



Press kit

Results of the national surveillance study on
dietary exposure
to chemical substances
(Total Diet Study 2 - 2006-2010)

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Dietary exposure to chemical substances ANSES publishes the results of the second French Total Diet Study

The Agency recently undertook to provide the broadest snapshot that has ever been taken of nutritional intakes and dietary exposure to chemical substances in the French population, in order to assess the long-term risk related to this exposure. Overall, TDS2 confirmed adequate levels of control over the health risks associated with the potential presence of chemical contaminants in foods in France, on the basis of the available regulatory thresholds and Health-Based Guidance Values.

However, for some population groups, this study also highlighted risks of exceeding the toxicological thresholds for certain substances such as lead, cadmium, inorganic arsenic and acrylamide, indicating that efforts are required to reduce exposure. Since these risks are often linked to high consumption of a given food or food group, ANSES emphasises the importance of a diversified and balanced diet by varying foods and the quantities consumed.

Lastly, the study highlights a need to improve scientific toxicological and analytical knowledge for a set of substances that are not regulated to date, but are found in foods, and for which it is not at present possible to draw a risk assessment conclusion.

Study method

This Total Diet Study (TDS), launched in 2006, was based on WHO references and studied 445 chemical substances (pesticides, heavy metals, contaminants resulting from human activities, phytoestrogens, additives, etc.) including 12 minerals, in 20,000 samples of foods belonging to 212 different categories. Nearly 250,000 analysis results were thus collected, and were cross-referenced with the food consumption data from the Agency's INCA2 study, in order to estimate consumers' overall dietary exposure to these various substances and to compare them, when applicable, to the available toxicological thresholds considered as posing no health risks.

This study was undertaken by ANSES thanks to the support of the Ministries in charge of Food, Health and Consumer Affairs, with a contribution from the French Observatory for Pesticide Residues. The TDS2 survey is the result of work that lasted over 4 years as follow-up to a first similar study that had been undertaken on a smaller scale from 2001 to 2005 (TDS1), and is an unprecedented source of information on account of the number of substances that were tested. The Report associated with the Agency's Opinion explains the method that was used and presents, for each substance taken into account (contaminants and minerals), the substance's origin, a hazard characterisation, the chief foods that contribute to consumer exposure, and a risk assessment related to this exposure on the basis of the available Health-Based Guidance Values.

First results of this study

- **Adequate levels of control over health risks:** for 85% of the substances that were assessed, risk can be ruled out for the general population, as consumer exposure always remained below the available Health-Based Guidance Values (HBGVs).

Moreover, when screening for pesticides, for a total of 283 active plant protection substances, the results confirmed the data of surveillance and monitoring plans which show a conformity level of over 95% in relation to the regulatory thresholds.

- **Downward and upward trends versus previous studies:** compared to the results of TDS1 (2000-2004), positive trends were observed for substances such as lead and certain persistent organic pollutants: for example, for dioxins and PCBs, the most recent results show that the percentage of adults and children potentially exposed at levels greater than

the toxicological threshold considered as being risk-free for long-term exposure (HBGV) decreased from 20 to 28% in 2005 to less than 1% today. This favourable trend is notably the result of the banning of PCBs in France for the past 15 years and the introduction of regulations governing the entire food chain for both dioxins and PCBs. Conversely, versus TDS1, exposure increased for certain substances such as cadmium, aluminium, chromium, and certain mycotoxins such as deoxynivalenol (DON).

- Risks of exceeding thresholds for around a dozen substances: for around a dozen substances, risk of exceeding the HBGV cannot be excluded for certain categories of the population, which are often characterised by high consumption of certain specific foods: this was the case for certain inorganic compounds (cadmium, inorganic arsenic, aluminium, methylmercury), sulfites (an additive mainly found in wine), one mycotoxin (deoxynivalenol, or DON, and its derivatives), acrylamide (a heat-induced contaminant formed during cooking) and one pesticide (dimethoate). It was also the case for lead and PCBs, despite the decreased exposure observed versus TDS1. These findings are consistent with those established by other authorities that have assessed the risks related to these substances (EFSA, WHO).

Moreover, note that the HBGVs for most of these substances have been revised downward over the past few years, after the most recent available scientific data on their potential health effects were taken into account.

- A diversified diet to prevent risks of excessive exposure: some foods were identified as contributing strongly to exposure to several of the substances for which risk cannot be excluded. These were highly contaminated foods that are consumed in significant quantities by very small populations (tuna in particular). They were also foods that are not necessarily highly contaminated but that are heavily consumed. For example, for some substances, the chief contributors were cereals and cereal derivatives (cadmium, lead, aluminium, DON and derivatives) coffee for adults (copper, inorganic arsenic and acrylamide) and, to a lesser extent, milk for children (lead, zinc). Risk management measures aimed at reducing the levels of these contaminants in the main contributing foods (regulations and actions targeting the industry) should be pursued.

