Maisons-Alfort, 7 December 2012

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

on the 2013 surveillance programme on pesticide residues in food

---

1. REVIEW OF THE REQUEST

On 5 July 2012, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) received a formal request from the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) for scientific and technical support in the form of recommendations for the 2013 forecast plan for surveillance of pesticide residues, concerning the dietary exposure of the French population and the results of previous surveillance campaigns.

2. BACKGROUND

Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin provides for the implementation of:

- a coordinated, multiannual Community control programme (Art. 29),
- a multiannual national control programme based on risk assessment (Art. 30).

The aim of these programmes is to assess both the level of consumer exposure and compliance with the applicable legislation. The Regulation stipulates that Member States shall submit their national programmes to the Commission and to the European Food Safety Authority (EFSA) at least three months before the end of each calendar year.

The national control programmes specifically include screening for pesticide residues in fruits and vegetables, cereals, foods for infant diets, foodstuffs of animal origin, and the surveillance of seafood and freshwater products. Only the scheduling of 2013 surveillance plans for fruits, vegetables and cereals was provided under this formal request.

As the aim of this Opinion was to study the dietary risk to the consumer, the assessment focused on the entire diet, including plant foodstuffs and foodstuffs of plant origin, animal foodstuffs and foodstuffs of animal origin, and water intended for human consumption.

French Agency for Food, Environmental and Occupational Health & Safety,
27-31 av. du Général Leclerc, 94701 Maisons-Alfort Cedex - Telephone: + 33 (0)1 49 77 13 50 - Fax: + 33 (0)1 46 77 26 26 - www.anses.fr

3. EXPERT APPRAISAL METHOD

This Opinion was prepared by the French Observatory for Pesticide Residues (ORP), part of ANSES's Risk Assessment Department and Regulated Products Department (Residues and Food Safety Unit). It underwent two technical consultations by the Expert Committee on Plant protection products: chemical substances and preparations, on 29 March and 26 September 2012, to discuss respectively the method used and the results obtained.

The method used, shown in Figure 1 below, is described in ANSES's Opinion No. 2011-SA-203 of 22 December 2011 on the 2012 surveillance programme on pesticide residues in food (ANSES, 2011a). It had already been applied in particular as part of the Agency's scientific and technical support (Ref Nos 2010-SA-110 and 2009-SA-171) on the strategy for surveillance of pesticide residues in food (ANSES, 2010; AFSSA, 2009a).

It drew on the following data:

- the results of the DGCCRF 2010 surveillance plans for pesticide residues in plant foodstuffs and foodstuffs of plant origin;
- the results of the Directorate General for Health (DGS) 2010 and 2011 surveillance plans for pesticide residues in water intended for human consumption;
- the results of the Directorate General for Food (DGAL) 2010 surveillance plans for pesticide residues in animal foodstuffs and foodstuffs of animal origin;
- food consumption data from the Inca 2 study (AFSSA, 2009b);
- maximum residue limits (MRLs) from the 14 August 2012 update of the "Pesticide residue MRLs" database (European Commission, 2012);
- toxicity reference values (TRVs) from the internal ORP database updated on 15 September 2012 from the EFSA database (January 2012 version), from the latest findings of EFSA and the Joint FAO/WHO meeting on pesticide residues (JMPR), and from the European Commission database (8 August 2012 version) (Annex 1);
- the Community status of active substances derived from the European Commission's "Pesticide residue MRLs" regulatory database (6 September 2012 version) (Annex 1);
- Commission Implementing Regulation (EU) no 1274/2011 of 7 December 2011 concerning a coordinated multiannual control programme of the Union for 2012, 2013 and 2014.

4. RATIONALE

Chronic and acute exposure of the French population was first estimated using the levels of food contamination observed in 2010 and 2011[1]. From these results, the substances to be monitored as a priority were identified by taking into account the risk of exceeding the toxicity reference values (TRVs) and the uncertainty associated with estimating exposure.

Then, the *pesticide-foodstuff* combinations for priority surveillance were identified based on their potential contribution to exceeded TRVs. For each foodstuff, the number of samples to be taken was determined based on the variability of contamination levels observed in 2010-2011 for the priority *pesticide-foodstuff* combinations.

In terms of the analytical efforts to implement, this approach, which is based on actual observations of food contamination, was supplemented by the results of theoretical calculations of exposure for pesticides and foods not analysed in France.

[1] For water only

1. Data considered

1.1 Study population and consumption data

This Opinion focuses on the general French population aged over 3 years whose consumption habits were described in the Inca 2 survey (AFSSA, 2009b). This survey was conducted in mainland France from December 2005 to April 2007 – thus incorporating seasonal effects – among 4079 individuals, both children and adults, representative of the French population. National representativeness was ensured by stratification (age, sex, individual socio-professional category and household size). The calculations only related to individuals making realistic assessments (individuals underestimating their food consumption were excluded), i.e. 1719 adults aged over 18 years and 1446 children aged 3-17 years.

Food intake of individuals was recorded for a week in a consumption booklet. The 1305 foods as consumed were broken down into 181 "raw agricultural foodstuffs" according to the nomenclature defined in Regulation (EC) No 600/2010. A food breakdown table containing 763 recipes that took into account the variety of industrial processes and domestic food preparation habits was used for this purpose.

1.2 Pesticides considered and contamination data

This assessment drew on the detailed results of the 2010-2011 surveillance plans of the DGCCRF, DGAL and DGS. Data from the control plans were also included.

The residue levels of compounds falling under the same residue definition for surveillance and control (active substances and possible degradation products in accordance with Regulation (EC) No 396/2005) were added together for each sample. Unlike the residue definition for risk assessment, which incorporates compounds that are relevant from a toxicological point of view, the residue definition for surveillance and control is generally limited to a few markers in order to simplify the analyses. Adjustments were also made using toxic equivalency factors (this was the case with dimethoate[2] and carbendazim) and/or molar mass ratios for the compounds involved (European Commission, 1997). All these groupings and adjustments are detailed in Annex 1. **The term "substance" or "pesticide" used in the remainder of the Opinion corresponds to the residue definition for risk assessment.** Foods were codified according to the nomenclature of Regulation (EC) No 600/2010.

Table 1: Data from the 2010-2011 surveillance programmes

Source	Type of data	Number of foodstuffs	Number of pesticides	Number of samples	Number of analyses
DGCCRF, 2010	Plant foodstuffs	153 *	306	5,162	797,225
DGAL, 2010	Animal foodstuffs	19 *	49	2,505	43,057
DGS, 2010-2011	Public water supply	1	459	22,974	2,638,253
TOTAL	**All foodstuffs**	**171 ***	**523**	**30,641**	**3,478,535**

* Honey and cow's milk were analysed by both the DGCCRF and DGAL

As shown in Table 1, the results of the most recent surveillance programmes yielded information on contamination levels of 170 raw agricultural foodstuffs and water from the public supply. After grouping and adjusting, 523 different substances were screened for, including 225 that are authorised at Community level (approved under Regulation (EC) No 1107/2009), 222 that are no longer authorised (not approved), four that are still being evaluated (metobromuron, halosulfuron-methyl, spiromesifen and ethametsulfuron-methyl) and 72 that are not regarded as plant protection

[2] For example, for assessing the chronic risk associated with dimethoate, we considered the sum of the levels of dimethoate and three times those of omethoate, expressed as dimethoate.

substances within the meaning of the Regulation (other metabolites and degradation products, biocides, anti-parasitics) (Annex 1).

In total, information was provided on 38,322 *pesticide-foodstuff* combinations, of which 98% relate to plant foodstuffs or foodstuffs of plant origin. A total of 3,478,535 analytical results were available to calculate the contamination means for each *pesticide-foodstuff* combination (two contamination scenarios were considered, see Section 2.1).

Considering all the analytical results, 0.62% of the results were quantified (n=21,589) and 39% of the samples contained at least one residue. A total of 282 pesticides were quantified in 109 different foodstuffs (compared with 267 pesticides in 99 foodstuffs for the previous campaign).

Concerning plant foodstuffs, 0.54% of the results were quantified and 39% of the samples contained at least one residue (137 pesticides quantified in 96 foods).

