preventive measures

The WG adopted the cost-effectiveness threshold of €100,000/DALY proposed in the work on prevention of *Campylobacter* in the Netherlands (Mangen *et al.*, 2007). Other thresholds are proposed in the literature (OECD \$50,000; WHO: 3 GDP/capita). The General Commission for Policy Planning (CGSP)³ has estimated that the reference value for a year of life in good health in France is €115,000₂₀₁₀.

Furthermore, because of the difficulty of rigorously establishing the cost of communication campaigns able to induce a 5 or 10% change in behaviour in the population, the WG did not assess the cost-effectiveness of each intervention but chose to estimate the maximum amount it would be acceptable to pay for such a campaign so as to reach the cost-effectiveness threshold of 100,000 Euros/DALY (see Table 2).

³ Report of the mission chaired by Émile Quinet - "L'évaluation socioéconomique des investissements publics" ["The socio-economic assessment of public investments"] - September 2013

Table 2: Maximum acceptable cost of communication campaigns to ensure that interventions are cost-effective at the threshold of €100,000/DALY

	Assumptions of the impact on changes in behaviour	DALYs gained	Maximum cost (million euros)	
			Multimedia communication campaign aimed at the general population	Multimedia communication campaign aimed at a target population
STEC/minced beef	5%	24	2.4	
	10%	47	4.7	
<i>Listeria monocytogenes</i> /ready-to-eat foods able to support its growth	5%	38	3.8	1.2 ^a
	10%	75	7.5	3.7 ^a
<i>Campylobacter</i> /poultry	5%	270	27	
	10%	1500	150	

^a According to the results of the modelling, the risk (DALY) is reduced by 5% when 10% of pregnant women apply the measure and by 10% when 15% of them comply with avoidance of foods presenting a risk.

The maximum costs of communication campaigns required to prevent microbiological risks in a cost-effective way vary widely according to the hazard/food combinations. These estimates give orders of magnitude. They show in particular that communication campaigns aimed at the general population on hazards corresponding to a major health burden such as *Campylobacter* may be cost-effective, in the light of the cost of communication campaigns estimated at 9 to 15 million euros. The maximum amounts allocated to communication campaigns on the *E. coli* STEC and *L. monocytogenes* risks are relatively low and suggest that these amounts would not be sufficient to conduct a cost-effective action able to modify 5% of consumer behaviour. However, these estimates are made by hazard/food combination and do not take into account the impact of applying the measures (appropriate storage of food, thorough cooking of minced beef, prevention of cross-contamination) on other risks. These estimates also show, as in the case of the prevention of listeriosis, that the acceptable costs of campaigns for targeted actions are lower than those required in the general population. It should be remembered, however, that the criterion of cost-effectiveness is not the sole decision criterion in the choice of public health action. In addition, the decision to set the cost-effectiveness threshold at €100,000 per DALY was made here primarily in order to be able to compare the systems: the public authorities (risk managers) are responsible for setting the threshold of action that they deem relevant.

3.4. Possible communication strategies according to the target populations and the complexity of the measures to be implemented

In order to identify which communication strategies to prioritise according to the objectives, the following criteria were considered: whether or not to target a specific population, the ease of reaching the target population (for example, it is easy to reach pregnant women via the medical monitoring networks) and the complexity of the message to be communicated (avoidance, or storage of food at 4°C are considered to be of low or moderate complexity, while prevention of cross-contamination is regarded as a complex message to convey). For each of the cases, the dissemination of a communication campaign is considered while bearing in mind the maximum amount of a "cost-effective" campaign (see Table 3).

The recommendations presented below assume that the risk reduction measures available are implemented, to the extent possible, by the professional sectors.