Other foods contributed significantly to exposure to certain substances since they are the foods that contain the highest levels. This was the case of fatty fish, for dioxins and PCBs, and tuna, for methylmercury. For these foods, it is advisable to follow the fish consumption recommendations issued by ANSES. These recommendations ensure optimal coverage of nutritional requirements while limiting the risk of over-exposure to chemical contaminants.

- Nutritional risks of excess or inadequate intake for certain minerals: for sodium, risk of excess intake cannot be ruled out for the general population. It would thus be advisable to continue efforts to reduce intake, by reducing the salt content of the main contributors (bread and dried bread products, delicatessen meats, cheese, etc.), in accordance with the guidelines of the French National Nutrition and Health Plan.

Risk of insufficient intake could not be ruled out for calcium, magnesium, iron, selenium, copper and zinc. Risk of excess intake cannot be ruled out for zinc and copper.

Regarding phytoestrogens, risk can be ruled out for the general population. Nevertheless, it would be advisable to undertake specific studies to assess intake levels in large consumers of soy-based products.

Required follow-up action

Some of the substances that were tested in TDS2 could not be assessed, since no formal risk assessment conclusions can be made in the current state of knowledge: supplementary work will be necessary to improve analytical methods and define Health-Based Guidance Values.

To continue processing the data collected in this study, cross-analyses will be undertaken with the biological surveillance data available in the framework of the French National Nutrition and Health Study (ENNS), which was recently implemented by InVS to better characterise actual exposure levels and to refine the assessment of health risks.

Moreover, it will be necessary to re-examine the current study's conclusions in light of the re-assessment of HBGVs for some of the substances that were studied, taking into account, where applicable, endocrine disrupting effects. Moreover, it appears necessary to undertake specific studies to estimate exposure levels in certain sensitive population groups, such as young children and pregnant women. In this context, a specific infant TDS survey was launched by the Agency in 2010 to examine the diets of children under the age of 3 years.

Given that cumulative effects were taken into account only when toxicological interpretations were available, work needs to be undertaken in order to improve the understanding of these effects. Likewise, it would be advisable to further take into account routes of exposure other than food in the risk assessment of the analysed substances.

As far as consumers are concerned, this study shows that nutritional and chemical risks can be minimised by avoiding the regular consumption of a small number of foods in large quantities. In this respect, the study confirms recommendations encouraging consumers to diversify their diets.

This study's results will be used for health purposes by the future Food Observatory under the French National Food Plan. Lastly, the study provides a very broad snapshot of consumer exposure to pesticide residues: these data will supplement the data of the French Observatory for Pesticide Residues (ORP) and correspond to one of the priority actions under the French National Environment and Health Action Plan (PNSE 2).

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Why undertake a Total Diet Study? How?

Knowledge of potential food contamination and of the nutritional composition of foods is a major health and nutritional policy tool. It is used to understand dietary exposure to microbiological, chemical and physical agents as well as nutritional intake in the population. It is therefore possible to assess risks related to this exposure and ultimately make enlightened risk management decisions (monitoring and regulations) at the national, European and international levels.

In France, food contamination is monitored on a regular basis in a regulatory framework through monitoring and surveillance plans that are managed by the competent ministries. This knowledge can be supplemented and strengthened by Total Diet Studies.

Why undertake a TDS?

Undertaken at the national level, **Total Diet Studies (TDSs)** primarily aim to **monitor 'background levels' of dietary exposure** in populations to substances of interest in terms of public health. Two types of substances are thus monitored: firstly, contaminants – pesticide residues, environmental contaminants, heat-induced contaminants, natural toxins, etc. – in addition to additives, for which the aim is to ensure that the population's exposure level does not pose long-term risks; and secondly, nutrients – particularly minerals and trace elements – for which the aim is to ensure that the population's requirements are met without exceeding the defined intake limits.

Using a standardised method that has been recommended for several years by the World Health Organization (WHO), these studies are thus designed to assess the mean quantity of a chemical substance that is ingested by the general population and within various sub-groups (region, age, etc.). This type of study also facilitates international comparisons related to consumer exposure. They are thus a major scientific tool for decision-making at the European and international levels regarding the regulation of chemical substances, the safety of food products, and consumer protection. TDS surveys are therefore implemented by numerous countries in order to assess nutritional and health risks.