Concerning animal foodstuffs, 0.95% of the results were quantified and 10% of samples contained at least one residue (27 pesticides quantified in 12 foods).

Concerning water from the public supply, 0.64% of the results were quantified and 43% of the samples contained at least one residue (195 pesticides quantified).

This analysis of the results is given for information simply to describe the contamination data and cannot be used to draw any conclusions about compliance with good agricultural practices. The quantification percentages correspond to the presence of residues and not to MRLs being exceeded.

1.3 Toxicity reference values

The acceptable daily intakes (ADIs) and acute reference doses (ARfDs) are detailed in **Annex 1.** They come from an internal ORP database that as of 14 September 2012 listed 518 ADIs and 276 ARfDs. This database is updated regularly from EFSA's database and supplemented by the European Commission database ("Pesticide residue MRLs") and other bibliographic sources such as the 15th edition of the *Pesticide Manual* (Tomlin et al, 2009). The ADIs and ARfDs used in this assessment were selected according to the same criteria as those defined in the Agency's previous Opinion on the 2012 surveillance programme (ANSES, 2011a).

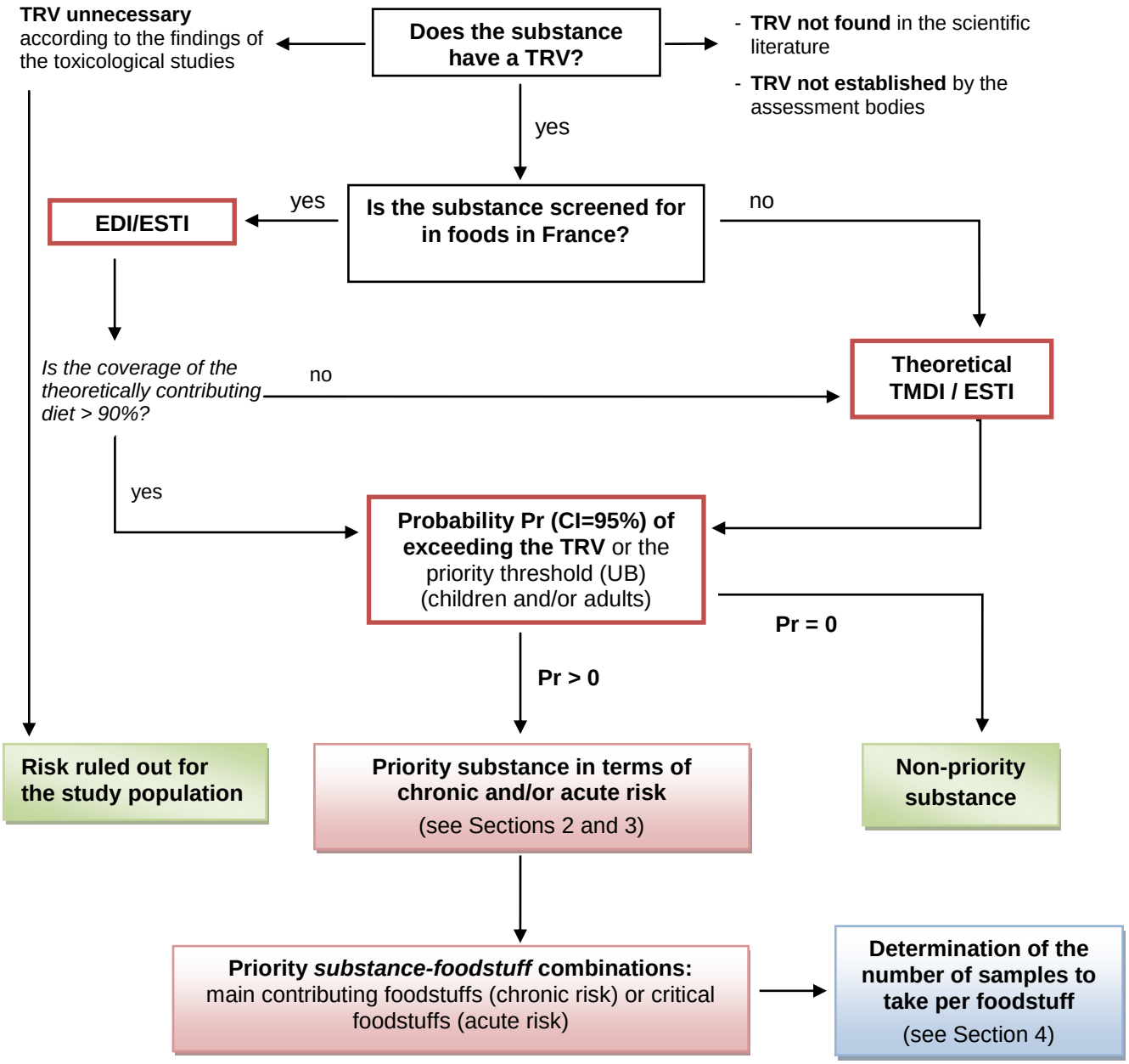

Figure 1: Principle of the method for identifying priority *pesticide-foodstuff* combinations for the surveillance of dietary exposure (acute and chronic)

Key:

ESTI: estimated short-term intake (acute risk indicator) (see Section 3)
EDI: estimated daily intake (chronic risk indicator) (see Section 2)
TMDI: theoretical maximum daily intake (chronic risk indicator) (see Section 2)
CI: confidence interval
UB: upper-bound chronic exposure scenario (see Section 2)
TRV: toxicity reference value (see Section 1)

This decision tree applies to a given population for a given risk type (chronic or acute).

2. Identifying priority *pesticide-foodstuff* combinations in terms of chronic dietary risk

2.1 Estimating chronic dietary exposure

✓ Methodology

The estimated daily intake (EDI) was determined by assuming that all food consumed daily is contaminated at the mean level observed in 2010-2011.

The data transmitted under this formal request only distinguished quantified results from unquantified results (values below the LQ[3]). Unlike in previous years, no distinction was made between undetected results (values below the LD[4]) and "trace" values (values between the LD and LQ).

Given the high rate of unquantified results (99.4%), the level of exposure was estimated between two bounds (scenarios), as recommended by international guidelines (GEMS/Food-EURO, 1995):

- a lower-bound scenario (LB) in which unquantified results are set to 0;
- an upper-bound scenario (UB) in which unquantified results are set to the LQ.

Regarding the *pesticide-foodstuff* pairs for which more than 40% of results were quantified, the unquantified results were set to half of the LQ (identical lower and upper bounds).

Exposure was calculated at the individual level. The mean and the 95th percentile of exposure, expressed as a percentage of the ADI, were then estimated for children aged 3-17 years and adults aged over 18 years according to the lower and upper bound scenarios.

✓ Results

Of the 523 pesticides screened for, 110 were not included in this assessment because:

- the ADI was not found in the databases or in the literature (N=77). This mainly concerns transformation products from active plant protection substances, most of which are screened for only in water. Some were regarded as toxicologically irrelevant in the context of the evaluation of the parent substance by Community (EFSA), international (JMPR) or national (e.g. ANSES) assessment bodies;
- the ADI was not established at the end of the assessment, mainly due to incomplete toxicological data (N=30);
- setting an ADI was not deemed necessary by the assessment bodies (bromadiolone, coumadin and difenacoum).

The results obtained for the 413 pesticides evaluated are detailed in Annex 2.