Table 3: Summary of proposed communication strategies

Risk	Target	Preventive measure	Actions considered	
			Actions whose cost-effectiveness was estimated (*)	Actions whose cost-effectiveness could not be estimated
HUS in young children	Parents of young children	Cooking beefburgers thoroughly	Conducting a multimedia communication campaign in the general population, with a component for young children: <i>probably not cost-effective**</i>	Considering the feasibility of deploying actions in the environment of consumers (nudges) Integrating the message in the information schemes that already exist (e.g. PNNS)
Listeriosis	Pregnant women Immuno-compromised individuals	Avoidance of foods presenting a risk	Conducting a multimedia communication campaign in the target population: <i>probably not cost-effective**</i>	Integrating the message in an interview with a medical, paramedical or social professional associated with an information medium Strengthening the training of these personnel <i>In order to be cost-effective, these actions should not exceed the threshold of €1.2M to modify the behaviour of 10% of pregnant women</i> Considering the feasibility of deploying actions in the environment of consumers (nudges)
Listeriosis	General population	Storage of food at a temperature < 4°C	Conducting a multimedia communication campaign in the general population: <i>probably not cost-effective**</i>	Considering the feasibility of deploying actions in the environment of consumers (nudges)
Campylobacteriosis	General population	Preventing cross-contamination Cooking	Conducting a multimedia communication campaign in the general population: <i>definitely cost-effective**</i>	Integrating the message in the information schemes that already exist (e.g. PNNS) Considering the feasibility of deploying actions in the environment of consumers (nudges)
Foodborne microbiological risks	General population	Cooking Storage Preventing cross-contamination Avoidance of consumption		Conducting a multimedia communication campaign in the general population on "good hygiene practices" <i>On the basis of the assessment of a communication campaign on the risk of campylobacteriosis, such action certainly seems cost-effective</i> Integrating the message in the informational schemes that already exist Considering the feasibility of deploying actions in the environment of consumers (nudges) Developing school education programmes

(*) Taking into account the uncertainty about assessing the costs of campaigns

(**) In relation to the cost/effectiveness threshold of €100,000/DALY

Bearing in mind the uncertainties taken into account in this assessment, the results of the cost-effectiveness assessment of campaigns for the *Campylobacter*/poultry combination seem to favour the development of a

communication campaign aimed at the general population, focusing not on a hazard/food combination but on all the microbiological risks. The three preventive measures with the greatest impact on reducing the overall disease burden (cooking, appropriate storage, prevention of cross-contamination) could be communicated in the framework of a campaign on general hygiene measures designed to act on the majority of microbiological risks. The WG was not able to assess the number of DALYs for all of the microbiological risks but it is reasonable to expect that the DALYs gained are greater than those assessed only in the framework of the prevention of campylobacteriosis.

➤ **The case of the prevention of infant botulism associated with honey**

The available data could not be used to quantitatively assess the impact of a communication campaign on the prevention of infant botulism associated with honey. The Working Group therefore adopted a qualitative approach. Infant botulism, which affects newborn babies and infants under 12 months of age, is the consequence of ingestion of spores of *C. botulinum*. In the majority of cases of infant botulism, the origin of the spores is unknown. Honey is the only food described in the literature as being associated with infant botulism. Between 2010 and 2014, six cases of infant botulism were reported in France, including two cases with possible consumption of honey.

The ingestion of honey by children less than a year old should be considered more in terms of childcare practices than dietary consumption. Honey is given to infants, most often on a dummy, to calm crying and coughing and help them fall asleep.

One measure to prevent this risk can be regarded as simple to implement; the avoidance of honey in infants under one year of age. The population that could be targeted by the communication is limited (parents of infants) and easily accessible via health professionals. Nevertheless, there is very little public awareness of this risk and it runs contrary to the positive image of honey, which may result in "resistance" on the part of both consumers and producers.

Labelling has been implemented by some European countries (Belgium, Great Britain, Switzerland and Finland). Nevertheless, no data are available on the impact of such labelling or more generally on labelling in the area of microbiological risks.

Recommendations of the collective expert appraisal

The recommendations listed have not been prioritised.

➤ **General recommendations on the implementation of communication strategies**

- Because communication only has a slight effect on changes in behaviour, a risk reduction strategy should as a priority explore the feasibility of improving control measures within the production sectors. Such improvements are not always possible and could have consequences in terms of an increase in price of the products and a transfer to consumption of lower quality products.
- Because a combination of different means of disseminating information increases the effectiveness of the communication, priority should be given to "multi-channel" (media, medical personnel, consumer associations, etc.) and "multi-place" (places of purchase, family, work, school) dissemination, addressing both the individual and their environment, as well as to encouraging actions over the long term. Providing information relating to health protection on a public or private website does not constitute a sufficient communication action.
- Any decision about a communication strategy should be preceded by a debate about the choice between a communication intended for a target population and/or a general population, and should take into account the potential negative consequences (optimism bias, stigmatisation of a population, increase in social inequalities in health, etc.).
- The actions chosen should be based on the best possible knowledge of actual behaviour related to risk practices.