TDS surveys around the world

Some thirty countries have undertaken or regularly undertake TDS surveys, including Australia, Cameroon, Canada, the United States, Finland, Italy, Portugal, the Netherlands, the Czech Republic and the United Kingdom

How is a TDS undertaken?

A Total Diet Study consists in taking samples of foods which are regularly consumed by the population, from different outlets, and which are representative 'shopping baskets' of food consumption, preparing them as they are consumed, i.e. washed, peeled and cooked if necessary, grouping them into 'composite samples', homogenizing them, and testing them for a series of toxic substances and nutrients. To the extent that the foods are analysed 'as consumed', the advantage of this method is that it

provides more realistic 'background level' exposure data than approaches based on food standards or the results of monitoring and control programmes.

The food samples, which are collected and prepared 'as consumed' (washed, peeled, cooked, etc.), are then analysed in order to screen for various substances of interest. This stage is undertaken in collaboration with National Reference Laboratories (NRLs) and with laboratories specialised in testing for various categories of substances.

The population's dietary exposure to the various substances is then calculated by combining the national food consumption data with the contamination data obtained through previous analyses.

French Total Diet Studies

A first French Total Diet Study (TDS1) was undertaken between 2000 and 2004 by the French National Institute for Agricultural Research (INRA), in collaboration with the French Food Safety Agency (AFSSA). Analysing 30 substances, it reviewed the population's exposure to inorganic contaminants and minerals, as well as mycotoxins.

In 2006, the Agency issued an internal request in order to undertake a second study, including 445 substances that would require updated or in-depth knowledge for public health purposes. This new study was financed by the Ministries in charge of Food, Health and Consumer Affairs, with a contribution from the French Observatory for Pesticide Residues. A budget of nearly 5 million euros was thus allocated to perform all of the necessary samples and analyses. All of the substances tested in TDS1 were included in this new study in order to monitor trends in the population's exposure. Many others were also added, in order to fill in gaps in knowledge. In particular, numerous non-regulated substances were included in the study to collect data to identify potential emerging risks.

TDS2: the most extensive study ever undertaken

In accordance with WHO's recommendations, Total Diet Studies are undertaken by various countries. Some thirty countries implement or have regularly implemented TDS surveys. However, the second French Total Diet Study, on account of the wide range of tested substances combined with the proportion of the French diet it covers, is one of the richest and most comprehensive studies that have even been undertaken in the world. It is thus a considerable source of information that is at everyone's disposal.

90% of the French diet covered

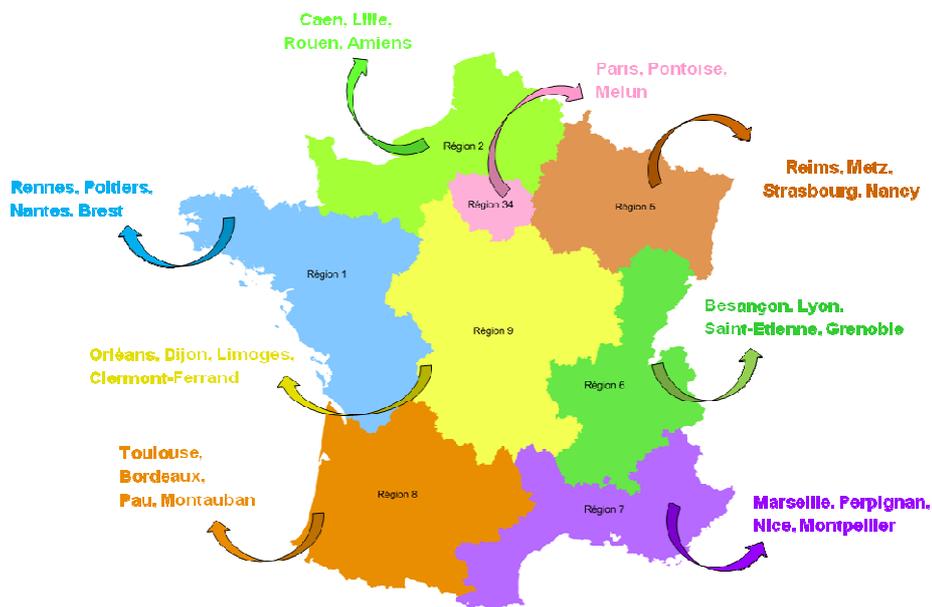
In order to best cover the French diet, the second French Total Diet Study (TDS2) used the food consumption data collected in the INCA 2 study. This study, which was undertaken by the Agency in 2006 and 2007, described the dietary habits of adults and children in France in terms of both foods consumed and quantities. Thanks to these data, ANSES selected both the foods that are the most heavily consumed by the French population (including drinking water) and foods that are not heavily consumed but are likely to contain high levels of the substances to be analysed. Two hundred and twelve food categories were thus selected, covering 90% of the adult and child population's diet. The remaining 10% corresponded to foods that are not heavily consumed by the general population and that did not appear to be likely to significantly contribute to intake and exposure in the general population for the targeted substances, since high-contribution foods were included in the sampling plan.