[3] Limit of quantification
[4] Limit of detection

With the lower-bound exposure scenario (LB), the ADI was not observed to have been exceeded for children or adults, either at the average or at the 95th percentile of exposure. This scenario is regarded as the most realistic and highlights the most frequently quantified pesticides (ANSES, 2011a; Nougadère *et al.*, 2011). The highest 95th percentile of exposure (LB) was 20.4% of the ADI in children and 14% in adults (dithiocarbamates).The highest mean exposure (LB) was 7.3% of the ADI in children (pirimiphos-methyl) and 5.6% of adults (dithiocarbamates). The highest mean exposures (estimated between 1% and 10% of the ADI) concerned the following substances authorised at Community level:

- insecticides used for storage of harvested cereal grains: **pirimiphos-methyl** (7.3% and 5% of the ADI in children and adults respectively) and **chlorpyrifos-methyl** (1.2% and 0.8% of the ADI), quantified in respectively 20% and 13% of cereal samples analysed in 2010 (uses authorised in France/MRLs not exceeded);
- **dithiocarbamates** (7.2% and 5.6% of the ADI), fungicides quantified in 13% of vegetable samples and 3% of fruits. The highest rates of quantification concerned leafy vegetables (16%) especially lettuce (21%), followed by table grapes (6%) (authorised uses/MRLs exceeded for 6.4% of the lettuce samples, one chard sample and one sample of beans for shelling);
- **imazalil** (4.1% and 2.3% of the ADI), fungicide quantified in 50% of citrus fruits analysed (authorised uses post-harvest/MRLs exceeded for one sample of pears, one orange juice (France) and 5% of samples of unprocessed citrus fruits) (see Table 3);
- **chlorpropham** (2.1% and 1.4% of the ADI), anti-germinative quantified in fruits and vegetables, especially potatoes (63% of samples) (authorised uses post-harvest/MRLs exceeded in one sample of carrots and lentils);
- **dimethoate** (1.2% of the ADI), systemic insecticide quantified in fruits and vegetables, especially cherries (48% of samples/MRLs exceeded in 18% of samples).

These exposure levels (LB) are similar to those estimated from the results of the previous analysis campaign (ANSES, 2011a).

With the most conservative upper-bound exposure scenario (UB), 14 pesticides were shown to exceed the ADI at the average level and 19 pesticides at the 95th percentile of exposure, in at least one of the two population sub-groups (children and/or adults). Among these substances:

- five are authorised at Community level (approved under Regulation (EC) No 1107/2009) and have authorisation for use in France: **dimethoate**[5]*****, **dithiocarbamates**[6]*****, ethoprophos, fenamiphos and **fipronil***;
- eight are no longer authorised (not approved) at Community level as plant protection substances: cadusafos, **carbofuran***, **chlorfenvinphos***, coumaphos, **diazinon**[7]*****, monocrotophos, quinalphos and **terbufos***;
- six (**chlordane***, **dieldrin**[8]*****, **endrin***, **heptachlor***, **technical HCH*** and **lindane (gamma-HCH)***) are persistent organic pollutants (POPs) listed in the Stockholm Convention.

Of these pesticides, 13 were quantified at least once in 2010 (substances in bold above). For the other six that were unquantified, the observed cases in which the ADIs were exceeded with the upper-bound exposure scenario (UB) were mainly due to the very low level of their ADIs: between 0.4 µg/kg bw/day for ethoprophos and cadusafos, and 0.8 µg/kg bw/day for fenamiphos, related to the LQ values applied for the unquantified results.

These results confirm the Agency's previous findings on the importance of refining the characterisation of the risk associated with the presence of these pesticides in food (ANSES, 2011a). For these other six unquantified substances, firstly more details are needed about the unquantified results (undetected or trace levels), and secondly the analytical methods should be improved. Improvements could draw on the results of the second Total Diet Study (TDS2) published

*** Substances quantified at least once**

[5] Sum of the levels of dimethoate and three times those of omethoate

[6] Carbon disulfide (CS_2) is the sum of maneb, mancozeb, metiram, propineb, thiram and ziram

[7] Although withdrawn as a plant protection substance in 2007, diazinon is still authorised as a biocide for eradicating insects from livestock buildings and as an external anti-parasitic for livestock in particular.

[8] Sum of aldrin and dieldrin

in 2011, which detail the analytical limits to achieve for each matrix in order to refine the estimated exposure to these pesticides (ANSES, 2011b).

2.2 Identification of pesticides for priority surveillance

✓ **Principle**

For each pesticide, a **priority threshold** for surveillance is defined by the ADI multiplied by the coverage rate of the assessment (ANSES, 2010; Nougadère *et al.*, 2011). It is expressed here as a percentage of the ADI, as with any exposure value (Annex 2).

This coverage rate is determined by the ratio between the diet covered by the assessment and the diet potentially contributing to exposure[9]. A high ratio shows that the assessment's coverage is good: in this case, the substances are prioritised with regard to the risk associated with chronic exposure of the population. A low ratio reflects insufficient coverage of the assessment: the substances are prioritised according to uncertainties about the contamination level of foodstuffs not taken into account. In this situation, screening of these substances should as a priority be extended to a greater number of foodstuffs.

For each pesticide, the potentially contributing diet is defined by foodstuffs whose MRL differs from the limit of quantification, indicating the potential presence of residues in these foodstuffs. This approach cannot be applied to unauthorised substances that only have MRLs set by default at the threshold or at the limit of quantification. For these substances (N=129/523, 25%) and in the absence of knowledge about foodstuffs likely to be contaminated, the entire diet is considered by default as potentially contributing to exposure.

The probability of exceeding the priority threshold is then estimated for each population sub-group as the percentage of individuals with exposure above the threshold, with a confidence interval of 95%. Pesticides that risk exceeding the threshold in at least one of the two population sub-groups are given priority.

✓ **Results**

The 29 pesticides for priority surveillance appear in bold in Annex 2. In addition to the 19 pesticides previously identified as having exceeded the ADIs (UB), 10 have a significantly non-zero probability of exceeding the priority threshold with the upper-bound exposure scenario (UB). Twenty-eight pesticides were found to be a priority in children, 19 of these also in adults. One substance (fluazinam) is a priority in adults alone.

Of these 29 priority pesticides:

- eighteen have a priority threshold greater than 90% of the ADI, reflecting the assessment's good coverage. These pesticides are a priority with regard to the risk of chronic exposure of the population;
- nine have a priority threshold of between 50 and 90% of the ADI;
- two have a priority threshold of between 20 and 50%. The assessment's coverage is low for these pesticides. Better targeting of the foods in which they are screened for is therefore necessary (see Section 2.4).

Forty-two pesticides were identified as a priority by the Agency in 2011 (ANSES, 2011a), of which 25 were also identified in 2012. More specifically:

- seventeen were no longer a priority in 2012 because:
    - they are no longer detected or authorised in Europe and/or their ADI has not been validated at Community level: carbophenothion, dialifos, disulfoton, EPN, iodofenphos, mirex, naled, phosphamidon, propetamphos, prothiofos, pyridafenthion, pirimiphos-ethyl, sulfotep;

[9] The diet here is the mean total food consumption (children or adults).

  - coverage of the assessment is better: bromides, coumatetralyl, methamidophos, phenthoate.
- four are priority for the first time due to:
  - a number of foodstuffs containing higher residues than in 2011 and/or the variation in the limits of quantification: cyfluthrin, fenpropimorph and fluquinconazole;
  - a new lower ADI value for lindane.

2.3 Identification of priority *pesticide-foodstuff* combinations

✓ **Principle**

The *pesticide-foodstuff* combinations for priority surveillance correspond to foodstuffs contributing more than 2.5% of the ADI (UB) for the previously identified priority pesticides and for the 5% of individuals most exposed in each population sub-group (adults and children).

✓ **Results**

Annex 3 presents the 518 *pesticide-foodstuff* combinations for priority surveillance and/or analytical improvements. They correspond to 78 foodstuffs (34 vegetables, 22 fruits, 7 animal foodstuffs or foodstuffs of animal origin, 6 cereals, 3 oil seeds, 3 dried legumes, tea, coffee and water from the public supply).

Seven foodstuffs (orange, wheat, apple, potato, tomato, grape, carrot) contribute more than 2.5% of the ADI (UB) for more than 20 pesticides, 11 foodstuffs for 10 to 20 pesticides and 20 foodstuffs for two to nine pesticides. The remaining 39 foodstuffs only contribute for a single pesticide.

Only 4% (21/518) of these pairs identified with the upper-bound scenario (UB) were associated with quantified residue levels, corresponding to 6 pesticides and 17 foodstuffs[10] (Table 2):

- dithiocarbamates quantified in apples, tomatoes, green beans, pears, grapes, strawberries, courgettes and leeks;
- lindane in cow's milk, seafood and freshwater products, eggs, poultry and water;
- dimethoate/omethoate in oranges, carrots, cherries and green beans;
- dieldrin/aldrin in cow's milk and cucumbers;
- oxydemeton-methyl and cyfluthrin in apples.