- The actions chosen should refer explicitly to a behavioural model backed by evidence. Accordingly, communication strategies should be based on:
 - o the perceived control of risks and the perceived ability to adopt the recommended behaviour;
 - o the development of opportunities, i.e. the conditions that make the behaviour possible; the deployment of nudges for developing opportunities should be explored;
 - o strengthening consumer knowledge is necessary and should be pursued, but it is not sufficient to permanently change behaviour and effectively reduce the risks.

➤ **Recommendations on the implementation of a communication strategy aiming to reduce foodborne microbiological risks**

- In spite of the uncertainties, the results of estimates of the cost-effectiveness of communication campaigns show that probably the most cost-effective campaign would be one on general hygiene measures (cooking, appropriate storage, prevention of cross-contamination) as well as avoidance of risky foods by susceptible populations, in order to reduce the majority of microbiological risks.
- This campaign should then be carried out over several consecutive years in media terms and would require working with communication professionals to express the scientific arguments in understandable language and facilitate the implementation and follow-up of the recommendations. The advantage of such an action is that it is able to plan for different objectives (for example, improve hygiene in the kitchen, prepare a barbecue) and target specific populations (for example, young children, the elderly, etc.) in the framework of a multi-year plan.
- The recommendations on general hygiene and behaviour related to food safety should be systematically included in campaigns on nutrition (for example in the framework of the PNNS) in order to propose coherent general dietary recommendations.
- These recommendations should be included in existing educational programmes on food, such as *La Semaine du Goût* or the educational pathway on health, in order to improve knowledge of the subject among young children.
- It may also be necessary to continue to strengthen and consolidate knowledge on microbiological risks in food among medical, paramedical and social workers, to enable them to provide better information to patients.

➤ **Recommendations on the prevention of infant botulism associated with honey**

- A recommendation for parents of infants should be introduced in the health record book. Practices using the medicinal properties of honey should be proscribed for infants under one year of age.
- The knowledge of health professionals should be strengthened and early childhood professionals should be informed more broadly.
- Beekeepers should be targeted via their professional networks to ensure that they inform their families and customers.
- It seems essential to ensure that beekeepers' websites do not contradict institutional communication; in particular, they should not promote the medicinal effects of honey for infants under one year of age; a charter on precautionary communication on the benefits of honey could be drawn up.
- The use of labelling as a first choice to reduce this risk is not a preferred strategy.

➤ **Recommendations intended to overcome the lack of knowledge and information available**

There is currently no analysis of social inequalities in health related to foodborne microbiological risks in France. To rectify this situation, data need to be collected, in particular:

- It would be interesting to consider changing the systems for monitoring foodborne infections in order to integrate the socio-demographic characteristics of affected people and their families. The aim of such

data collection would be to identify whether there were specific vulnerable populations in order, if necessary, to adapt public policies.

- With regard to nutrition, the nutritional section of the Observatory of Food Quality (Oqali) monitors changes in the nutritional characteristics of food products over time. This monitoring of the quality of the food supply means that changes made by the economic players can be characterised according to the categories of products as well as the ranges of products (entry-level, middle or top of the range) and types of brands (national, own-brand, hard discount). Knowledge of this type may be useful in the area of food safety to be able to interpret any differences that may appear in disease prevalence according to the social categories.

Research and studies should be supported in several areas:

- the effectiveness of the actions aimed at changing behaviour; the assessments should be integrated systematically in the design and the communication strategy, especially in terms of a cost-effectiveness analysis or an impact study;
- the health determinants, including socio-demographic and cultural determinants, in behaviour related to foodborne microbiological risks;
- the effectiveness of labelling on microbiological risks;
- the use of nudges in the area of food safety (provision of meat thermometers, positioning wash basins at the entrance to canteens, colour-coded chopping boards, etc.); their impacts should also be assessed;
- the use of social media, apps, connected objects in the area of foodborne microbiological risks;
- communication to vulnerable populations and the elderly;
- communication to immunocompromised individuals after their return home from hospital;
- the effectiveness of school and/or educational programmes.

Lastly, a specific study on the feasibility conditions of a communication campaign on hygiene measures, intended for the general population and with the aim of reducing the majority of microbiological risks, could be carried out in partnership with communication professionals.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety endorses the conclusions of the BIORISK CES and the Working Group on "Consumer information on biological risks related to foods".

Marc Mortureux

KEYWORDS

Consumer information; communication strategies; microbiological risks.