All of mainland France taken into account

Out of these 212 food categories, 116 were considered as having no or little inter-regional variability. They were sampled in only one region. The 96 others were specifically sampled at the regional level in order to take into account potential variations in composition or contamination among the regions which might reflect, for example, different production and/or animal feeding methods or environmental pressure.

For each selected food category, a sampling plan was followed taking into account consumption habits in the French population: flavour, the product's origin, points of purchase, market shares, etc. Lastly, each sample was acquired at two different periods of the year to take possible seasonal variations into consideration. In the end, around 20,000 foods were purchased all across mainland France (eight regions and around thirty cities), whereas three major cities had been included in the previous study (TDS1).

Regions studied in TDS2 and cities where regional sampling was undertaken



445 substances tested

In the second French Total Diet Study, ten times as many substances were tested as for the first French TDS. Work to identify the substances to be tested was undertaken by ANSES based on a series of criteria: existing risk assessment requirements, the need to describe exposure trends and supplement the description of exposure for certain contaminants, the identification of emerging substances in the literature for which it would be valuable to undertake a risk assessment, the monitoring recommendations formulated by the Agency in its Opinions, and analytical possibilities. In all, 445 substances were tested. These substances may be found in foods because:

- They are naturally present in foods or the environment (phytoestrogens, minerals, metals) or they contaminate the environment either naturally (mycotoxins) or due to human activities (persistent organic pollutants, metals)
- They are used as processing aids (additives) or for agricultural reasons (plant protection products), or they are formed during the production, processing or storage of the raw material or food (heat-induced contaminants).

250,000 analytical results collected

For each product, only the edible part was used to prepare the foods 'as consumed' by the population. Fruits and vegetables were washed, and vegetables, meat and seafood products were cooked: braised, pan-fried, grilled, baked, deep-fried, etc. The purchased and prepared foods were then grouped to form 1,319 composite samples representative of the French population's shopping baskets and were analysed by 13 laboratories. Each substance was tested in those foods that were known or assumed to contain it to ultimately produce around 250,000 analytical results.

The substances tested in the French TDS2

In the second French Total Diet Study, 445 substances, grouped into 11 categories, were tested. What were these substances and where do they come from?

Inorganic contaminants or trace elements: these are mostly metals, which are naturally found in the environment (water, soil, etc.) or are the result of human activities. They are found in their inorganic and/or organic form. With the exception of mercury, it is the toxicity of the inorganic forms that causes the greatest concern. These substances are different from minerals in that they are not necessary for the proper functioning of the body.

Examples of trace elements tested for in TDS2 are lead, cadmium, mercury and aluminium.

Minerals: Minerals are chemical elements naturally found in the soil and water; they are required for the proper functioning of the body and participate in various physiological functions.

Examples of minerals tested for in TDS2 are calcium, sodium, iron, copper and zinc.

Dioxins and furans: these groups of compounds are persistent organic pollutants that form during combustion. They can be found in the environment either naturally (forest fires) or as the result of human activities.

PCBs: polychlorinated biphenyls are a large family of over 200 compounds that have been used by industry, as mixtures, for their insulating properties (transformers) and their chemical stability (ink, paint). Banned since 1987, they persist in the environment and can accumulate in the food chain.

Two PCB sub-families were tested in TDS2: dioxin-like PCBs (DL-PCBs) and non-dioxin-like PCBs (NDL-PCBs).

Perfluorinated compounds: A large class of hundreds of compounds that have been manufactured since the 1950s, perfluorinated compounds are used in multiple industrial applications and commonly consumed non-food products for their stain- and water-resistant properties. Highly resistant to degradation, they are found in all compartments of the environment and in the food chain.

Examples of perfluorinated compounds tested in TDS2 are PFOA, PFBA, PFPA and PFOS.

Brominated flame retardants: Used to prevent combustion and/or inhibit the spread of fire in various materials, most of these organic compounds made by humans are persistent environmental pollutants.

Examples of brominated flame retardants tested in TDS2 are certain polybrominated diphenyl ethers (PBDEs), certain polybrominated biphenyls (PBBs) and hexabromocyclododecane (HBCD).

