Director General

Maisons-Alfort, 20 June 2014

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

on a request for scientific support for a reassessment of the regulatory provisions for protecting bystanders and residents of areas treated with plant protection products

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

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

Its opinions are made public.

This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 20 June 2014 shall prevail.

On 8 November 2013, ANSES received a request from the French Directorate General for Food (DGAL) for a scientific opinion reassessing the regulatory provisions for protecting bystanders and residents close to areas treated with plant protection products.

1. BACKGROUND AND PURPOSE OF THE REQUEST

As background to the Request, the Ministry of Agriculture stated the following:

The protection of public health is a major concern for the Ministry of Agriculture's Directorate General for Food. As a result, and in view of the recent reports by the French Senate[1] "Pesticides: eliminating risk" and by INSERM[2] "Pesticides: effects on health", the Ministry wished to investigate the preservation of the health of bystanders and residents close to areas treated by plant protection products.

Plant protection products are governed by a series of regulations. There are strict procedures for the placing of plant protection products on the market and for monitoring their use that are harmonised at European level. Marketing authorisation (MA) for plant protection products is granted by the Ministry of Agriculture on the basis of assessment in France, undertaken by ANSES, of the risks to human health and the environment. If a product assessment reveals an unacceptable risk, no MA is granted. In other cases, if a product assessment reveals a specific risk, the MA imposes specific conditions of use.

[1] Pesticides: vers le risque Zéro. Information Report No. 42 (2012-2013). Joint Mission for Information on Pesticides, filed on 10 October 2012

[2] Pesticides. Effets sur la santé. Collective expert appraisal. Editions Inserm, July 2013.

In addition, these provisions are supplemented by those of the Order of 12 September 2006 on the placing on the market and use of plant protection products. This Order imposes measures to make the use of these products safer for the applicator, the consumer and the environment, including local residents and bystanders.

The Order of 27 June 2011, meanwhile, governs the use of plant protection products in areas frequented by the general public or groups of vulnerable individuals (school playgrounds, play areas in parks and gardens, hospital complexes, etc.) in order to reduce the risks related to exposure to plant protection products in public places. Products classified as toxicologically hazardous for health are strictly prohibited in such places. Recommendations are included regarding safety distances to protect certain public places, but these do not include residential buildings.

In this context, ANSES was asked to provide a scientific opinion analysing the efficacy of the regulatory provisions described above, governing the placing on the market and use of plant protection products, regarding aspects related to protection of the health of people residing close to treated areas. This therefore involves ensuring that risks resulting from the drift of plant protection products are controlled by existing regulatory measures. If ANSES judges that current measures governing the drift of plant protection products are insufficient as regard these risks, the Agency is asked to specify the measures to be implemented, especially the safety distances to be applied, possibly by category of products, or the imposition of a “residential untreated area” as part of the Marketing Authorisation for each plant protection product. The Orders of 12 December 2006 and 27 June 2011 will be reviewed in the light of the results of this scientific and technical support.

2. ORGANISATION OF THE EXPERT APPRAISAL

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

The appraisal was carried out by the ANSES Regulated Products Department, and the Expert Committee (CES) on Plant Protection Products: Chemical Substances and Preparations was consulted on 4 June 2014.

3. APPROACH ADOPTED AND ANALYSIS

The analysis carried out by ANSES was broken down into the following phases:

- presentation and analysis of European and French regulatory requirements,
- presentation of currently available risk assessment methodologies for residents and bystanders,
- presentation of the results of the risk assessments on the basis of these methodologies.

3.1. Presentation and analysis of European and French regulatory requirements

3.1.1. European regulatory documents on risk assessment

Regarding the placing on the market of plant protection products, Regulation (EC) No. 1107/2009[3] entered fully into force on 14 June 2011. In particular, it repeals Directive No. 91/414/EEC[4].

Both texts are accompanied by Amending Directives[5] [6] or Implementing Regulations specifying the requirements, especially in terms of risk assessment for humans as well as the decision-making criteria concerning marketing authorisation for products, known as "uniform principles".

According to the provisions of Directive No. 91/414/EEC and Directive No. 94/79/EC, replaced on a transitional basis by Implementing Regulation (EU) No. 545/2011[7] of 10 June 2011, there must be an estimation of the exposure of bystanders (and anyone who happens to be incidentally exposed) during the application of a plant protection product. Regulation (EU) No. 545/2011 was repealed by Implementing Regulation (EU) No. 284/2013[8] of 1 March 2013. However, it continues to apply as regards applications for authorisation submitted no later than 31 December 2015 for products containing at least one active substance whose application for approval or renewal of approval was submitted no later than 31 December 2013. This is currently the most commonly occurring situation.

In the context of Regulation (EC) No. 1107/2009 and especially the new Implementing Regulation (EU) No. 284/2013 of 1 March 2013 which followed Regulation (EU) No. 545/2011, a definition of resident is introduced and presented alongside the definitions of bystanders[9].

It should be noted that, under Regulation (EC) No. 1107/2009, there is no definition of the French term "*riverain*". For the purpose of this Opinion, the terms defined in the Regulation, i.e. bystanders and residents will be used to cover the idea of "*riverains*".

According to Implementing Regulation (EU) No. 284/2013, an extract from which is given below, an estimation must be made of bystander and resident exposure.

7.2.2 Bystander and resident exposure

Information shall be provided to permit an assessment of the extent of exposure to the active substances and toxicologically relevant compounds likely to occur under the proposed conditions of use, taking into account, where relevant, cumulative and synergistic effects.

It shall also provide a basis for the selection of appropriate protective measures, including restricted entry intervals, exclusion of residents and bystanders from treatment areas and separation distances.

7.2.2.1. Estimation of bystander and resident exposure

An estimation shall be made, using where available a suitable calculation model in order to permit an evaluation of the bystander and resident exposure likely to arise under the proposed conditions of use. Where relevant, this

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3 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.

4 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.

5 Commission Directive 94/79/EC of 21 December 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

6 Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market.

7 Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

8 Commission Regulation (EU) No. 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, 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.

9 According to the Regulation (EC) No. 284/2013, the following definitions apply:
c) '***bystanders'*** are people who casually are located within or directly adjacent to an area where application of a plant protection product is in process or has taken place, but not for the purpose of working on the treated area or with the treated commodity;
d) ***"residents"*** are people who live, work or attend any institution near to areas that are treated with plant protection products, but not for the purpose of working on the treated area or with the treated commodity.

estimation shall take into account cumulative and synergistic effects resulting from the exposure to more than one active substance and toxicologically relevant compounds, including those in the product and tank mix.

The applicant shall take into consideration that bystanders can be exposed during or after the application of plant protection products and residents may be exposed to plant protection products, mainly, but not only, by inhalation and dermal route and that infants and toddlers exposure may also occur by the oral route (through hand-mouth transfer).

Circumstances in which required
An estimation of bystander and resident exposure shall always be performed.

Estimation conditions
An estimation of bystander and resident exposure shall be made for each relevant type of application method. Specific information including maximum total dose and spray concentration shall be included. The estimation shall be made with the assumption that bystanders and residents do not use any personal protective equipment.

7.2.2.2. Measurement of bystander and resident exposure
The study shall supply data for an evaluation of the exposure to which bystanders and residents are likely to be subjected under the proposed specific conditions of use. The study shall be ethically sound.

Circumstances in which required
Exposure data for the relevant exposure routes shall be required where the model-based risk assessment indicates that the relevant reference value is exceeded or where there are no representative data in available calculation models.
The study shall be done under realistic exposure conditions taking into account the proposed conditions of use.

Regarding bystanders and residents, Regulation (EU) No. 284/2013 (7.2.2.1) states: *"Where relevant, this estimation shall take into account cumulative and synergistic effects resulting from the exposure to more than one active substance and toxicologically relevant compounds, including those in the product and tank mix".* This assessment is very complicated to implement. It has been the subject of several European studies under the aegis of EFSA[10] and the European Commission, and in which ANSES has actively participated.

This methodology is based partly on an estimation of exposures[11] and partly on the identification of cumulative assessment groups[12] for active substances that will be subjected to cumulated assessment.