[10] Ranked by decreasing number of contributors and then by decreasing level of contribution (children).

Table 2: *Foodstuff-pesticide* pairs contributing more than 2.5% of the ADI in highly exposed individuals with the upper-bound exposure scenario (UB)
(substances quantified at least once)

Pesticide	Foodstuff	Number of samples analysed	Number of samples quantified	Mean contamination (mg/kg FW)		97.5th percentile of contamination (mg/kg FW)	UB contribution (% ADI)	
				LB	UB		Child-ren	Adults
Cyfluthrin	Apples	149	1 (1%)	6.10^{-5}	0.04	0.1	3.5	-
Dieldrin*	Cow's milk	90	2 (2%)	9.10^{-8}	4.10^{-4}	0.0008	10.6	-
	Cucumbers	91	1 (1%)	2.10^{-4}	0.01	0.015	6.0	-
Dimethoate*	Oranges	146	1 (1%)	2.10^{-4}	0.05	0.105	33.1	4.0
	Carrots	100	2 (2%)	0.001	0.06	0.105	6.9	-
	Cherries	27	13 (48%)	0.160	0.16	1.14	6.0	6.4
	Beans (not shelled)	51	3 (6%)	0.003	0.05	0.105	5.4	-
Dithiocarbamates	Apples	63	1 (2%)	0.04	0.77	1.005	43.7	21.4
	Tomatoes	67	1 (1%)	0.01	0.74	1.005	20.5	13.7
	Beans (not shelled)	9	2 (22%)	0.64	1.2	5.226	20.2	7.3
	Pears	32	1 (3%)	0.03	0.86	1.005	11.5	12.9
	Table grapes	33	2 (6%)	0.05	0.68	1.005	7.0	5.9
	Strawberries	66	1 (2%)	0.02	0.63	1.005	4.6	3.9
	Courgettes	7	1 (14%)	0.07	0.73	1.005	4.3	3.9
	Leeks	39	2 (5%)	0.09	0.9	2.01	2.7	-
Lindane (HCH-gamma)	Cow's milk	80	4 (5%)	3.10^{-6}	2.10^{-4}	0.0004	54.1	10.8
	Seafood and freshwater products	227	11 (5%)	6.10^{-6}	1.10^{-3}	0.002	14.0	10.4
	Hen's eggs	79	1 (1%)	2.10^{-6}	6.10^{-4}	0.002	8.8	-
	Poultry meat	308	20 (6%)	2.10^{-5}	7.10^{-4}	0.002	5.1	-
	Water from the public supply	13,606	10 (0%)	2.10^{-8}	1.10^{-5}	0.00002	3.5	2.7
Oxydemeton-methyl*	Apples	103	1 (1%)	2.10^{-4}	0.01	0.01	10.2	4.9

* See residue definition (Annex 1)

2.4 Foodstuffs and pesticides not taken into account in the assessment

✓ **Contributing foodstuffs not taken into account**

For the 29 pesticides highlighted as a priority, the foodstuffs not covered in the surveillance programmes but theoretically contributing more than 5% of the ADI (result of the TMDI calculation) were identified by considering all individuals. Two foodstuffs were not identified as a priority via the EDI calculation and should therefore be included: **cocoa (fermented beans) and lamb/mutton meat** (Annex 4, Table 1). The following persistent organic pollutants (POPs) were associated with the theoretical intakes identified: **dieldrin and heptachlor.** These results are related to the MRLs for these foodstuffs and not to the actual residual levels from previous plans.

✓ **Pesticides not screened for or for which the assessment is incomplete**

In order to take into account **substances not screened for or for which coverage of the theoretically contributing diet is inadequate** (below 90%, see Annex 2), the analysis was supplemented with regard to surveillance priorities identified based on:

- the TMDI calculated *a posteriori* for the general French population (Inca 2). Priority substances were considered to be firstly those active substances approved by Regulation (EC) No 1107/2009 or under evaluation (but authorised for use on European territory) and having a non-zero probability of exceeding the ADI, and secondly other substances not approved by the Regulation, but for which the TMDI (95^{th} percentile) exceeds the ADI. Only pairs contributing more than 5% of the ADI were listed (Annex 4, Table 2);
- the TMDI calculated as part of the *a priori* risk assessment procedure*:* substances with a TMDI (calculated from the MRLs) or a refined TMDI (calculated from the median residues, STMR) exceeding 75% of the ADI with the European exposure prediction model (EFSA, 2007) were regarded as a priority. Only pairs contributing more than 10% of the ADI were listed (Annex 4, Table 3).

The theoretical *a posteriori* assessment highlighted 30 pesticides (93 pesticide-foodstuff pairs) to be considered as a priority: 13 recommended for inclusion in the next surveillance plans according to analytical capabilities and 17 others that should undergo broader screening in the main food contributors mentioned (Annex 4, Table 2) in order to improve the coverage of the realistic evaluation (EDI). Among the new substances not currently screened for, flubendiamide, mandipropamid and tembotrione (herbicide) are being evaluated at Community level.

In addition, the theoretical *a priori* assessment highlighted 13 pesticides (36 *pesticide-foodstuff* pairs*)* to be given priority: six recommended for inclusion in the next surveillance plans according to the analytical possibilities, five others that should undergo broader screening in the major food contributors mentioned and a further two for which a risk has subsequently been identified and for which the analytical limits should be lowered (Annex 4, Table 3). These recommendations aim to improve the coverage level of the realistic assessment (EDI). The *a priori* assessment confirmed the need to include screening for copper and its compounds, tritosulfuron (authorised in Europe), as well as emamectin benzoate, gamma-cyhalothrin and meptyldinocap (currently under evaluation), in the surveillance plans. It is also recommended that screening for pyrethroids (cyfluthrin, deltamethrin), fipronil and flusilazole be extended to include other animal foodstuffs, and screening for dithiocarbamates and quizalofop-P be extended to all fruits and vegetables.

Lastly, it is recommended that 18 new substances be added to the 2013 surveillance plans (plant and/or animal foodstuffs, see Annex 4): bifenazate, copper and its compounds, cyhexatin, emamectin benzoate, ethephon, etoxazole, fenbutatin oxide, fentin acetate, fentin hydroxide, flonicamid, flubendiamide, fluorides, gamma-cyhalothrin, mandipropamid, meptyldinocap, spirodiclofen, tembotrione and tritosulfuron. MRLs for these pesticides are being revised at Community level, either in accordance with Article 12 of Regulation (EC) No 396/2005 or due to the ongoing collective European assessment.

3. Identifying priority *pesticide-foodstuff* combinations in terms of acute dietary risk

3.1 Estimating acute dietary exposure

✓ **Methodology**

The method for calculating dietary exposure and characterising acute risk is described in a previous Opinion of the Agency (ANSES, 2011a).

Acute exposure was estimated for *pesticide-foodstuff* pairs for which:

- one or more residues have been quantified;
- an acute reference dose (ARfD) is available;
- the food was consumed by at least one individual from the Inca 2 study.

The calculation was performed at the individual level. For each foodstuff studied, a day's consumption was selected at random from all the days during which the individual actually consumed the foodstuff. The studied foodstuff was regarded as contaminated to a high level (97.5^{th} percentile of contamination). An intra-sample variability factor, set at between 1 and 7 depending on the food, was also taken into account (EFSA, 2005, 2007). The other foodstuffs consumed by the individual on the same day were regarded as contaminated at an average level (UB), as estimated in the assessment of chronic exposure.

The different equations used for calculating acute exposure are detailed in Annex 5 and the parameters used are those described in a previous Opinion (ANSES, 2011a).

In the same way as for chronic exposure, individual exposure was compared to the ARfD. The probability of exceeding the ARfD – expressed by the ratio between the number of consumers with exposure exceeding the ARfD and all the consumers studied – and the 97.5^{th} percentile of exposure were estimated for each relevant population sub-group with regard to the acute risk: children aged from 3 to 6 years, children aged from 7 to 10 years, children aged from 11 to 14 years, adults aged over 15 years with a maximum of respectively 321, 432, 261 and 2151 consumers.