Mycotoxins: Produced by certain moulds in the field or during the storage of foodstuffs of plant origin, mycotoxins are natural contaminants found in numerous foodstuffs of plant origin. They can also be found in milk, eggs, meat and offal, if the animals were exposed to a diet contaminated with mycotoxins.

Examples of mycotoxins tested in TDS2 are group B and G aflatoxins, fumonisins B1 and B2, and ochratoxin A and B

Phytoestrogens: This term encompasses several compounds with different structures that are produced by plants but whose structure is similar to that of estradiol, one of the main female hormones.

Examples of phytoestrogens tested in TDS2 are isoflavones, lignans and coumestanes.

Active plant protection substances: Used to make plant protection products (generally called pesticides), these substances are the product's active ingredient. They are used for agricultural reasons.

Examples of active plant protection substances tested in TDS2 are pirimiphos-methyl, parathion and dimethoate.

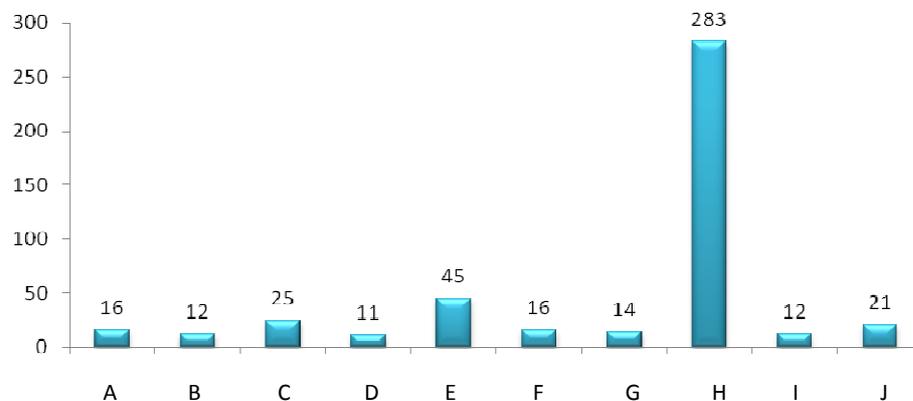
Additives: Added to foodstuffs for technological purposes during the production, processing, preparation, treatment, packaging, transport or storage of foodstuffs, additives are found in the composition of finished products.

Examples of additives tested in TDS2 are annatto, nitrites and sulfites.

Heat-induced contaminants: Substances that form during food processing (drying, smoking, cooking), though some are also found in the environment.

Examples of heat-induced contaminants tested in TDS2 are acrylamide and polycyclic aromatic hydrocarbons (PAHs).

Breakdown of tested substances by category



- A - Inorganic contaminants
- B - Minerals
- C - Mycotoxins
- D - Phytoestrogens
- E - Dioxins, furans and PCBs
- F - Perfluorinated compounds
- G - Brominated flame retardants
- H - Pesticides: active substances
- I - Additives
- J - Heat-induced contaminants

TDS2: the main lessons

By virtue of the number of analytical results that were collected and processed, the second French Total Diet Study is an unprecedented survey that gives a detailed snapshot of levels of contaminants, minerals and trace elements in foodstuffs. Thanks to this information, ANSES was able to assess the population's long-term nutritional intake and dietary exposure to chemical substances. In general, these results show adequate levels of control over health risks, with regard to the available regulatory thresholds and Health-Based Guidance Values, but certain points warrant particular vigilance.

Minerals: efforts be made regarding salt levels

Twelve minerals were tested in TDS2. On the basis of the collected data, the nutritional requirements of the majority of the population appear to be covered. However, TDS2 once again highlighted excess sodium intakes and underlined the importance of continuing efforts to reduce intakes, by reducing the salt content of the main contributing foods (bread and dried bread products, delicatessen meats, cheese, etc.).

Moreover, in certain population categories, the study showed risk of excess intake for zinc (some children) and copper (some adults and children), as well as insufficient intake for zinc (some children especially), iron (women and girls), calcium (adolescents), magnesium (adults and children with the lowest intakes), selenium (the elderly) and copper (some children).

However, on the basis of these data alone, it is not possible to draw a definitive conclusion as to a risk or absence of risk for the general population, as the nutritional requirements related to these substances still need to be explored. In this context, ANSES underlines the importance of using biomarkers to assess the nutritional status of the population.

Chemical contaminants

Overall, the TDS2 results confirm the information available from surveillance and monitoring plans, i.e. that **health risk related to chemical contaminants is generally under control**, with regard to the available regulatory thresholds and Health-Based Guidance Values.