[10] European Food Safety Authority

[11] EXTERNAL SCIENTIFIC REPORT submitted to EFSA. Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment. Glass R. et al.. Fera, EFSA question No 2010-0086. Accepted for Publication on 11/09/2012. http://www.efsa.europa.eu/fr/supporting/pub/346e.htm

[12] SCIENTIFIC OPINION. EFSA Panel on Plant Protection Products and their Residues (PPR). Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile. EFSA Journal 2013; 11(7):3293. . http://www.efsa.europa.eu/fr/efsajournal/pub/3293.htm- SCIENTIFIC OPINION. EFSA Panel on Plant Protection Products and their Residues (PPR). Scientific Opinion on the relevance of dissimilar modes of action and its appropriate application for cumulative risk assessment of pesticide residues in food. EFSA Journal 2013;11(12):3472.http://www.efsa.europa.eu/fr/efsajournal/pub/3472.htm
- EXTERNAL SCIENTIFIC REPORT submitted to EFSA. Identification of Cumulative Assessment Groups of Pesticides. Prepared by Dr. Elsa Nielsen et al.. National Food Institute. Technical University of Denmark. EFSA question No. 2009-01092. Accepted for Publication on 09/04/2012. http://www.efsa.europa.eu/en/supporting/pub/269e.htm
- EXTERNAL SCIENTIFIC REPORT submitted to EFSA. CFT/EFSA/PRAS/2012/07-CT 01, 02 and 03 "Toxicological data analysis to support grouping of pesticide active substances for cumulative risk assessment of effects on liver, on the nervous system and on reproduction and development" French Agency for Food, Environmental and Occupational Health & Safety (ANSES); National Institute for Public Health and the Environment (RIVM); Azienda Ospedaliera Luigi Sacco - Polo Universitario. http://www.efsa.europa.eu/fr/supporting/doc/392e.pdf
- Under way: EXTERNAL SCIENTIFIC REPORT to be submitted to EFSA. GP/EFSA/PRAS/2013/02. "Toxicological data collection and analysis to support grouping of pesticide active substances for cumulative risk assessment of effects on the nervous system, liver, adrenal, eye, reproduction and development and thyroid system" French Agency for Food, Environmental and Occupational Health & Safety (ANSES); National Institute for Public Health and the Environment (RIVM); Azienda Ospedaliera Luigi Sacco - Polo Universitario.
- ACROPOLIS http://www.acropolis-eu.com/

Other methodologies[13] concerning cumulative risk assessment could also be adapted for assessing the risk for bystanders and residents in certain exposure situations, especially in the case of direct exposure to spray drift.

3.1.2. Principles for assessing exposure and risks, and decision-making criteria

Regulation (EC) No. 1107/2009, and previously Directive 91/414/EEC, specify that an estimation of exposure must be carried out. However, the decision-making process that can lead to the granting of an MA requires a risk assessment, which takes into account an estimation of exposure relative to use and comparison with a reference toxicity value (AOEL[14]**)** established at the time of approval of the active substances.
Regulation (EU) No. 546/2011 on uniform principles for the evaluation and authorisation of plant protection products thus states that authorisation may be granted if:

> *2.4.1.4. Waiting and re-entry or other precautions must be such that the exposure of bystanders or workers exposed after the application of the plant protection product does not exceed the AOEL level established for the active substance or toxicologically relevant compound(s) nor any limit values established for those compounds in accordance with the EU provisions referred to in point 2.4.1.1.*
>
> *2.5.1.4. No authorisation shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators, bystanders or workers as referred to in point 2.4.1 are exceeded.*

Regulation (EU) No. 546/2011 on uniform principles for the evaluation and authorisation of plant protection products, taking into account the requirements of Directive 97/57/EC, only includes evaluation for bystanders. However, the decision-making principles applying to bystanders can be assimilated for application to residents.

More specifically, the estimation of exposure is based on studies or models of exposure, which quantify external exposure. The estimation of external exposure is transformed into systemic exposure by taking into account dermal absorption[15], absorption by inhalation (considered to be 100% of the exposure dose), and oral absorption. This systemic exposure is compared to the AOEL[16]. It should be noted that unlike the methods for establishing AOELs, the methods for acute AOELs (AAOELs[17]) have not yet been harmonised and are currently under discussion at European level.
Whether or not it is necessary to establish an AAOEL will depend on the substances' toxicological properties. While awaiting harmonised methods for establishing this value, the risks for bystanders and residents may be considered acceptable as stated by Regulation (EC) No. 1107/2009 [Implementing Regulation (EU) No. 546/2011] when systemic exposure is lower than the AOEL.

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[13] ECHA. Guidance for Human Health Risk Assessment. Volume III, Part B. GUIDANCE ON REGULATION (EU) No 528/2012 CONCERNING THE MAKING AVAILABLE ON THE MARKET AND USE OF BIOCIDAL PRODUCTS (BPR). Version 1.0. December 2013, p.345-353.

[14] Working document. Draft GUIDANCE FOR THE SETTING AND APPLICATION OF ACCEPTABLE OPERATOR EXPOSURE LEVELS (AOELs). EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL. Directorate E – Safety of the food chain. E3 - Chemicals, Contaminants, Pesticides. SANCO 7531 - rev.10. 7 July 2006.

[15] Dermal absorption is determined according to the harmonised methodology specified in the guidance document: SCIENTIFIC OPINION. Guidance on Dermal Absorption. EFSA Panel on Plant Protection Products and their Residues (PPR). EFSA Journal 2012; 10(4):2665. http://www.efsa.europa.eu/fr/efsajournal/pub/2665.htm

[16] An AOEL (Acceptable Operator Exposure Level) is the reference value against which non-dietary exposure to pesticides is currently compared. It is intended to define a daily exposure level throughout a spraying season, from year to year, below which there is no expected adverse systemic effect. An AOEL is usually obtained by applying a safety factor (most frequently 100) to a No Observed Adverse Effect Level (NOAEL) (which may be corrected to take account of incomplete oral absorption) on the basis of a toxicology study in which animals have received a daily dose for 90 days or more. Less frequently, the critical NOAEL is taken from a study with a shorter dosage period (for example, a development study).

[17] AAOEL (Acute Acceptable Operator Exposure Level) is the term used in the EFSA 2014 document to describe a reference value for comparison with acute non-dietary exposure (i.e. exposure that could occur in a single day). This would only be relevant for plant protection products for which such exposure may produce significant toxicity.

3.1.3. French regulatory documents

Furthermore, apart from the European regulatory framework governing authorisations for the placing of plant protection products on the market, France applies various national regulations. In particular, this means the Order of 12 September 2006 on the placing on the market and use of products covered by Article L. 253-1 of the Rural and Maritime Fishing Code and the Order of 27 June 2011 on the ban against using certain products mentioned in Article L. 253-1 of the Rural and Maritime Fishing Code in places frequented by the general public or groups of vulnerable people.

Various articles of the **Order of 12 September 2006** specify measures designed to limit environmental contamination, especially concerning spray drift from plant protection products.

Article 2 of this Order lays down the following measures whose purpose is to limit spray drift:

Article 2

- *Irrespective of any changes to weather conditions during the use of products, appropriate methods must be implemented to prevent spray from drifting outside the field or area being treated.*
- *Products may only be used for dusting or spraying if wind strength is lower than or equal to Force 3 on the Beaufort Scale.*

The general measures indicated, especially those whose purpose is to reduce spray drift, are also likely to reduce the exposure of bystanders and residents. Nevertheless, it would be worth specifying and better quantifying the impact of appropriate measures such as anti-drift nozzles for example or, in certain conditions, a reduction of the volume sprayed. Data for quantifying the influence of these measures, especially if concomitant, would therefore be useful to refine the recommendations to users and could also be taken into account in assessments by ANSES.
Articles 11 to 14 list specific provisions for nonsprayed areas in the vicinity of water sources. These articles propose measures for managing spray drift in order to limit the contamination of aquatic environments by introducing the notion of nontreated areas.
These measures, whose purpose is to reduce the exposure of aquatic environments, can contribute to limiting the exposure of residents and bystanders. A similar principle to the one leading to the establishment of nontreated areas around water sources could also be implemented for the protection of residents and bystanders and lead to the establishment of safety buffer zones around residential areas. The zone would be defined in relation to the risk assessment; however as with nontreated areas near water sources, a minimum size for the non-treated area could be applied.