The "critical" *pesticide-foodstuff* combinations, for which the probability of exceeding the ARfD is significantly non-zero, were given priority for surveillance.

✓ **Results**

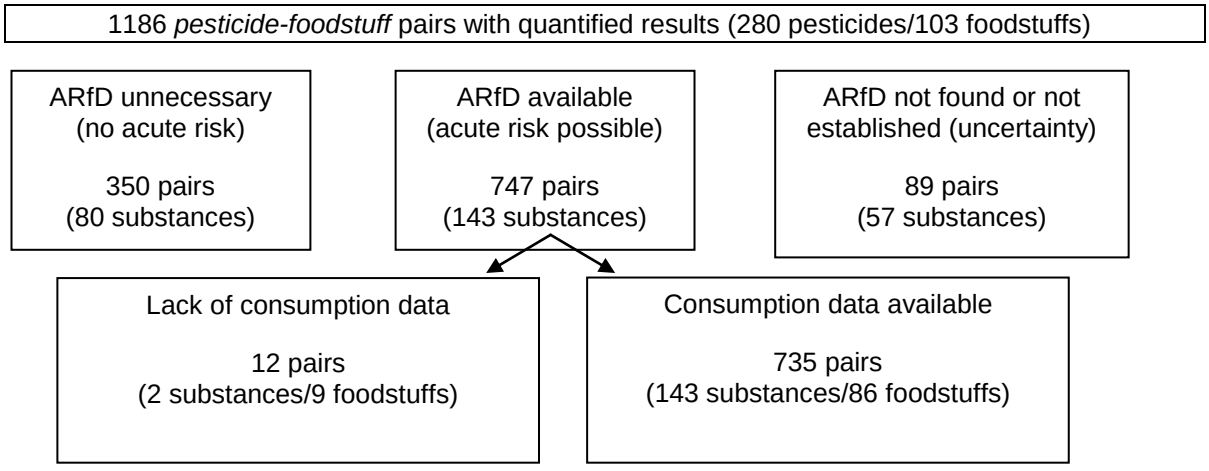

Figure 2: Combinations taken into account in the assessment

Among the 1186 *pesticide-foodstuff* pairs with at least one quantified result, 89 were not taken into account in the assessment due to uncertainty about the acute risk (ARfD not found in the literature, not established or not proposed by Community or international assessment bodies) (Figure 2).

Among the 747 pairs with an ARfD, 16 were found to have a significantly non-zero probability of exceeding the ARfD for at least one of the four population sub-groups studied, in connection with seven pesticides and 13 foodstuffs. The results are detailed in Annex 6 and Table 3.

3.2 Identification of priority *pesticide-foodstuff* combinations

✓ **Methodology**

The "critical" *pesticide-foodstuff* combinations for which the probability of exceeding the ARfD is significantly non-zero were regarded as a priority for surveillance.

✓ **Results**

Among the seven pesticides associated with 16 critical combinations (Table 3), five had already been identified in a previous Opinion (ANSES, 2011a) (bitertanol, carbendazim, dimethoate, dithiocarbamates and imazalil) and two were identified for the first time (carbofuran and prochloraz).

Only carbofuran is no longer authorised at Community level. This substance was quantified in a sample of aubergine from the Dominican Republic at levels exceeding the MRL (0.02 mg/kg) (Table 3).

The 13 foodstuffs associated with these critical combinations were nine fruits (avocados, bananas, cherries, lemons, mandarins, oranges, grapefruits, pears, apples) and four vegetables (aubergines, carrots, courgettes, lettuce). No other plant foodstuff (cereals, for example), animal foodstuff, or water from the public supply was found to have significantly exceeded the ARfD.

Exceeded ARfDs were observed with two pesticides for cherries, oranges and grapefruits and with a single pesticide for the other foodstuffs. Critical combinations concerned at least two at-risk population sub-groups, with the exception of carbendazim (cherries), dimethoate (carrots, courgette and oranges), dithiocarbamates (apples) and prochloraz (avocados), which concerned children aged from 3 to 6 years only and dithiocarbamates in lettuce, which concerned adults only (aged over 15 years).

In 2011, the following critical combinations had already been identified (ANSES, 2011a):

- bitertanol (bananas);
- dimethoate (cherries and courgettes);
- dithiocarbamates (lettuce);
- imazalil (citrus fruit and pears).

Note however that the acute risk highlighted should be put in perspective, given the fact that in the national surveillance plans plant foodstuffs are analysed together with their skin, whereas most of these fruits are primarily consumed without their skin (e.g. avocado, bananas, citrus fruits).

3.3 *Pesticide-foodstuff* combinations not taken into account in the assessment

With regard to the surveillance priorities identified, the analysis was supplemented by taking into account the Estimated Short Term Intake (ESTI) recently calculated as part of the *a priori* risk assessment procedure. The *pesticide-foodstuff* combinations associated with a refined theoretical ESTI (Highest residue, HR) exceeding more than 75% of the ARfD with the European exposure prediction model (EFSA, 2007) were regarded as priorities. Annex 4 (Table 4) only lists those pesticides not screened for in 2010 in the theoretical priority foodstuffs identified, or for which the number of analyses of these critical foods was insufficient (n<30) (Annex 4, Table 4).

Ultimately, in addition to the *a posteriori* assessment, 11 substances should be regarded as a priority for surveillance regarding acute exposure (Annex 4, Table 4). These are:

- two substances recommended for inclusion in the next surveillance plans (emamectin benzoate and ethephon);

- four substances that should undergo broader screening in the critical foodstuffs mentioned: ioxynil in vegetables, flufenacet and glufosinate in potatoes and fipronil and its metabolites in milk and meat;

- five substances for which coverage of the assessment should be improved and the number of samples of critical foodstuffs should be increased to a minimum of 30 to allow proper statistical analysis with a view to refining the realistic assessment (ESTI):

  - lettuce, scarole (broad-leaf endive) and celery for abamectin;
  - bananas and beef for fenpropidin;
  - table grapes and wine grapes for fluazinam;
  - bananas, melons and watermelons for oxamyl;
  - lettuce, scarole, leeks, spinach and kohlrabi for propamocarb.

Ultimately, emamectin, ethephon, ioxynil, flufenacet, glufosinate and fipronil should be included, and the current number of analyses for the priority *pesticide-foodstuff* combinations above should be increased. Note that the MRLs of these pesticides are under review at Community level, either in accordance with Article 12 of Regulation (EC) 396/2005 or due to the ongoing European collective assessment.

Table 3: Pesticides associated with a risk of exceeding the ARfD based on the results of the 2010 surveillance plans