In fact, out of the 445 analysed substances, 433 are chemical substances for which ANSES wanted to examine the long-term risks. On the basis of current toxicological knowledge, 361 substances for which a Health-Based Guidance Value was available were assessed. For 85% of them (307 substances), on the basis of available knowledge and an assessment of dietary intake alone, risk can be ruled out for the general population.

These results should be confirmed by **maintaining surveillance** to verify potential contamination or exposure levels as appropriate. In any case, it is necessary to encourage any efforts that will **reduce levels of contaminants in foods**.

Substances requiring particular vigilance

Nevertheless, **for around a dozen substances or groups of substances, risk of exceeding the Health-Based Guidance Values cannot be ruled out for certain consumer groups**. This is particularly the case for lead, cadmium, inorganic arsenic, aluminium, methylmercury, dioxins

and PCBs, deoxynivalenol (DON) and its derivatives, acrylamide, sulfites and dimethoate. These findings are consistent with those established by other authorities that have assessed the risks related to some of these substances (EFSA, JECFA, FSA, NZFSA, etc.).

Some foods were identified as chiefly contributing to exposure to several of these substances for which long-term risk cannot be excluded. These were heavily contaminated foods that are consumed in significant quantities by very small populations only (tuna in particular), but they also included foods that are not necessarily highly contaminated but are heavily consumed. For example, for some substances, the chief contributors were bread (cadmium, lead, DON and derivatives) and pasta (aluminium), coffee for adults (copper, inorganic arsenic and acrylamide) and milk for children (lead, inorganic arsenic). **Risk management measures aimed at reducing the levels of these contaminants in the main contributing foods (regulations and actions targeting the industry sectors concerned) should be pursued.**

Other foods contributed significantly to exposure to certain substances since they are the foods that contain the highest levels. This was the case of fatty fish, for dioxins and PCBs, and tuna, for methylmercury. For these foods, it is advisable to follow the fish consumption recommendations issued by ANSES^{1,2}. These recommendations ensure optimal coverage of nutritional requirements while limiting the risk of over-exposure to chemical contaminants. More generally, ANSES also recommends the importance of a **diversified and balanced diet by varying the species and origin of foods consumed whenever possible.**

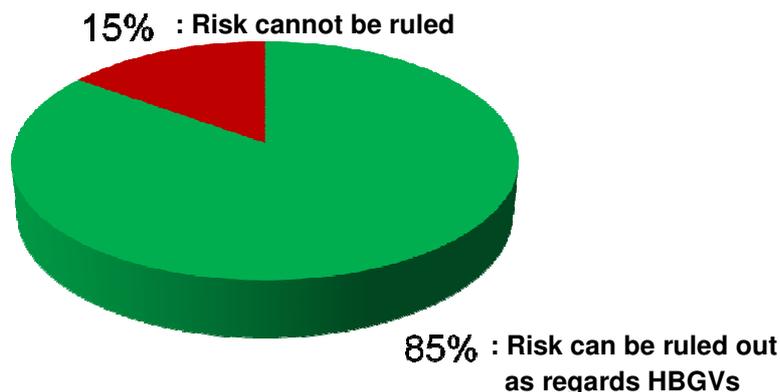
For 72 remaining substances that could not be assessed, in the vast majority of cases (particularly for non-regulated substances), **in the current state of scientific knowledge, it is not possible** to draw a formal risk assessment conclusion: supplementary work will be necessary to improve analytical methods and define Health-Based Guidance Values.

¹ Opinion of the French Food Safety Agency of 14 June 2010 concerning the benefits and risks related to fish consumption

² Opinion of the French Food Safety Agency of 17 April 2009 regarding the interpretation of analytical results from the 2007 chemical contaminant surveillance plan, and particularly mercury testing in lampreys and in various Selachii species

Chemical substances assessed

In TDS2, 445 chemical substances were analysed. Apart from 12 minerals, they were substances that required a toxicological assessment. On the basis of current knowledge, 361 substances for which a Health-Based Guidance Value was available were assessed. For 85% of them (307 substances), risk can be ruled out for the general population. For 15% of the assessed substances, i.e. around a dozen substances or groups of substances, risk of exceeding the Health-Based Guidance Values cannot be ruled out for certain consumer groups.



Identified gaps in knowledge

For some elements, it was not possible to draw a risk conclusion. This was particularly the case for inorganic mercury, tin, gallium, germanium, strontium, silver, tellurium, vanadium, certain perfluorinated compounds, HBCD, 38 pesticide residues and 6 mycotoxins, either in the absence of a robust Health-Based Guidance Value, or due to insufficiently powerful analytical methods for a complete exposure characterisation. For these substances, it would be advisable to **undertake additional toxicological studies or develop new analytical tools**, on a case-by-case basis, in order to remove uncertainty related to risk. For several of these substances, risk management measures aimed at reducing the levels of these contaminants in the main contributing foods (regulations and actions targeting certain industry sectors) should also be pursued.