The Order of 27 June 2011 governs the use of plant protection products in places frequented by the general public or groups of vulnerable people (children, the sick or the elderly).

Article 2 clearly indicates that the use of plant protection products with a toxicological classification or humans:

- *Is prohibited in places such as school playgrounds and areas usually frequented by pupils on school grounds; areas usually frequented by children in kindergartens, drop-in child care facilities and leisure centres; play areas for children in parks, gardens and green spaces open to the public.*

- *Is prohibited within 50 m of buildings visited by or accommodating vulnerable people located in such establishments as hospital complexes and hospitals, private clinics, care homes, rehabilitation institutions, establishments visited by or accommodating the elderly; establishments caring for disabled adults or people suffering from serious medical conditions (see Point II of the Order's Annex), without this prohibition applying outside the boundaries of these premises.*

This Order reinforces the risk assessment procedure required by Regulation (EC) No. 1107/2009. It is intended to reduce non-dietary exposure to plant protection products to negligible proportions for certain categories of the population identified as vulnerable.

3.1.4. Testimonies received by ANSES between 19/02/2014 and 22/05/2014

ANSES received personal testimonies from local residents and bystanders declaring that they had been exposed to plant protection products during application. The majority were responding to a call for testimony from non-governmental organisations, distributed among members of associations.
ANSES received 74 such testimonies.

They originated from 17 of France's 27 Regions. Twenty-two percent of testimonies came from Limousin, followed by Rhône-Alpes with 12%, Brittany with 9.5% and Aquitaine with 8%.
Regarding the type of crop, 35% of testimonies concerned orchards and 16% vineyards.
Forty-five percent reported simple nuisance: odours, obliged to close windows, unable to stay in the garden during spraying, which sometimes occurred at weekends or on holidays, and contamination of washing hung out to dry, of play facilities for children, or of fruit and vegetables produced in gardens.
Fifty-five percent reported, in addition to these nuisances, health affects potentially related to exposure.
Among the health effects, the most frequently reported were signs suggesting irritation of the eyes and respiratory tract.
It should be noted that neither ANSES nor (as far as ANSES knows) the regional State services were able to follow up these reports.
In any event, ANSES emphasises the importance of training programmes for farmers in good agricultural practice and wishes to reiterate that usage conditions and the regulations in force must be respected, as they contribute to reducing exposure and especially that of residents and bystanders.

3.2. Presentation of currently available risk assessment methodologies for residents and bystanders

There are several methodologies that have been used at European level since the coming into force of Regulation (EC) No. 1107/2009 in the context of enabling the evaluation of applications for plant protection products in separate zones. While these methodologies are based on the same principle, the parameters used may differ by Member State, leading to different results.

It should be noted that, for several years now, EFSA has been working on the complex task of harmonising these methodologies at European level[18].

The methodologies presented below are those most frequently used by the experts in Member States, but only the studies most relevant to this Opinion are included.

3.2.1. Presentation of methodologies used by ANSES

In this context and while awaiting the adoption of a harmonised methodology, ANSES applies the methodologies described below.

Evaluation for bystanders

The evaluation methodology is based on the European Predictive Operator Exposure Model (EUROPOEM II[19]) developed by the European Commission's Directorate-General for Agriculture (DG VI), one purpose of which was to develop a predictive bystander exposure model regarding particle drift from plant protection products.

[18] In 2010, EFSA published an initial document intended to harmonise evaluations, "Scientific Opinion on Preparation of a Guidance Document on Pesticide. Exposure: Assessment for Workers, Operators, Bystanders and Residents. EFSA Panel on Plant Protection Products and their Residues (PPR). EFSA Journal 2010; 8(2):1501. http://www.efsa.europa.eu/fr/efsajournal/doc/1501.pdf
In order to take into account the new data available as well as the comments received on this version, EFSA has produced a new draft guidance document, which has been made available for comment: http://www.efsa.europa.eu/en/consultations/call/140401.htm

[19] EUROPOEM II. Project FAIR3 CT96-1406. Report from the bystander working group. December 2002.

Bystanders are considered to be exposed if they happen to be in or immediately adjacent to an area treated, during or shortly after treatment, for a brief period. They may be on the edge of a field, downwind of spray drift and at a distance of about 8 metres from the sprayer treating a row near the edge of the field.

Four exposure scenarios have been identified. These are exposure to drift from a boom sprayer treating field crops, from a rotating atomiser, or from airblast sprayers in orchards, with or without the presence of leaves. The distribution of the data was studied in all four scenarios and the 90th percentile of the drift values was used to estimate exposure.
Exposure was measured on subjects by inhalation[20] and the dermal route after a single pass of a sprayer at a distance of 8 metres.
External dermal contamination was measured by the passive dosimetry method over the entire body from deposits collected on the overalls, gloves and face. These results were normalised in millilitres per subject and per pass of the sprayer; the percentage of the application dose, in litres or kg/ha, was also taken into account.

Potential bystander exposure by inhalation was determined with the use of masks fitted with filter cartridges worn by volunteers. This is expressed in millilitres of mixture sprayed per cubic metre of air inhaled (equivalent to one hour's respiration). Contaminations correspond respectively to 0.03 mL and 0.06 mL of mixture sprayed per cubic metre of air, for low-growing and high-growing crops (e.g. orchards) respectively, with values at the 90th percentile.

It was found that spray drift depends on several factors such as the method of application (on high-growing or low-growing crops), the volume and quality of the application, wind strength and vehicle speed.
The measurements for drift thus obtained are comparable to those reported by Ganzelmeier and Rautmann[21], whether on field crops, vegetable crops, fruit crops, hops or vines.

The external dermal exposure measured is weighted by dermal absorption in order to estimate systemic (internal) exposure. Internal exposure by inhalation is not weighted, as absorption is considered to be total.
Systemic exposure of bystanders is the sum of the systemic exposures by both exposure routes. This estimated exposure is compared to the AOEL.

Evaluation of residents (exposure by inhalation)

When values from air measurements[22] are available, ANSES carries out an evaluation. The exposure value is estimated taking into account the maximum value measured in the air, and the respiratory volume over a period of twenty-four hours. For risk assessment, this result is compared with the substance's ADI[23]. The ADI was chosen because there was initially no harmonised AOEL for all substances. Once the methodologies used have been harmonised, the AOEL will be used.

The advantage of this assessment procedure is that it takes into account measured values for the most frequently encountered substances. Its limitations concern the small number of measurements available and the need to update them.

[20] 250 measurements were generated by the Application Hazards Unit (AHU) of the Central Science Laboratory (CSL) run by the UK's Ministry of Agriculture.
[21] Ganzelmeier H, Rautmann D, 1995. Studies on the spray drift of plant protection products. Mitteilungen aus der BBA für Land-und Forstwirtschaft Berlin-Dahlem, Heft 305, 113.
Rautmann D, Streloke M and, Winkler R, 2001. New drift values in the authorisation procedure for plant protection products. Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft (Federal Biological Research Center for Agriculture and Forestry), 383, Berlin, 133-141.
[22] *Recommandations et perspectives pour une surveillance nationale de la contamination de l'air par les pesticides. Synthèse et recommandations du comité d'orientation et de prospective scientifique de l'observatoire des résidus de pesticides* (ORP). [Recommendations and outlook for national surveillance of atmospheric contamination by pesticides] October 2010.
[23] ADI: The Acceptable Daily Intake of a chemical product is an estimate of the amount of active substance found in food or drinking water that can be ingested daily over a lifetime without appreciable health risk to the consumer, taking into account all known factors at the time of assessment. It is expressed in milligrams of chemical per kilogram of body weight (WHO, 1997).

The maximum value could be replaced by more representative data if a larger number of measurements became available.

Risk assessment for children re-entering areas treated by herbicides

Regarding preparations for application on lawns or sports grounds likely to be used subsequently by children, ANSES conducts exposure assessment based on the BREAM[24] model. Estimated exposure is compared to the AOEL.