Pesticides	Observations
Bitertanol (authorised in Europe)	Acute risk only associated with the consumption of **bananas** (Annex 6). These results confirm those of the previous assessment conducted using the results of the 2009 surveillance plans (ANSES, 2011a). Substance quantified in 24% of banana samples analysed (n=7/29). No exceeding of the MRL (3 mg/kg) was shown. The maximum quantified value was 1 mg/kg. Substance approved in Europe in 2012 (Regulation 1278/2011/EC). In France, uses such as for banana conservation (storage) were authorised until 31 December 2010.
Carbendazim and thiophanate-methyl, (see residue definition, Annex 1) (authorised in Europe)	Acute risk only associated with the consumption of **cherries** (Annex 6). Carbendazim and/or thiophanate-methyl, fungicides quantified in 7% of cherry samples (n=2/27). The MRL (0.3 mg/kg) was reported to have been exceeded for thiophanate-methyl in a sample of cherries from mainland France (6.3 mg/kg). Carbendazim was approved in 2007 according to Regulation 1107/2009/EC (Reg. 542/2011/EC), but withdrawn in France in 2008 under the Ecophyto 2018 plan. The substance is also a metabolite of thiophanate-methyl, approved in 2005, and for which many uses are authorised in France in arable crops and vegetable and fruit crops (including authorised use on cherry trees).
Carbofuran (not authorised in Europe)	Acute risk associated with the consumption of **aubergines** and **grapefruits** (Annex 6). Substance quantified in a sample of aubergines (n=90) and a sample of grapefruits (n=46). The MRL (0.02 mg/kg) was reported to have been exceeded (0.06 mg/kg) in a sample from the Dominican Republic. Substance not approved in Europe as of 2007 (Decision 2007/416/EC).
Dimethoate and omethoate, (see residue definition, Annex 1) (dimethoate authorised in Europe)	Acute risk associated with four different foodstuffs **(carrots, cherries, courgettes** and **oranges)** (Annex 6). These results for cherries and courgettes confirm those from previous assessments conducted using the results of surveillance plans from 2008 (ANSES, 2010) and 2009 (ANSES, 2011a). The levels of quantification of dimethoate and/or its metabolite omethoate vary from 0.7% (oranges, n=146) to 48% (cherries, n=27). Exceeded MRLs concerned five cherry samples (origin mainland France, MRL=0.2 mg/kg), one sample of courgettes (French overseas territories, MRL=0.02 mg/kg) and one sample of oranges (Tunisia, MRL=0.02 mg/kg). Maximum levels were measured in cherries (0.8 mg/kg). Uses on carrots and cherries are authorised in mainland France. At Community level, the substance was approved in 2007 under Regulation 1107/2009/EC (Reg. 540/2011/EC).
Dithiocarbamates (total) (authorised in Europe)	Acute risk associated with the consumption of **lettuce** and **apples** (Annex 6). These results for lettuce confirm those from previous assessments conducted using the results of surveillance plans from 2008 (ANSES, 2010) and 2009 (ANSES, 2011a). Quantified in 23% of lettuce samples (n=69/298) and one apple sample (n=1/63). Seven lettuce samples (from France and Belgium) were concerned by MRLs being exceeded (5 mg/kg) with levels of between 5 and 13 mg/kg. The majority of dithiocarbamates (mancozeb, maneb, metiram, propineb, thiram and ziram) are approved (Reg. 540/2011/EC). Zineb was withdrawn in 2001. Many commercial plant protection products are authorised in France for controlling downy mildew on lettuce.
Imazalil (authorised in Europe)	Acute risk associated with the consumption of **oranges**, **mandarins**, **grapefruits**, **lemons** and **pears** (Annex 6). These results confirm those from previous assessments conducted using the results of surveillance plans from 2008 (ANSES, 2010) and 2009 (ANSES, 2011a). The levels of quantification are respectively 40%, 66%, 74%, 46% and 10%. The MRLs for citrus fruits (5 mg/kg for fruits and 0.25 mg/kg for juice)

Imazalil (cont.) (authorised in Europe)	were mentioned as having been exceeded for fruits from third countries (orange juice, lemons) or the EU (mandarins from Spain). The MRL was also shown to have been exceeded on one sample of pears (Portugal). Substance approved in Europe since 1999 and renewed in 2011 under Regulation 1107/2009/EC (Reg. 705/2011/EC). In France, the active substance is only authorised for post-harvest treatment of bananas (conservation).
Prochloraz (authorised in Europe)	Acute risk associated with the consumption of **avocados** (Annex 6). Substance quantified in one avocado sample from organic agriculture (from Peru) (n=13 samples analysed). The MRL (5 mg/kg) was not exceeded. Substance approved in Europe in 2012 under Regulation 1107/2009/EC (Reg. 1143/2011/EC). In France, uses are authorised for open-field treatment of arable crops and certain vegetable crops (garlic, shallot).

4. Definition of the sampling plan

4.1 Principle

For each priority *pesticide-foodstuff* pair, the number of samples to be taken is determined by the levels of contamination observed, using the following formula (Bouyer, 2000):

$$n = \frac{z_{(\alpha)*}^2 s^2}{i^2}$$

where:

n: minimum number of samples to take;

$z_{(\alpha)}$: standard score (z-score) corresponding to the agreed risk. For α=0.05, $Z_{(\alpha)}$ =1.96;

s^2: estimated variance in the level of contamination;

i: estimation error.

The calculation is performed with a level of error around the average of 40%, generally regarded as statistically acceptable (ANSES, 2010). The number of samples used for each foodstuff is the number sufficient to describe the mean levels of contamination associated with all the priority pesticides in this foodstuff with regard to the risks associated with chronic and acute exposure.

Because the calculated numbers can sometimes be high (making the sampling plan more difficult to implement) and because 30 representative samples per foodstuff are the minimum needed for a statistical evaluation, the numbers are subsequently reassessed as follows:

- if the theoretical number is greater than 150, then it is limited to 150;
- if the theoretical number is less than 30, then it is set to 30.

The number of samples to be taken is also set to 30:

- when the variability in the estimated residue level is zero, for example when all the results for a priority *pesticide-foodstuff* pair are lower than the same LQ;
- for foodstuffs only theoretically found to be a priority.

4.2 Results

Table 4 shows the number of samples to be taken for plant foodstuffs and honey.

With regard to the surveillance of dietary exposure of the general population of mainland France established in 2012, screening for pesticide residues was relevant in 79 raw agricultural foodstuffs, including 69 plant foodstuffs: 20 fruits, 34 vegetables and legumes, 6 cereals, 3 oil seeds and 6 other plant foodstuffs.

Seventeen foodstuffs not identified as a priority by ANSES in the previous campaign (ANSES, 2011a) should be retained or added to the next surveillance programme in 2013: avocado, table olives, globe artichoke, asparagus, chard, kale, aromatic plants (parsley, basil, etc.) and/or infusion plants (mint, etc.), lamb's lettuce, mango, watermelon, radish, soybeans, barley, rye, oats and sugar cane. Spices, identified as a priority in 2011 by ANSES, do not appear as such in this assessment.

The foodstuffs not sampled in 2012 (or not specified), and which should be added to (or retained in) the next surveillance plan in 2013 are:

- fruits: table olives and table grapes;
- vegetables: aubergine, cauliflower, kale, fresh herbs (parsley, basil, mint, etc.), bell pepper and peas (shelled).

It is recommended that the number of samples taken be increased – as shown in Table 4 – and the analytical results for each of the following relevant foodstuffs be clearly distinguished:

- oil seeds and oleaginous fruits: sunflower, olive and soybean;
- tea, coffee and infusions (main infusion plants on the market, including mint).

Among the foodstuffs sampled in 2012, eleven do not appear as a priority in this assessment: garlic, Brussels sprouts, pumpkin, shallot, fennel, rhubarb, buckwheat, spelt, triticale, sorghum and spices. However, it is advisable to retain surveillance so as to verify compliance with good agricultural practices.

For fruits, it is recommended that the planned number of samples in 2013 be increased for avocado, banana, cherry, lemon, mandarin, mango, orange and orange juice, red berries (including raspberries), pear and plum. The proposed number of samples for avocado is fifteen times higher than in 2012. In addition, the EU Regulation requires France to take a minimum of 66 samples of peach and apple for 2013. However, the planned number for apricot and kiwi can be reduced.

For vegetables, it is recommended that the planned number of samples in 2013 be increased for globe artichoke, asparagus, beetroot, chard, broccoli, celeriac, mushrooms, headed cabbage, spinach, beans (not shelled), lettuce and other salads, lamb's lettuce, sweet corn, turnip, potato, radish and lentils. However, the planned number for carrot, celery, cucumber, courgette, chicory, melon, onion, tomato and beans (shelled) can be reduced.

For cereals, it is recommended that the number of samples in 2013 be maintained at the level from the 2012 surveillance plan.

These differences in sample numbers reflect the observed variability in contamination of these foodstuffs regarding priority surveillance for pesticides, and not the level of risk associated with the consumption of each foodstuff.