Several approaches to be explored

In general, it appears necessary to obtain **biological surveillance** data for most of the analysed substances, in order to better characterise actual exposure levels, all routes combined, and refine the assessment of health risks.

In light of recent improvements to toxicological knowledge, particularly regarding potential endocrine disrupting effects, it will be necessary to re-examine this study's conclusions subsequent to the reassessment of certain Health-Based Guidance Values for certain substances.

Moreover, it appears desirable to undertake **specific studies** to estimate exposure levels in certain **sensitive population groups**, such as young children and pregnant women. To that end, an infant TDS, specifically targeting children under the age of 3 years, was recently launched by ANSES.

Given that cumulative effects were taken into account only when toxicological interpretations were available, work needs to be undertaken in order to improve the **understanding of these effects**. ANSES, as well as some of its foreign counterparts, is working on this subject. The results of the Péricle's research programme which is being undertaken by the Agency and will end in 2012 will offer insight into this scientific issue.

Lastly, it would be advisable to further take into account the various **routes of exposure** (air and dust in particular) in the risk assessment of the analysed substances. In this context, the new model of ANSES as a health agency providing a cross-disciplinary approach to health issues takes on its full meaning.

Regulatory standards, toxicological thresholds: key notions

Many notions specific to health and safety are used throughout the TDS2 report. Some have meaning from a toxicological viewpoint and are reference points for assessing risks to the population, while others are regulatory values set by the public authorities to manage these risks on the basis of risk assessments undertaken by agencies like ANSES. Below is an overview of these values.

1- Health-Based Guidance Values: maximum threshold levels

Health-Based Guidance Values (HBGVs) are exposure levels considered to be acceptable in relation to a chemical substance. These values are set by international authorities such as the World Health Organization (WHO), by national expert assessment agencies such as ANSES, or by European expert assessment agencies such as the European Food Safety Authority (EFSA). They establish a relationship between exposure to a given chemical substance and an adverse effect on human health or a likelihood of this effect's occurrence. They are the result of a risk's characterisation in relation to human health and are required when assessing the risks of chemical substances. These HBGVs are established on the basis of animal studies and, when possible, epidemiological studies (lead, arsenic, aflatoxin).

The most commonly used guidance values are listed below:

- The **ADI**: Acceptable Daily Intake, which applies to substances that are voluntarily added to foodstuffs, such as additives (added for technological reasons such as for food storage), pesticides (added for plant protection reasons) and veterinary medicinal products (added for animal health reasons). Their presence in foods can thus be expected. The ADI was defined by WHO as the quantity of a substance that can be ingested daily, over a lifetime, without any risk for consumer health. For each use, a value or maximum authorised limit is defined by the regulations on the basis of the ADI.
- The **TDI**: Tolerable Daily Intake, which is used for substances whose presence in foodstuffs is not intended or is inevitable (environmental contaminants such as certain metals, NDL-PCBs and certain mycotoxins). A TDI is established for each substance or group of substances (NDL-PCBs) considered, using the same principles as for ADIs.
- The **TWI** and **TMI**: Tolerable Weekly Intake and Tolerable Monthly Intake, which are used for a substance or a group of substances whose presence in foodstuffs is not intended or is inevitable and which accumulate in the body (e.g. mercury, dioxins and DL-PCBs). These intakes may be qualified as provisional (PTWI and PTMI) when the toxicological data available at the time of their establishment are considered incomplete by the authorities.
- The **BMD**: BenchMark Dose. This value has been used for several years to best define dose-effect relationships based on toxicity studies in animals or epidemiological studies. Unlike the ADI/TDI approach which is based on the absence of an effect at tested intake

levels, the BMD is a statistical modelling approach based on animal testing data for an exposure level that causes a low but measurable response. The adverse effect's intensity level (Benchmark Response or BMR) is set at 1, 5 or 10% depending on the case. This value is used to calculate the BMDL (Benchmark Dose Lower Confidence Limit), which is the lower limit of the BMR's 95% confidence interval.

- The **MoE**: Margin of Exposure, which represents the relationship between the threshold at which an adverse effect appears in a toxicity study in animals and the human exposure level. Proposed by EFSA's scientific council in 2005 and WHO the same year, this approach was initially intended to classify genotoxic and carcinogenic substances (certain environmental contaminants and heat-induced contaminants, for example) in relation to their risk and thus help managers define action priorities. Over the past few years, this approach has also been used for contaminants that are neither genotoxic nor carcinogenic. The larger the margin of exposure, the less the substance is considered to be worrisome. This approach is advantageous in that it can distinguish between adults and children, or even other sensitive groups such as pregnant women and women of childbearing age, depending on the critical effect used.