Specific risk assessment for derogations to the prohibition of aerial spraying

Article 9-1 of Directive 2009/128/EC[25] establishing a framework for Community action to achieve the sustainable use of pesticides states that "Member States shall ensure that aerial spraying is prohibited", while Article 9-2 states that, "By way of derogation from Paragraph 1, aerial spraying may only be allowed in special cases", providing the risks related to this type of application are assessed. This Directive was transposed into French Law by the Order of 31 May 2011[26] and supplemented by the Order of 23 December 2013[27].

For this purpose, ANSES was requested to undertake specific evaluations of exposure regarding bystanders and residents during aerial application.

- Evaluation of bystander exposure during application by aircraft

For the purpose of the evaluation, it was considered that exposure of bystanders passing close to a field treated by an aircraft was lower than or equal to that of people on the ground who might be flagging the area to be treated. The evaluation for flaggers can be considered to fall within the same "risk envelope"[28] as for bystanders. This evaluation is for a worst-case scenario, as bystanders are exposed to spray drift for shorter periods.
Exposure for "flaggers" is assessed on the basis of the PHED[29] model.
Estimated exposure is compared to the AOEL.

- Evaluation of resident exposure

Exposure of residents (adults and children) is evaluated on the basis of the AgDRIFT[30] model and the AFSSE-INERIS report[31].
Residents can be exposed in different ways:
- By inhalation or by the dermal route from spray drift,
- Indirectly by the dermal route from contact with residues on grass,
- By the oral route in children.
Estimated exposure is compared to the AOEL.

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[24] PSD (Pesticides Safety Directorate, UK) (2008) Bystander Exposure. Guidance. http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/B/Bystander-exposure-guidance.pdf

[25] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

[26] Order of 31 May 2011 on aerial spraying conditions for products listed in Article L. 253-1 of France's Rural and Maritime Fishing Code.

[27] Order of 23 December 2013 on aerial spraying conditions of products listed in Article L. 253-8 of France's Rural and Maritime Fishing Code, published in the Official Journal No. 0301 of 28 December 2013, application of which was suspended by an Order of the Council of State on 6 May 2014.

[28] Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach" EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL. Directorate E – Safety of the food chain. Unit E.3 - Chemicals, contaminants, pesticides. SANCO/11244/2011 rev. 5.14 March 2011.
http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/risk_envelope_gd_rev_14032011_en.pdf

[29] Pesticide Handler Exposure Database (PHED): http://www.epa.gov/pesticides/science/handler-exposure-data.html#phed

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[30] Spray Drift Task Force (SDTF). 2002. A User's Guide for AgDRIFT 2.0.05: A Tiered Approach for the Assessment of Spray Drift of Pesticides. Regulatory Version. Teske ME, Bird SL, Esterly DM, Curbishley TB, Ray SL, Perry SG. 2000 AgDRIFTt: A model for estimating near-field spray drift from aerial applications. Environ Toxicol Chem 21:659-671.

[31] *Impact sanitaire de l'épandage aérien de produits anti parasitaires* (Impact on health of aerial spraying of pesticides), AFSSE – INERIS.

3.2.2. Presentation of the methodology, based on the publication by Martin *et al.* (2008)[32]

Only what are considered to be the most important details are given in this Opinion. The elements and parameters used for calculations are given in the publication. This methodology is used especially by the German evaluation agency.

Bystanders are considered to be inadvertently exposed in a treated area or an immediately adjacent area, for a brief period, i.e. a few minutes, when the treatment was under way or had just taken place. They are mainly exposed to spray drift by the dermal route or to spray droplets by inhalation. This is acute exposure, involving a single treatment.

Residents who live or work close to a treated area are potentially subject to chronic exposure if their garden or place of work is adjacent to a treated area. They are therefore also potentially exposed by contact with deposits from spray drift and by inhalation of vapours volatilised from the product.

Exposure of bystanders

Potential exposure of bystanders (adults and children) is estimated by taking into account spray drift, as the exposure routes are dermal and by inhalation.

Dermal exposure caused by spray drift depends on the dose applied, the percentage of drift and the body surface area exposed. The estimate is corrected by dermal absorption to obtain systemic exposure.
It is calculated using the following formula:

SDE_B = (AR x D x BSA x DA)/BW	
SDE_B = Systemic Dermal Exposure of the bystander in mg/kg of body weight per day	
AR = Application Rate in mg of active substance/cm^2	DA = Dermal Absorption of the active substance in %
D = drift in % at 10 m	BW = body weight (60 or 16.15 kg)
BSA = Body Surface Area exposed in m^2	

The parameters used are explained in detail in the publication.

Exposure via spray drift is based on data from the work by Rautmann[33]. Bystanders are considered to be at a distance of 10 m downwind of the spraying.

Exposure by inhalation that can be caused by spray drift depends on the dose applied (Application Rate) on the entire surface area treated, the concentration in the air and the volume of air inhaled for an exposure lasting 5 minutes, without correction to the rate of absorption by inhalation, considered as equal to 100% (everything inhaled contributes to the internal dose).
It is calculated using the following formula:

$SIE_B = (I^*_A$ x AR x A x T x $I_A)$/BW	
SIE_B = Systemic Inhalation Exposure of bystanders in mg/kg of body weight/day	
I^*_A = specific exposure by Inhalation in mg/kg of active substance handled per day	T = duration of exposure: 5 min

[32] Guidance for Exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after Application. S. Martin, D. Westphal, M. Erdtmann-Vourliotis, F. Dechet, C. Schulze-Rosario, F. Stauber, H. Wicke and G. Chester. J. Verbr. Lebensm. 3 (2008): 272-281.

[33] New drift values in the authorisation procedure for plant protection products. In: Forster, B. and Streloke, M. (eds.) Workshop on Risk Assessment and Risk Mitigation Measures (WORMM). 27–29 September 1999, Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, booklet 383, 2001; updated version of 27th March 2006: Rautmann, D. (2006) Aktuelle Abdrifteckwerte (Current Drift Values).
http://www.jki.bund.de/cln_045/nn_926124/SharedDocs/10_FA/Publikationen/Pflanzenschutzgeraete/abdrifteckwerte_xls.html
Rautmann, D. (2004) Testing and Listing of Drift Reducing Sprayers in Germany. Biological Research Centre for Agriculture and Forestry, Application Techniques Division,
http://www.bba.de/english/inst_eng/ap_eng/ap_pub/lossredequip/beschreibung_e.pdf

AR = Application Rate in kg of active substance/ha	I_A = rate of absorption by Inhalation (100%)
A = Surface Area treated (ha/d)	BW = Body Weight (60 or 16.15 kg)

The parameters used are explained in detail in the publication.

Systemic (internal) exposure of bystanders is the sum of systemic exposures resulting from both routes of exposure, for adults and children:

$$\mathbf{SE = SDE_B + SIE_B} \text{ in mg/kg of body weight/day}$$

Estimated exposure is compared to the AOEL.

Exposure of residents

Several exposure situations are taken into account:

- dermal exposure (indirect) in adults and children during contact with a surface contaminated by spray drift,
- exposure by inhalation, for adults and children, to vapour drift after application,
- for children, two additional exposure situations are taken into account: exposure by the oral route of children playing on grass contaminated by a treatment and of children transferring contaminated objects to their mouths.

The methodology[34] is based on the work of the UK's Pesticides Safety Directorate, now the HSE-CRD[35] and the US EPA. Residents are considered to be at a distance of 10 m downwind of spraying.

- Dermal exposure by spray drift

This systemic exposure depends on the dose applied, the percentage of drift and the transfer to the resident's skin of spray deposited on treated grass for an exposure time estimated at 2 hours. It is corrected by dermal absorption of the substance to obtain systemic exposure. It is calculated using the following formula:

$\mathbf{SDE_R = (AR \times D \times TTR \times TC \times H \times DA)/BW}$	
SDE_R = Systemic Dermal Exposure of residents in mg/kg of body weight/day	
AR = Application Rate in mg of active substance/cm^2	TTR = Turf Transferable Residues in %
D = Drift in % for one or more applications	TC = Transfer Coefficient in cm^2/h (adult or child)
H = duration of exposure (2h)	BW = body weight (60 or 16.15 kg)

The parameters used are explained in detail in the publication.