Table 4: Breakdown of the number of samples per foodstuff

EU code	Foodstuffs	2012 number of samples	2013 coordinated EU programme	Proposed number of samples for 2013	Proposed total number of samples for 2013 (including the coordinated programme)
100000	**Fruits**	**682**	**264**	**1255**	**1399**
140010	Apricot	47	-	30	30
163080	Pineapple	29	-	30	30
163010	Avocado	10	-	150	150
163020	Banana	46	-	123	123
140020	Cherry	39	-	150	150
110030	Lemon (including limes)	48	-	122	122
152000	Strawberry	30	66	30	66
162010	Kiwi	39	-	30	30
110050	Mandarin (including clementines)	52	-	68	68
163030	Mango	5	-	30	30
161030	Table olives	NS	-	30	30
110020	Orange (including orange juice)	68	-	99	99
110010	Grapefruit and pomelo	32	-	33	33
140030	Peach	46	66	30	66
150000	Red berries (including raspberries)	22	-	30	30
130020	Pear	48	-	150	150
130010	Apple	85	66	30	66

EU code	Foodstuffs	2012 number of samples	2013 coordinated EU programme	Proposed number of samples for 2013	Proposed total number of samples for 2013 (including the coordinated programme)
140040	Plum	21	-	30	30
151010	Table grapes	NS	-	30	30
151020	Wine (wine grapes)	15	66	30	66
200000	**Vegetables**	**864**	**264**	**991**	**1099**
220010	*Garlic*	*3*	-	-	-
270050	Globe artichoke	7	-	30	30
270010	Asparagus	8	-	30	30
231030	Aubergine	NS	-	30	30
213010	Beetroot	22	-	30	30
270020	Chard, cardoon	9	-	30	30
241010	Broccoli	26	-	30	30
213020	Carrot	110	-	30	30
270030	Celery	79	-	30	30
270030	Celeriac	24	-	30	30
280010	Mushrooms	24	-	30	30
242010	*Brussels sprouts*	*5*	-	-	-
242020	Headed cabbage	28	66	30	66
243020	Kale	NS	-	30	30
241020	Cauliflower	NS	-	30	30
233020	*Pumpkin*	*13*	-	-	-
232010	Cucumber	35	-	30	30
233020	Squash	NS	-	-	-
232030	Courgette	41	-	30	30
251040	Watercress	NS	-	-	-
220030	*Shallot*	*4*	-	-	-
255000	Chicory	42	-	30	30
252010	Fresh or frozen spinach	26	-	30	30
270040	*Fennel*	*9*	-	-	-
260010	Beans (not shelled)	34	-	40	40
251000	Lettuce and other salads	2	66	81	81
251010	Lamb's lettuce	2	-	30	30
234000	Sweet corn	19	-	30	30
233010	Melon	53	-	30	30
213110	Turnip	23	-	30	30
220020	Onion	37	-	30	30

EU code	Foodstuffs	2012 number of samples	2013 coordinated EU programme	Proposed number of samples for 2013	Proposed total number of samples for 2013 (including the coordinated programme)
233030	Watermelon	29	-	30	30
212020	*Sweet potato*	*NS*	-	-	-
256000	Fresh aromatic plants: parsley, basil, mint, etc.	NS	-	30	30
270060	Leek	34	66	30	66
231020	Bell pepper	NS	-	30	30
211000	Potato	19	-	30	30
213080	Radish and black radish	18	-	30	30
270070	*Rhubarb*	*8*	-	-	-
231010	Tomato	71	66	30	66
300000	**Dried legumes**	**68**	**-**	**90**	**90**
300010	Beans (shelled)	50	-	30	30
300020	Lentils	18	-	30	30
300030	Peas (shelled)	NS	-	30	30
400000	**Oil seeds and oleaginous fruits**	**15**	**-**	**90**	**90**
402010	Olives for oil	NS	-	30	30
401050	Sunflower seeds (oil)	NS	-	30	30
401070	Soybeans	NS	-	30	30
500000	**Cereals**	**354**	**-**	**180**	**246**
500050	Oats	30	33	30	33
500090	Wheat	90	-	30	90
500030	Maize	30	-	30	30
500010	Barley	30	-	30	30
500060	Rice	30	-	30	30
500020	*Buckwheat*	*60*	-	-	-
500070	Rye	30	33	30	33
500080	*Sorghum*	*12*	-	-	-
500990	*Other cereals: spelt, triticale, etc.*	*42*	-	-	-
600000	**Tea, infusions, coffee, cocoa**	**56**	**-**	**120**	**120**
610000	Tea	NS	-	30	30
620000	Coffee	NS	-	30	30
630000	Infusions (mint and other aromatic plants)	NS	-	30	30
640000	Cocoa (fermented beans)*	NS	-	30	30
800000	**Spices**	**15**	**-**	**-**	**-**

EU code	Foodstuffs	2012 number of samples	2013 coordinated EU programme	Proposed number of samples for 2013	Proposed total number of samples for 2013 (including the coordinated programme)
900000	**Sugar crops**	**15**	**-**	**72**	**72**
900010	Sugar beet	15	-	42	42
900020	Sugar cane	NS	-	30	30
1000000	**Animal foodstuffs and foodstuffs of animal origin**	**NS**	**-**	**527**	**377**
1040000	**Honey**	**NS**	**-**	**30**	**30**
TOTAL		**2069**	**528**	**2828**	**3146**

Key:

- **2012 number of samples:** number of samples taken in 2012 according to information provided by the DGCCRF, including samples required as part of the 2012 coordinated programme (Regulation (EU) No 915/2010).
  NS: not specified
- **2013 coordinated programme:** sample numbers imposed by the European Commission within the framework of the 2013 coordinated Community programme (Regulation (EU) No 1274/2011).
- **Proposed number of samples for 2013** to achieve optimal characterisation of chronic and acute dietary exposure of the French mainland population.
- *In italics: foodstuff undergoing surveillance in 2012 but not appearing as a priority for surveillance*.

* Foodstuff included with regard to the theoretical risk only

5. UNCERTAINTIES

The expert appraisal method used was based on the consumption and food contamination data available in September 2012.

Firstly, it is important to stress that, despite the large number of individuals participating in the Inca 2 study, the description of the consumption habits of certain foods undergoing screening for pesticides is based on a very small number of consumers. The acute risk associated with the consumption of certain foodstuffs may accordingly be underestimated as well as overestimated. In addition, infants and young children aged under 3 years were not specifically addressed in this work. A specific study (TDSi, for Total Diet Study: Infants) is currently under way (2012-2014) with the aim of estimating the exposure of this particularly vulnerable population *via* foods "as consumed".

Contamination levels of plant foodstuffs were in turn estimated only on the basis of the results of 2010 surveillance programmes, which for some *pesticide-foodstuff* pairs may be based on low sample numbers, possibly leading to the risk being under- or overestimated.

Moreover, the analytical results reported cannot be used to calculate exposure with sufficient detail under the upper-bound contamination scenario (UB). This is because there is no distinction between unquantified results (undetected or at trace levels). It does not seem appropriate to systematically assign the limit of detection (LD) to all unquantified results, given the uncertainties related to actual contamination levels and actual agricultural practices, despite the regulatory status of the active substances. Therefore, taking into account the limits of quantification (LQ) instead of the limits of detection leads to levels of chronic and acute exposure being overestimated.

For future surveillance plans, it is strongly recommended that all laboratories systematically specify the level of detail for unquantified results: lower than the LD or between the LD and the LQ.

6. CONCLUSION

Levels of dietary exposure to pesticide residues in the general French population aged over 3 years were estimated from actual levels of food contamination observed in 2010 and 2011. Nearly 3,480,000 analytical results from foodstuffs of plant and animal origin, as well as from water from the public supply (0.6% of quantified results) were used to assess exposure and characterise acute and chronic dietary risk. Based on these results and with a view to preparing for the 2013 surveillance plan for pesticide residues, ANSES proposes:

- a **minimum number of samples for each foodstuff** in order to describe the mean contamination of pesticides considered as having priority with an acceptable level of uncertainty. Differences in terms of proposed sample numbers reflect the observed variability in contamination of these foodstuffs for these pesticides and not the level of risk associated with the consumption of each foodstuff;

- **continued surveillance of all the pesticides** listed in the Annexes and in particular the substances regarded as a priority in terms of acute and chronic dietary exposure of consumers in mainland France (Annexes 3, 4 and 6);

- **broadening surveillance to include the** pesticides for which coverage of the theoretically contributing diet is insufficient, or those not screened for in the main contributing foods (chronic exposure) or in theoretically critical foodstuffs (acute exposure). In particular, screening should be extended for substances authorised at Community level or undergoing assessment and associated with authorisations for use such as bifenazate, copper and its compounds, emamectin benzoate, ethephon, etoxazole, fenbutatin oxide, fipronil, flonicamid, flubendiamide, flufenacet, fluorides (sulfuryl), gamma-cyhalothrin, glufosinate, ioxynil, mandipropamid, meptyldinocap, spirodiclofen, tembotrione and tritosulfuron. These active substances are being revised at Community level, either in accordance with Article 12 of Regulation (EC) No 396/2005 or due to the ongoing European collective assessment.