2- Regulatory values for monitoring the safety of marketed foodstuffs

In order to ensure that consumers are not exposed to quantities of contaminants that can pose risks to their short- or long-term health, regulatory measures have been taken at the European and/or national levels.

Maximum levels have been established, substance by substance, in certain foods, including drinking water. They are based on a risk assessment but also take into account agricultural or technological requirements where applicable.

- The **MRL** (Maximum Residue Level) is the maximum authorised level of pesticide residues that can be found in and on products intended for human food or animal feed. It is an agricultural standard that reflects compliance with good agricultural practices while ensuring consumer safety. It is defined for each active substance (and its degradation products if necessary) and each plant for which there is an authorised use. If there is a risk of accumulation in production livestock fed with treated plants, MRLs are also set in products of animal origin.
- The **AME** (maximum authorised level of use) is the maximum quantity of an additive that can be used by professionals in a given food. It is defined for each additive and each food in which it is authorised so that the population's intake of this additive does not exceed the HBGV.
- The **ML** (maximum limit) is the maximum concentration of a given contaminant that can be found in food products or animal feed.

These values are defined for untreated foodstuffs, i.e. foodstuffs that have not been washed or peeled. If they are exceeded, the food is withdrawn from the market.

3- Case of minerals and trace elements

➤ **An objective: the estimated average requirement**

Requirements for a given nutrient are defined as the quantity of this substance that is required to ensure the maintenance and metabolic and physiological functioning of a healthy individual including requirements related to physical activity and thermoregulation and additional requirements related to certain periods of life such as growth, gestation and lactation.

The **estimated average requirement** (EAR), the quantity that an individual needs to absorb to cover his needs, takes into account the quantity that is actually absorbed by the body after digestion. These values are defined on the basis of experimental studies. Thanks to these values, national and international authorities such as ANSES define population reference intakes (ANCs), which are objectives to be reached to meet a population's needs and take into account inter-individual variability.

➤ **A maximum value: the Tolerable Upper Intake Level**

Nutrients can be toxic above a certain quantity, which is why Tolerable Upper Intake Levels are defined, using the same method that is used to establish ADIs. These limits correspond to the maximum quantity that can be ingested over a lifetime by an individual without any harmful effects.

TDS2: key figures

- Over **4** years of work
- **445** substances tested including **283** active plant protection substances
- Nearly **5** million euros allocated for samples and analyses
- **212** categories of foods investigated
- Around **20,000** food products purchased, prepared and analysed
- **90%** of the adult and child population's diet covered
- Nearly **250,000** analytical results collected and processed
- Some **thirty** cities involved across mainland France

ANSES, a new health & safety authority

The French Agency for Food, Environmental and Occupational Health & Safety was founded on 1 July 2010 following the merger of two French health agencies, the French Food Safety Agency (AFSSA) and the French Agency for Environmental and Occupational Health Safety (AFSSET). In combining their respective missions, ANSES provides a cross-disciplinary approach to health issues and thus enjoys a global perspective of the various forms of exposure to which people are subjected, through their lifestyles and consumption habits and the characteristics of their environment, the workplace included.

Protecting human, animal and plant health

ANSES contributes to the protection of human health with respect to the environment, the workplace and food. It also assesses risks related to animal and plant health. On the basis of its scientific reports, it issues opinions and recommendations to the public authorities.

Guaranteeing food safety and quality

The Agency assesses nutritional and health risks in the food processing industry. It assesses the nutritional properties of substances used in human food and animal feed and the related benefits. It monitors dietary habits and trends and identifies the most exposed populations. Lastly, it assesses the quality of drinking water.

Assessing health risks related to the environment

Health and the environment are two closely related spheres. ANSES assesses the environment's impacts on human health to better identify health risks linked to pollution in various living environments (air, water, soil). It has several areas of intervention: cancer and the environment, exposure to biological, chemical and physical agents, regulation of the use of hazardous chemical substances, etc.

Assessing health risks in the workplace

Exposure to occupational diseases, and delayed risks related to chemical substances such as those found in nanomaterials and asbestos, are issues of growing concern. ANSES examines mechanisms of exposure in the workplace and health risks specific to various professions thanks to innovative assessment methods and tools. In the National Network for Monitoring and Prevention of Occupational Diseases (RNV3P), ANSES actively contributes to improving knowledge of hazards and exposure in the workplace and to defining vigilance strategies.