- Exposure by inhalation through the drift of vapour after application

Exposure is estimated on the basis of the highest concentration in the air, averaged over 24 hours, in accordance with the volatility of the substance and the volume of air inhaled per day. It is estimated that the resident inhales vapour for the 24 hours following the treatment.
It is calculated using the following formula:

$\mathbf{SIE_B = (I^*_A \times AR \times A \times T \times I_A)/BW}$	
SIE_R = Systemic Inhalation Exposure of residents in mg/kg of body weight/day	
AC_v = Airborne Concentration of volatilised AS (mg of active substance/m^3)	I_A = absorption by Inhalation (%)
IR = Inhalation Rate (volume of air inhaled per day) in m^3/day (adults or children)	BW = Body Weight (60 or 16.15 kg)

The parameters used are explained in detail in the publication. Regarding airborne concentrations of active substance, values of 1 µg/m^3 for semi-volatile substances (vapour pressure between 0.01 and 5 mPa) and of

[34] PSD (Pesticides Safety Directorate, UK) (2008) Bystander Exposure. Guidance. http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/B/Bystander-exposure-guidance.pdf
[35] The Chemicals Regulation Directorate (CRD) is a Directorate of the Health & Safety Executive (HSE).

15 µg/m^3 for volatile substances (vapour pressure greater than 5 mPa) were chosen[36]. Exposure by inhalation can be refined by replacing the default values of 1 or 15 µg/m^3 with the atmospheric concentrations measured on site.

- Exposure of children playing on grass contaminated by a treatment

In this situation, exposure by the oral route is also taken into account.

Contamination by oral exposure of children touching their mouths with soiled hands depends on the dose applied, the percentage of drift, and the transfer of deposits of spray on treated grass by hand-to-mouth contact for an exposure time estimated at 2 hours. Oral exposure is corrected by oral absorption of the substance to obtain systemic exposure. The parameters used are explained in detail in the publication.
It is calculated using the following formula:

SOE_H= (AR x D x TTR x SE x SA x Freq x H x OA)/BW	
SOE_H = Systemic Oral Exposure of children by hand-to-mouth contact in mg/kg body weight/day	
AR = Application Rate in mg of active substance/cm^2	Freq = Frequency of hand-to-mouth gestures (number of occurrences/hour)
D = Drift in % for one or more applications	H = duration of exposure in hours
TTR = Turf Transferable Residues in %	OA = coefficient of Oral Absorption in %
SE = Saliva Extraction factor in %	BW = Body Weight (16.15 kg)
SA = Surface Area of hands in cm^2	

The parameters used are explained in detail in the publication.

- Exposure of children putting contaminated objects in their mouths

Contamination, by oral exposure, of children carrying contaminated objects to their mouths depends on the dose applied, the percentage of drift and transfer of spray deposited on treated grass by contact between soiled objects and the mouth, for an exposure time estimated at 2 hours. Oral exposure is corrected by oral absorption of the substance to obtain systemic exposure.

It is calculated using the following formula:

SOE_o = (AR x D x DFR x IgR x OA)/BW	
SOE_H = Systemic Oral Exposure of children by contact with a soiled object in mg/kg body weight/day	
AR = Application Rate in mg/m^2	IgR = Ingestion Rate of grass in cm^2
D = Drift in % for one or more applications	OA = coefficient of Oral Absorption in %
DFR = Dislodgeable Foliar Residues in %	BW = Body Weight (16.15 kg)

The parameters used are explained in detail in the publication.

Exposure of adult residents is the sum of systemic exposures by both routes of exposure, for adults.

$$SE = SDE_R + SIE_R$$

Exposure of child residents is the sum of exposures by the dermal, inhalation and oral routes.

$$SE = SDE_R + SIE_R + SOE_H + SOE_o$$

The exposures estimated are compared to the AOEL.

[36] Winkler, R. and Koch, W. (2005) Exposure Via Air (EVA 2.0.1) Assessment of the Short Range Transport and Deposition of Pesticides for Aquatic and Terrestrial Ecosystems. German Federal Environmental Agency (UBA) http://www.bvl.bund.de/cln_027/nn_492042/DE/04_Pflanzenschutzmittel/11_AntragstellerAnwender/02_Zulassungsverfahren/07_Naturhaushalt/naturhaush_node.html_nnn=true
and Siebers, J and Binner, R and Wittich KP (2003) Investigation on downwind short-range transport of pesticides after application in agricultural crops. Chemosphere 51(5):397-407

3.2.3. Presentation of the methodology based on the BREAM system (Bystander and Residential Exposure Assessment Model)[37]

Only what is considered to be the most important information is presented in this Opinion, as the elements and parameters used for the calculations are explained in detail in the publication.
This methodology is used in particular by the CRD HSE.

Exposure of bystanders and residents

Exposure estimation of bystanders and residents takes into account the following three scenarios:
- dermal and inhalation exposure from spray drift at the time of application,
- exposure by inhalation of vapour after application,
- dermal exposure (indirect) from contact with a contaminated surface.

In addition, for children, two additional exposure situations are taken into account: these are contamination by the oral route for children playing on grass contaminated by treatment and transfer to the mouth of contaminated objects.

In this methodology, the estimated exposures of bystanders and residents are combined and provide a single estimate covering both sub-populations.

Potential exposure of bystanders is estimated by taking into account spray drift. Exposure is via the dermal and respiratory routes. As dermal exposure can be caused by spray drift, it depends on the dose applied, the percentage of drift and the body surface area exposed.
Spray drift is measured for a bystander 8 metres from a boom sprayer for low-growing crops and 5 metres from an airblast sprayer in orchards and vineyards, according to Lloyd and Bell (1983) and Lloyd *et al.* (1987)[38].

It is calculated using the following formula:

SE_B = (PDE x SC x % absorbed) + PIE x SC x 100%)/BW	
SE_B : Systemic Exposure by the dermal route in mg/kg of body weight/day	
PDE = Potential Dermal Exposure (in mL of spray mix)	% absorbed = dermal absorption of the substance in the diluted preparation
PIE = Potential Inhalation Exposure (in mL of spray mix)	BW = Body Weight (60 or 15 kg)
SC = Soluble Concentrate of the active substance in the spray mix	

Exposure by inhalation following volatilisation from the crop treated or the ground is calculated using a formula similar to that of Martin *et al*. (2008).

- Exposure by contact with contaminated surfaces after re-entering a treated area

Exposure of children putting contaminated objects in their mouths or of children playing on grass contaminated by spraying is calculated using a formula similar to that of Martin *et al.* (2008).
However, spray drift is measured using shorter distances than in the method described by Martin *et al.* (2008) and, as a result, gives higher percentages of drift. Exposure by oral and dermal routes (indirect) is not calculated for adults but is considered to be covered by that for children.

[37] PSD (Pesticides Safety Directorate, UK) (2008) Bystander Exposure. Guidance.
http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/B/Bystander-exposure-guidance.pdf
[38] Lloyd GA and Bell GJ, 1983. Hydraulic nozzles: comparative spray drift study, Agricultural Development and Advisory Service, Ministry of Agriculture Fisheries and Food, UK.
Lloyd GA, Bell GJ, Samuels SW, Cross JV and Berry AM, 1987. Orchard sprayers: comparative operator exposure and spray drift study, Agricultural Science Service, Agricultural Development and Advisory Service, Ministry of Agriculture Fisheries and Food, UK.

Each category of exposure including bystanders and residents is taken into account separately in evaluations depending on the four following situations:

- dermal and inhalation exposure to spray drift at the time of application, exposure to vapour by inhalation after application,
- for children entering treated grass, dermal exposure (indirect) during contact with a contaminated surface,
- for children, the two exposure situations by the oral route (playing on grass contaminated by treatment and transferring a contaminated object to the mouth) are cumulated.

The exposures estimated are compared to the AOEL.