The results confirm the findings of previous Opinions and reports by the Agency (ANSES, 2011a; ANSES, 2011b; ANSES, 2010) concerning the importance of:

- **refining the estimate of chronic exposure** in order to be able to draw conclusions in terms of the health risk for pesticides quantified in foods in 2010 and 2011, given the cases in which the priority threshold was exceeded in the upper-bound scenario: cyfluthrin, dieldrin*, dimethoate*, dithiocarbamates*, lindane and oxydemeton-methyl. Cyfluthrin, dimethoate and most dithiocarbamates are approved at Community level and have many authorised uses in France, including for fruit and vegetable crops. For these six pesticides, it is recommended that the current surveillance be maintained and that the number of samples be increased for some foodstuffs as specified in Table 4. In order to refine the estimate for these pesticides, with regard to the future results of the surveillance plans, it is necessary firstly to obtain details on the unquantified results (undetected or at trace levels) and secondly to improve the analytical methods as recommended in the TDS2 report detailing the target analytical limits for each matrix (ANSES, 2011b).

- **enhancing surveillance of acute exposure** for the following critical combinations that are associated with a risk of exceeding the ARfD reference dose: bitertanol in bananas, carbendazim (thiophanate-methyl) in cherries, dimethoate (omethoate) in carrots, cherries, courgettes and oranges, dithiocarbamates in lettuce and apples, and imazalil in citrus fruits. These combinations, corresponding mainly to the uses authorised in France and Europe, had already been identified in 2011, with the exception of the combinations thiophanate-methyl/cherries, dimethoate/oranges and dithiocarbamates/apples. In this respect, particular vigilance is needed concerning compliance of foodstuffs, especially for cherries, given new MRLs for dimethoate (0.2 mg/kg) that came into force in July 2010. This regulatory change should help in the short term to reduce residue levels and exposure levels for this pesticide. Finally, ANSES confirms its previous findings on the importance of revising the MRLs for the other substances mentioned, especially those of imazalil on citrus fruits and pears, given the estimated risk for the consumer, as required under Article 12 of Regulation (EC) No 396/2005.

  ** Substances mentioned as a priority in the conclusion of the TDS2 report (ANSES, 2011b)*

The Director General

Marc MORTUREUX

KEY WORDS

Surveillance programmes, pesticide residues, sampling strategy, dietary exposure, chronic risk, acute risk, general population, France

REFERENCES

AFSSA, 2009a, Appui scientifique et technique relatif à la stratégie de surveillance des résidus de pesticides dans les aliments [*Scientific and technical support relating to the strategy for surveillance of pesticide residues in food*]. Response to Request 2009-SA-171. 87 p. Available online: www.anses.fr

AFSSA, 2009b, Report of the Individual and National Study on Food Consumption 2. AFSSA Blue Papers. 225 p. Available online: www.anses.fr

AFSSA, 2009c, Appui scientifique et technique relatif à l'entrée en vigueur du règlement (CE) N°396/2005 concernant les LMR de pesticides dans les denrées alimentaires [*Scientific and technical support relating to the entry in force of Regulation (EC) No 396/2005 on MRLs of pesticides in food and feed*]. Response to Request 2008-SA-070. 73 p. Available online: www.anses.fr.

ANSES, 2010, Avis de l'Agence nationale de sécurité sanitaire des aliments relatif au programme 2011 de surveillance des résidus de pesticides dans les aliments [*Opinion of the French food safety agency on the 2011 surveillance programme on pesticide residues in food*], Response to Request 2010-SA-110. 22 p. + annexes

ANSES, 2011a, Avis de l'Agence nationale de sécurité sanitaire des aliments relatif au programme 2012 de surveillance des résidus de pesticides dans les aliments [*Opinion of the French food safety agency on the 2012 surveillance programme on pesticide residues in food*], Response to Request 2011-SA-203. 23 p. + annexes

ANSES, 2011b, French Total Diet Study 2 (TDS2), Volume 2, Pesticide residues, additives, acrylamide and polycyclic aromatic hydrocarbons, June 2011, Scientific Edition, 362 p.

Bouyer, J., 2000, Méthodes statistiques Médecine-Biologie. Editions INSERM. 351 pages.

European Commission, 2012, Pesticide Residue MRLs, Regulatory database on pesticides: http://ec.europa.eu/sanco_pesticides/public/index.cfm

European Commission, 1997, Metabolism and distribution in plants, Annex A 7028/VI/95 rev.3.

EFSA, 2005, Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from Commission related to the appropriate variability factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables. EFSA publications, 61 p.

EFSA, 2007, Reasoned Opinion on the potential chronic and acute risk to consumers' health arising from the proposed temporary EU MRLs according to Regulation EC No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007, 106 p.

EFSA, 2008a, Conclusion regarding the peer review of the pesticide risk assessment of the active substance flutolanil. EFSA Scientific Report 126. 63 p. Available online: www.efsa.europa.eu.

EFSA, 2008b, Conclusion regarding the peer review of the pesticide risk assessment of the active substance cyromazine. EFSA Scientific Report 168. 94 p. Available online: www.efsa.europa.eu.

EFSA, 2009, Modification of existing MRL for fludioxonil in celeriac on request from the European Commission. EFSA Journal 2009; 7(10): 1345. 22p. Doi: 10.2903/j.efsa.2009.1345. Available online: www.efsa.europa.eu.

EFSA, 2010, Modification of the existing MRLs for dimethoate in various crops. EFSA Journal 2010; 8(3):1528. 35p. Doi: 10.2903/j.efsa.2010.1528. Available online: www.efsa.europa.eu.

EFSA, 2011, The 2009 European Union Report on Pesticide Residues in Food, EFSA Journal 2011;9(11):2430, 225 pp.

GEMS/Food-EURO, 1995, Second Workshop on Reliable Evaluation of Low-level contamination of food, Kulmach, Germany.

Hercberg, S., Deheeger, M. & Preziosi, P., 1994, SU-VI-MAX. Portions alimentaires. Manuel photos pour l'estimation des quantités. Paris (FR): Editions Poly Technica.

Nougadère A., Reninger J.C., Volatier J.L., Leblanc J.C., 2011, Chronic dietary risk characterization for pesticide residues: A ranking and scoring method integrating agricultural uses and food contamination data. Food Chem. Toxicol. 49(7):1484-1510

Nougadère A., Sirot V., Kadar A., Fastier A., Truchot E., Vergnet C., Hommet F., Baylé J., Gros P. and Leblanc J.C. (2012). Total diet study on pesticide residues in France: Levels in food as consumed and chronic dietary risk to consumers, Environment International, 45: 135–150.

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJEU, 16/03/2005) and regulations modifying its Annexes II, III and IV on maximum levels applicable to residues of products appearing in its Annex I

Commission Regulation (EC) No 178/2006 of 1 February 2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply

Commission Implementing Regulation (EU) No 705/2011 of 20 July 2011 approving the active substance imazalil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

Tomlin C.D.S., 2009, Pesticide Manual, A World Compendium, 15th edition, BCPC, 1457 p.

WHO, 1997, Guidelines for predicting dietary intake of pesticides residues (revised). Prepared by the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food) in collaboration with the Codex Committee on Pesticide Residues. WHO Publications. WHO/FSF/FOS/97.7., 31 p.

ANNEXES

Annex 1: List of active substances assessed, regulatory status, adjustments for the calculation of dietary exposure and toxicity reference values

Annex 2: Results from the calculation of chronic exposure (Estimated daily intake, EDI)

Annex 3: *Foodstuff-substance* pairs contributing more than 2.5% of the acceptable daily intake (ADI) in the most highly exposed individuals under the upper-bound exposure scenario (UB)

Annex 4: Additional assessment *(a priori* and *a posteriori* theoretical chronic risk)

Annex 5: Equations for calculating acute exposure

Annex 6: Results from the calculation of acute exposure (ESTI)