Annex 1 : Request letter



2012-SA-0118

COURRIER ARRIVE

- 4 MAI 2012

DIRECTION GENERALE

MINISTRE DE L'AGRICULTURE, DE L'ALIMENTATION, DE LA PÊCHE,
DE LA RURALITÉ ET DE L'AMÉNAGEMENT DU TERRITOIRE

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Service de l'alimentation
Sous-direction de la Sécurité Sanitaire des
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Le Directeur général de l'alimentation
à
Monsieur le Directeur général
de l'Agence nationale de sécurité sanitaire
de l'alimentation, de l'environnement et du travail
27-31 avenue du Général Leclerc
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94701 MAISONS ALFORT CEDEX

Paris, le 2 - MAI 2012

Objet : Saisine de l'ANSES – Mentions de recommandations de consommation sur l'étiquetage des aliments pour la prévention des dangers biologiques

Conformément à l'article L. 1313-1 du code de la santé publique, j'ai l'honneur de consulter l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail sur la pertinence de faire figurer des recommandations de consommation sur l'étiquetage des denrées alimentaires pour la prévention de certains dangers biologiques.

En début d'année 2010, l'Institut de veille sanitaire (InVS) signalait l'augmentation des cas de botulisme infantile chez les jeunes enfants âgés de moins de 12 mois, notifiés par la Déclaration Obligatoire (DO) en France depuis 2004 : 7 cas de botulisme infantile sont en effet survenus entre 2004 et 2009, à raison d'un cas par an jusqu'en 2008 et deux cas en 2009. Aucun cas n'a été enregistré pour la période 1991-2003 et un seul cas a été publié avant 1991. Le principal facteur de risque alimentaire identifié pour cette forme de botulisme est la consommation de miel. L'InVS, précisait, au vu des données épidémiologiques les plus récentes, qu'une sensibilisation des parents de nourrissons et des professionnels de santé concernés sur le risque de botulisme infantile associé à la consommation de miel s'avérait nécessaire. La question de la pertinence et de la faisabilité de la mention de ce risque sur les pots de miel destinés à la vente en France était par ailleurs soulevée.

Dans une note adressée le 16 avril 2010 aux trois directeurs généraux concernés (DGS, DGCCRF, DGAL), vous avez attiré leur attention sur l'intérêt d'un étiquetage de précaution sur les conditionnements de miel.

Conformément à ses recommandations, la DGCCRF a élaboré un projet de décret modifiant le décret n°2003-587 du 30 juin 2003 pris pour l'application de l'article L. 214-1 du Code de la consommation en ce qui concerne le miel. Ce décret prévoit d'intégrer une mention spécifique d'étiquetage du miel destiné au consommateur final sous la forme : « Ne pas donner au nourrisson de moins de 12 mois ».

Enfin, en réponse à la transmission, en juillet 2011, de l'étude initiale du guide de bonnes pratiques d'hygiène « apiculture » relatif à l'hygiène de production de miel, l'avis rendu par l'agence le 15 mars dernier, sous la référence saisine n°2011-SA-0170, rappelle en conclusion « l'importance d'une mention d'étiquetage concernant la consommation du miel pour les nourrissons de moins de 12 mois, afin de prévenir tout risque de botulisme infantile ».

Les informations récentes communiquées par l'InVS montrent qu'aucun cas de botulisme infantile n'a été recensé en 2010. Un cas a été signalé en 2011 (chez un nourrisson qui aurait peut-être consommé du miel une fois en quantité très limitée), et un cas depuis le début de l'année 2012 (sans lien avec la consommation de miel). Si des cas très rares continuent à être diagnostiqués, il n'est donc pas observé de franche augmentation. Il est par ailleurs possible que les cas soient mieux identifiés qu'autrefois, même si cette hypothèse ne peut être confirmée à ce jour.

La DGAL s'interroge sur les bénéfices en termes d'amélioration de la santé publique d'un étiquetage obligatoire pour le miel destiné au consommateur final. Les représentants des organisations professionnelles de la filière apicole ont exprimé à plusieurs reprises leurs inquiétudes face à une telle mesure, qu'ils considèrent comme disproportionnée par rapport au risque encouru. Si le seul facteur de risque alimentaire identifié pour cette forme de botulisme est en effet la consommation de miel (qui n'a été confirmée que dans un seul cas), d'autres sources de contamination sont possibles du fait du caractère ubiquitaire des spores de *Clostridium botulinum*.