Moreover, the UK's Chemical Regulatory Directorate, which manages the BREAM model, has commissioned studies to improve knowledge of the subject. These studies especially concern:

- new ways of measuring drift in field crops with tractor-borne sprayers with longer booms and different types of nozzle[39],
- a predictive dispersion model of volatilisation for estimating the exposure of residents and bystanders[40],
- the development of probabilistic exposure models for bystanders and residents[41].

A new contamination situation has also been identified for bystanders and residents.
This is when they re-enter a treated field. The corresponding formula is as follows:

Potential dermal exposure = DFR x TC x T
DFR: quantity of Dislodgeable Foliar Residues (µg/cm^2)
TC: Transfer Coefficient from crops (cm^2/h)
T: contact Time (h)

The recommendations of the Bystander Risk Assessment Working Group (BRAWG)[42, 43] on the subject should also be noted.

3.2.4. Presentation of the methodology based on the draft guidance document published by EFSA in April 2014

This draft guidance document is a new version of the guidance document published previously together with the Opinion[44] of the EFSA group of experts in 2010. This project was submitted for public consultation on the EFSA website on 1 April 2014[45].

[39] Bystander exposure to pesticide spray drift: New data for model development and validation. M.C. Butler Ellis, A.G. Lane, C.M. O'Sullivan, P.C.H. Miller, C.R. Glass. Biosystems Engineering. Volume 107, Issue 3, November 2010, Pages 162–168.
[40] Modelling the dispersion of volatilised pesticides in air after application for the assessment of resident and bystander exposure. M.C. Butler Ellis, B. Underwood, M.J. Peirce, C.T. Walker, P.C.H. Miller. Biosystems Engineering. Volume 107, Issue 2, October 2010, Pages 149–154.
[41] BREAM: A probabilistic Bystander and Resident Exposure Assessment Model of spray drift from an agricultural boom sprayer. Marc C. Kennedy, M. Clare Butler Ellis, Paul C.H. Miller. Computers and Electronics in Agriculture. Volume 88, October 2012, Pages 63–71.
[42] BRAWG was a working group made up of experts from the "Advisory Committee on Pesticides" and the "Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment", whose mission was to identify the methods used for evaluating the risks to bystanders and residents from pesticides.
[43] http://www.pesticides.gov.uk/Resources/CRD/ACP/BRAWGvfinal2.pdf
[44] Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents. EFSA Panel on Plant Protection Products and their Residues (PPR). EFSA Journal 2010;8(2):1501 http://www.efsa.europa.eu/fr/efsajournal/doc/1501.pdf
[45] Guidance of EFSA. Guidance for the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA, 2014.
http://www.efsa.europa.eu/en/consultations/call/140401.htm

The work of the EFSA working group is based, in particular, on the results of the "Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents[46]".
EFSA states that the evaluation of the exposure of bystanders and residents is based on limited data taken from studies carried out in the 1980s and on data from the USEPA. EFSA thus recommends that new studies be carried out to refine the proposed evaluation. It should be noted that new proposals for methodologies have recently been generated as a part of the BROWSE[47] research programme. These will soon be available. Furthermore, biomonitoring studies of residents in the United Kingdom according to a published methodology[48] will also soon be finalised[49].

Only those elements considered to be the most important are presented in this Opinion. For a detailed explanation and knowledge of certain parameters, see the EFSA document.

The four routes of exposure presented below are taken into consideration for the evaluation of bystander and resident exposure.

Exposure routes are related to:
-Spray drift (at the time of application)
-Vapour (may occur after the plant protection product has been applied)
-Surface deposits
-Entry into treated crops

Depending on whether bystanders or residents are involved, and also on the potential toxicity of acute exposures, risk evaluations must be carried out as indicated in the table below.

Group potentially exposed	PPPs with no systemic toxicity from exposure during a day (no AAOEL)	PPPs with systemic toxicity from exposure during a day (established AAOEL)
Residents	L	A, L
Bystanders	L *)	A

L: long-term risk assessment; A: acute risk assessment
*) worst case, covering exposure events for an entire day
PPP : Plant Protection Product

The exposure assessments must be compared with the specific reference values, i.e. the AOEL and the AAOEL. As there is currently no harmonised method available for establishing AAOELs, EFSA states that an acute risk assessment cannot be performed.

Exposure of residents

Estimation of resident exposure is based on the 75th percentile of values.
The 75th percentile and mean values will be calculated for each route of exposure for residents. Final exposure of residents is the sum of the mean values for each potential route of exposure.

- Dermal and inhalation exposure to spray drift at the time of application of the product

For field crops, data from the updated version of the BREAM model, which give a better estimate of exposure, were chosen and correspond more closely to current practices. The BREAM model takes spray drift data into consideration, specifically for children during applications on low-growing crops.

[46] "Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents".
EFSA AGREEMENT NUMBER EFSA/PPR/2007/01 FINAL REPORT.28 NOVEMBER 2008."
http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf
[47] Information on BROWSE is available at https://secure.fera.defra.gov.uk/browse/index.cfm
[48] Biological monitoring of pesticide exposures in residents living near agricultural land. Karen S Galea, Laura MacCalman, Kate Jones, John Cocker, Paul Teedon, Anne J Sleeuwenhoek, John W Cherrie and Martie van Tongeren. *BMC Public Health* 2011, 11:856. http://www.biomedcentral.com/1471-2458/11/856
[49] http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=17319&FromSearch=Y&Publisher=1&SearchText=residents&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description

For applications on orchards, the study by Lloyd *et al.* (1987)[50] was deemed the most appropriate and was chosen. This study also shows that there is a clear correlation between the levels of bystander exposure and the volume of spraying applied. EFSA chose to consider the exposure data obtained regarding the largest volume of spraying applied.

Exposure values for the dermal and inhalation routes at the 75th percentile taken from the previously mentioned studies are indicated in the following table[51].

These values are the **75th Percentiles** for residents (assuming average breathing rates for inhalation exposures)				
	Dermal (mL of spray mix/person)		Inhalation (mL spray dilution/person)	
Method of application/distance from sprayer	Adult	Child	Adult	Child
Arable/ground boom sprayer				
2 m	0.47	0.33	0.00010	0.00022
5 m	0.24	0.22	0.00009	0.00017
10 m	0.20	0.18	0.00009	0.00013
*Orchard/broadcast air assisted applications**				
2-3 m	5.63	1.689	0.0021	0.00164
5 m	5.63	1.689	0.0021	0.00164
10 m	5.63	1.689	0.0021	0.00164

*the only available values are for the 8 m distance from broadcast air assisted sprayer in orchard; the same value is used for 2-3, 5 and 10 m.

Concerning spray drift from airblast sprayers in orchards and vineyards, it should be noted that the exposure values were only measured experimentally at a distance of 8 m.
The mean exposure values by the dermal and inhalation routes for residents considering mean respiratory rates for exposure by inhalation) are also presented in the EFSA document of 2014.

It should be noted that there are no data available for manual application. EFSA proposes to use the spray drift values given in the above table as a first stage of evaluation. Once specific data have been validated, these may be used on a case-by-case basis.

- Exposure by inhalation of vapour that may be produced after the application of plant protection products

Resident exposure by inhalation of volatilised pesticides is estimated using the BREAM methodology and that of Martin *et al.* (2008), on the basis of the highest atmospheric concentration averaged over 24 hours, depending on the volatility of the substance.
It is calculated using the following formula:

SER_I = (VC x IR x IA)/BW	
SER_I = Systemic Exposure of Residents via the Inhalation Route in mg/kg of body weight/day	
VC = Vapour Concentration of active substance (mg of active substance/m^3)	I_A = absorption by Inhalation (%)
IR = Inhalation Rate per day in m^3/day	BW = Body Weight (60 or 10 kg)

[50] Lloyd GA, Bell GJ, Samuels SW, Cross JV and Berry AM, 1987. Orchard sprayers: comparative operator exposure and spray drift study, Agricultural Science Service, Agricultural Development and Advisory Service, Ministry of Agriculture Fisheries and Food, UK.
[51] Table taken from pages 30-31 of the EFSA document, Guidance for the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA, 2014.

A concentration of active substance in the air equal to 1 µg/m^3 for low or moderately volatile substances (vapour pressure lower than 5 mPa) and to 15 µg/m^3 for volatile substances (vapour pressure between 5 and 10 mPa) was chosen.

- Dermal exposure (indirect) during contact with a contaminated surface

The methodology is taken from the EPA 2001 model[52].

For an adult:
Exposure is estimated by applying the following formula:

SEB_D = (AR x D x TTR x TC x H x DA)/BW	
SEB_D = Systemic Exposure of residents in mg/kg of body weight/day	
AR = Application Rate in mg of active substance/cm^2	
D = Drift in % for 1 or more applications, see table	H = duration of exposure (2h) *
TTR = Turf Transferable Residues (5% for liquids and 1% for granules)*	BW = body weight (60 or 10 kg)
TC = Transfer Coefficient in cm^2/h, 7300 cm^2/h for an adult and 2600 cm^2/h for a child	

*Values taken from BREAM

The following drift percentages are used, for the corresponding crops:

	Field crops*	Fruit crops, early stages**	Fruit crops, late stages**	Vineyards**	Hops**
	95th percentile	90th percentile	90th percentile	90th percentile	90th percentile
2-3 m	8.5	29.20	15.73	8.02	19.33
5 m	3.5	19.89	8.41	3.62	11.57
10 m	1.9	11.81	3.60	1.23	5.77

*Values taken from BREAM
**Values taken from Ganzelmeier & Rautmann[53]

For a child:
Exposure by the oral route is added to dermal exposure.

Potential exposure of children by the oral route **by touching the mouth with soiled hands** is estimated by applying the following formula:

SOE_H= (AR x D x TTR x SE x SA x Freq x H x OA)/BW	
SOE_H = Systemic Oral Exposure of children by **hand-to-mouth** contact in mg/kg body weight/day	
AR = Application Rate in mg of active substance/cm^2	Freq = Frequency of hand-to-mouth gestures: 9.5 events/hour*
D = Drift in %	H = duration of exposure in hours (2h)*
TTR = Turf Transferable Residues (5% for liquids and 1% for granules)*	OA = Oral Absorption in %
SE = Saliva Extraction factor (50%)*	BW = Body Weight (10 kg)
SA = Surface Area of hands in cm^2	

*EPA values (2001)

[52] EPA (U.S. Environmental Protection Agency), 2001. Science Advisory Council for Exposure, Policy 1064 Number 12, Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential 1065 Exposure Assessments. Office of Pesticide Programs, Health Effects Division. Washington D.C.

[53] Ganzelmeier H, Rautmann D, 1995. Studies on the spray drift of plant protection products. Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft Berlin-Dahlem, Heft 305, 113.
Rautmann D, Streloke M and, Winkler R, 2001. New drift values in the authorisation procedure for plant protection products. Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft (Federal Biological Research Center for Agriculture and Forestry), 383, Berlin, 133-141.

Potential exposure of children by the oral route **by transferring a contaminated object to the mouth** is estimated by applying the following formula:

SOE_o = (AR x D x DFR x IgR x OA)/BW	
SOE_H = Systemic Oral Exposure of children by contact with a contaminated object in mg/kg body weight/day	
AR = Application Rate in mg of active substance/cm^2	IgR = Ingestion Rate of grass in cm^2, 25 cm^2 by default*
D = Drift in %	OA = Oral Absorption in %
DFR = Dislodgeable Foliar Residues (20% by default)*	BW = Body Weight (10 kg)

*EPA values (2001)

- Estimation of resident exposure from re-entering treated fields

When re-entering treated areas, for example when walking in a treated field, only dermal exposure is estimated. In such cases, dermal exposure is estimated in the same way as for worker exposure, but only for 15 minutes of exposure.

- Estimation of total resident exposure, for adults and children

Systemic exposure of adults is the sum of the following exposures:

1) Exposure by the dermal and inhalation routes to spray drift at the time of application of the plant protection product,
2) Exposure by inhalation to vapours that may be produced after application of the product,
3) Dermal exposure (indirect) during contact with a contaminated surface deposit?
4) Estimation of resident exposure when re-entering fields.

Systemic exposure of children is the sum of the following exposures:

1) Exposure by the dermal and inhalation routes to spray drift at the time of application of the plant protection product,
2) Exposure by inhalation to vapours that may be produced after application of the product,
3) Dermal exposure (indirect) during contact with a contaminated surface taking into account exposure by the oral route (hand-to-mouth transfer and object- to-mouth transfer),
4) Estimation of resident exposure when re-entering fields.

The exposures estimated are compared to the AOEL.

Exposure of bystanders

Bystander exposure is taken into account separately; either based on spray drift at the time of application, or on the inhalation of vapour that can occur after application, or on surface deposits, or on re-entering treated crops.
Bystander exposure is estimated in the same way as for residents, except for the use of the 95th percentile of values.
The exposures estimated are compared to the AOEL.

Information on the BROWSE research project (currently being finalised)

The BROWSE project (Bystanders, Residents, Operators and Workers Exposure models for plant protection products) is a European research project.
This programme uses sophisticated modelling tools. The results of this research project are scheduled for June 2014. An intermediate report is available[54]. These results will be analysed at European level in order to identify any elements that could be incorporated in risk assessment for improvement purposes.

[54] Bystanders, Residents, Operators and Workers Exposure models for plant protection products. SEVENTH FRAMEWORK PROGRAMME. Theme: Environment (including climate change) Deliverable 5.1 DRAFT-December 2013. Work Package 3: Models of exposure to agricultural pesticides for bystanders and residents. Date 12/09/2013.

3.3. Presentation of the results of the risk assessments on the basis of these methodologies

Estimations of exposure and bystander and resident risk are presented below, by applying respectively the methodologies applied by ANSES, Martin *et al*. (2008), BREAM and EFSA 2014 for two preparations authorised in France containing respectively folpet (FOLPAN SC) and pendimethalin (CODIX).

The preparations were chosen with consideration for the uses and properties of the substances. The estimated exposures represent some of the most serious potential exposure situations in field crops and perennial crops with upward spraying.

The following parameters were chosen for the calculations:

Product (MA number)	**FOLPAN SC, active substance folpet (MA No. 8900620)**	**CODIX, active substance pendimethalin (MA No. 2130140)**
Crop	Vineyard	Soft winter wheat, durum winter wheat, winter barley
Activity	Fungicide	Herbicide
Type of application	High-growing crops – upward spaying– tractor-borne or drawn airblast	Low-growing crops – downward spraying – tractor-borne or drawn boom sprayer
Dose (L of product/ha)	3 L/ha	2.5 L/ha
Application rate (kg of active substance/ha)	1.5 kg/ha	1 kg/ha
Formulation	Suspension concentrate	Suspension concentrate
Volume of mixture[55] #	100 to 500 L/ha	100 to 400 L/ha
Surface treated per day (Ha)	8	20
Maximum number of applications	7	1
AOEL (mg/kg bw/day)	0.1	0.234
ADI (mg/kg bw/day)	0.1	0.125
Dermal absorption of the active substance	1% undiluted 6% diluted*	0.2% undiluted 10% diluted*
Vapour pressure of the substance	$2.1.10^{-2}$ mPa	1.94 mPa
Maximum value measured in the atmosphere**	3949 ng/m^3	3.94 ng/m^3
Foliar DT 50	30 days by default	***

The minimum volume of mix is used in the worst case in the estimate.
* Dermal absorption of the active substance in the spray dilution.
** Summary and recommendations of the steering and scientific prospective committee of the Observatory for Pesticide Residues (ORP). Scientific Report. October 2010.
*** Not relevant for the calculation for a single application.

3.3.1. Exposure and risk assessment by ANSES in its investigation of MA applications

PPP (Plant Protection Product): FOLPAN SC

- **Risk assessment for bystanders**

Assessment is carried out with the EUROPOEM II model. Considering a drift percentage of 3.6% and an inhaled volume of 0.06 mL/h, for a 60 kg adult positioned 7 metres from the crop treated and exposed for 5 minutes to spray drift, bystander exposure is estimated at 6.7% of the AOEL.

https://secure.fera.defra.gov.uk/browse/software/documentation/Resident%20and%20Bystander%20Models%20Technical%20Report%20-%20WP3.pdf

[55] Spray dilution: generally mixed in water, in a plant protection product intended for application by spraying.