Dans le contexte réglementaire européen du Paquet Hygiène, la stratégie de gestion des risques sanitaires est avant tout fondée sur la prévention des dangers à toutes les étapes de la chaîne alimentaire. Le contrôle des produits finis, les mesures de décontamination en fin de process ou d'étiquetage spécifique destiné à alerter les consommateurs sensibles sur les risques potentiels liés au produit pourraient en effet s'avérer faussement sécuritaires si les opérateurs se sentaient ainsi dédouanés de leur responsabilité primaire et n'axaient plus leurs efforts sur la prévention des contaminations en amont des filières et la maîtrise des risques à chaque étape de la chaîne alimentaire. Même si une information spécifique sur l'étiquetage des denrées alimentaires, notamment pour les aliments consommés crus, pourrait sembler avoir un impact complémentaire positif, les modalités de sa mise en œuvre doivent faire l'objet d'une concertation préalable entre les différents acteurs (experts scientifiques, administrations, professionnels) afin de permettre aux ministères concernés d'adopter les mesures de gestion les plus pertinentes pour la protection de la santé publique sans démobiliser les filières professionnelles dans leurs démarches de maîtrise préventive des dangers, notamment biologiques.

La stratégie de gestion des risques sanitaires représentés par les aliments doit en conséquence reposer sur l'association des mesures les plus pertinentes destinées aux exploitants du secteur alimentaire, aux administrations, aux professionnels de santé et aux consommateurs. L'impact des mesures mises en place, en termes de bénéfices pour la santé publique et de contraintes pour la filière concernée, doit par ailleurs être proportionné au risque considéré.

Ainsi, à ce stade de la réflexion, il ne nous apparaît pas opportun de rendre obligatoire un étiquetage spécifique des pots de miel déconseillant sa consommation aux nourrissons de moins de 12 mois, sans que la valeur ajoutée de cette disposition par rapport à d'autres possibilités (information via les professionnels pédiatriques ou de la petite enfance par exemple) n'ait été démontrée. En effet, si cette question se pose pour le miel et le botulisme infantile, elle peut être étendue à des cas de figure similaires tels les *Escherichia coli* STEC dans les viandes hachées de bœuf ou les *Listeria monocytogenes* dans les produits au lait cru. Un lien direct entre la consommation de certains aliments par des populations sensibles et la survenue de cas d'infections d'origine alimentaire (SHU, listériose, salmonellose) est en effet d'ores et déjà établi sans ambiguïté, avec une incidence nettement plus élevée que pour le botulisme infantile.

L'InVS vient par ailleurs de nous faire parvenir une copie du rapport d'investigation de l'épidémie d'*Escherichia coli* producteurs de Shiga-toxine (STEC) O157:H7 survenue dans le nord de la France en juin-juillet 2011. Dans sa conclusion, ce rapport souligne l'importance de la recommandation de cuire à cœur les viandes hachées de bœuf, en particulier lorsqu'elles sont destinées à être consommées par des jeunes enfants, cette recommandation apparaissant comme insuffisamment connue des parents concernés, comme en témoignent les 18 cas de syndrome hémolytique et urémique (SHU) survenus lors de cette épidémie. L'InVS insiste également sur la nécessité d'améliorer la communication et la diffusion des recommandations de consommation des viandes hachées et préparations à base de viande hachée auprès des populations sensibles pour diminuer la fréquence des infections à STEC. Un étiquetage obligatoire conseillant une cuisson à cœur des produits concernés pour ces populations pourrait s'avérer pertinent.

En conséquence, je vous saurais gré de bien vouloir répondre aux questions suivantes :

- Quelle méthodologie appliquer pour définir de façon hiérarchisée et proportionnelle au risque les mesures destinées à chacun des acteurs (exploitants du secteur alimentaire, professionnels de santé, consommateurs), et comment les associer pour aboutir à une efficacité optimale du dispositif de maîtrise sanitaire en termes de bénéfices pour la santé publique, tout en restant proportionné aux contraintes pour la filière considérée ?
- L'agence peut-elle établir une liste des couples dangers / aliments prioritaires pour lesquels un étiquetage spécifique (référence au danger considéré ou conseils et précautions d'utilisation pour les populations sensibles) rendu obligatoire serait de nature à améliorer de façon sensible la protection des consommateurs, après avoir examiné les autres possibilités d'information ciblée des publics concernés ?

Je souhaiterais disposer des éléments de réponse pour le 31 octobre 2012. Mes services se tiennent à votre disposition pour vous apporter toute information complémentaire.

Je vous remercie de bien vouloir accuser réception de la présente demande.

Le Directeur Général de l'Alimentation



Patrick DEHAUMONT