- **Risk assessment for residents**

Since 2001, surveillance programmes initiated in France by different AASQAs[56] (ORP 2010[57]) have detected and quantified folpet in the atmosphere. The data currently available show a range of values reaching a maximum value of 3949 ng/m^3 (daily maxima). Folpet is one of the 21 most frequently detected substances in the atmosphere at high concentrations (>10 ng/m^3). This substance was detected 1268 times by 10 AASQAs and 45% are above the limit of quantification.

The maximum value quantified in air is used to evaluate exposure by the respiratory route of bystanders close to spraying areas. Maximum exposure[58] is estimated taking into account the maximum value measured for a substance and the daily respiratory volume (24 m^3/day for a 60 kg adult). For risk assessment, this result is compared with the substance's ADI. The ADI was chosen because there was initially no harmonised AOEL for all substances. In the context of methodology improvement, AOEL will be used.
On the basis of the maximum value of 3949 ng/m[3] of folpet in the atmosphere (daily maxima), exposure by the respiratory route of persons residing near spraying areas was estimated at 1.6% and 2.1% of the ADI[59] of the substance, for adults and children respectively.

PPP: CODIX

- **Risk assessment for bystanders**

Assessment is carried out with the EUROPOEM II model. Considering a drift percentage of 0.41% and an inhaled volume of 0.03 mL/h, for a 60 kg adult positioned 7 metres from the crop treated and exposed for 5 minutes to spray drift, bystander exposure is estimated at 0.5% of the AOEL.

- **Risk assessment for residents**

Since 2001, surveillance programmes initiated in France by different AASQAs have detected and quantified pendimethalin in the atmosphere. The most recent data available (2001-2006) in the ORP report show a range of values reaching a maximum value of 3.94 ng/m^3 (daily maxima) for pendimethalin.
The maximum value quantified in air is used to evaluate exposure by the respiratory route of bystanders close to spraying areas. Maximum exposure[60] is estimated taking into account the maximum value measured for a substance and the daily respiratory volume (24 m^3/day for a 60 kg adult). For risk assessment, this result is compared with the substance's DJA. The DJA was initially chosen because there was no harmonised AOEL for all substances. In the context of the methodology improvement, AOEL will be used..

On the basis of the maximum value of 3.94 ng/m^3 of pendimethalin in the atmosphere (daily maxima), exposure by the respiratory route of persons residing near spraying areas was estimated at 1.6% and 0.0017 % of the ADI of the substance, for adults and children respectively.

[56] AASQA: *Associations Agréées de Surveillance de la Qualité de l'Air* (certified air quality institutions)

[57] ORP, 2010. Exposure of the general population to pesticide residues in France. Summary and recommendations of the steering and scientific prospective committee of the Observatory for Pesticide Residues (ORP). Scientific Report. 365 p.

[58] The maximum value measured in the air was chosen for an initial calculation in order to ensure acceptable risks in this situation; this value could be refined in order to make it more representative.

[59] The ADI and the AOEL of folpet have the same value: 0.1 mg/kg/day

[60] The maximum value measured in the air was chosen for an initial calculation in order to ensure acceptability of risks in this situation; this value could be refined in order to make it more representative.

3.3.2. Evaluation of exposure and risks according to Martin et al. (2008)

PPP: FOLPAN SC

For this evaluation, the following parameters were used:

Body weight: 60 kg (adult) and 16.15 kg (child)
Number of applications: 1 or 7
Distance between the field and the bystanders or residents: 10 m
Drift deposition for 1 application: For bystanders and residents: 1.23% (90th percentile)[61]
Drift deposition for 7 applications: For bystanders 1.23% (90th percentile) For residents: 0.94% (69th percentile) x 7
Atmospheric concentration: 0.001 mg/m^3

- **Risk assessment for bystanders**

The results are as follows:

	% AOEL	
	Adult	Child
Exposure by spray drift		
Dermal exposure	1.85	1.44
Exposure by inhalation	0.05	0.11
Total *	**1.90**	**1.55**

** The total is the sum of the systemic exposures. A single application is considered for bystanders*.

Total systemic bystander exposure in adults or children to the preparation FOLPAN SC containing folpet is respectively 1.90% and 1.55% of the AOEL of folpet.

- **Risk assessment for residents**

For **1** application, the results are as follows**:**

	% AOEL	
	Adult	Child
Indirect exposure after the application		
Exposure by inhalation due to vapour drift	0.27	0.51
Dermal exposure during contact with a surface deposit by spray drift	0.14	0.18
Contamination of children by the oral route		
Transfer from hand to mouth	-	0.23
Transfer of object to mouth	-	0.05
Total*	**0.41**	**0.98**

** The total is the sum of the systemic exposures.*

Total systemic exposure of adult and child residents to the preparation FOLPAN SC containing folpet is respectively 0.41% and 0.98% of the AOEL of folpet.

[61] Rautmann *et al.* (2001)

For **7** applications, the results are as follows:

	% AOEL	
	Adult	Child
Indirect exposure after the application		
Exposure by inhalation due to vapour drift	0.28	0.51
Dermal exposure from surface deposit by spray drift	0.72	0.95
Contamination of children by the oral route		
Hand-to-mouth transfer	-	1.22
Object-to-mouth transfer	-	0.31
Total*	**1.00**	**2.99**

** The total corresponds to the sum of systemic exposures.*

Total systemic exposure of adult and child residents to the preparation FOLPAN SC containing folpet is respectively 1.0% and 2.99% of the AOEL of folpet.

PPP: CODIX

Body weight: 60 kg (adult) and 16.15 kg (child)
Number of applications: 1
Distance between the field and the bystanders or residents: 10 m
Drift deposition for one application: 0.29% (value used for the calculation for bystanders and residents)
Atmospheric concentration: 0.001 mg/m^3

- **Risk assessment for bystanders**

The results are as follows:

	% AOEL	
	Adult	Child
Exposure by spray drift		
Dermal exposure	0.21	0.16
Exposure by inhalation	0.002	0.004
Total *	**0.21**	**0.17**

** The total is the sum of systemic exposures.*

Total systemic exposure of adult and child bystanders to the preparation CODIX containing pendimethalin is respectively 0.21% and 0.17% of the AOEL of pendimethalin.

- **Risk assessment for residents**

The results are as follows:

	% AOEL	
	Adult	Child
Indirect exposure after the application		
Exposure by inhalation due to vapour drift	0.12	0.22
Dermal exposure from surface deposit by spray drift	0.015	0.02
Contamination of children by the oral route		
Transfer from hand to mouth	-	0.015
Transfer of object to mouth	-	0.004
Total oral contamination		*0.019*
Total*	**0.135**	**0.26**

** The total is the sum of systemic exposures.*

Total systemic exposure of adult and child residents to the preparation CODIX containing pendimethalin is respectively 0.135% and 0.26% of the AOEL of pendimethalin.

3.3.3. Evaluation of exposure and risk according to the BREAM model

- **Risk assessment for bystanders and residents**

Preparation: FOLPAN SC

For this evaluation, the following parameters were used:

Body weight: 60 kg (adult) and 15 kg (child)
Potential dermal exposure: 3.7 mL at 8 m
Potential exposure by inhalation: 0.002 mL at 8 m
Atmospheric concentration: 15 µg/m^3
Respiratory rate: 15.2 m^3 of air/day in adults and 8.3 m^3 in children.
Drift: 5.4%

The risks for adult and child bystanders and residents for each category of exposure are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Dermal exposure	56	*
Exposure by inhalation	0.5	*
Total	57	*
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	3.8	8.3
Indirect exposure following deposition of spray drift		
Dermal exposure from surface deposit	- **	1.69
Hand-to-mouth transfer	- **	1.08
Object-to-mouth transfer	- **	0.27
Total oral contamination	-**	*1.35*

**Exposure of children is covered by exposure of adults.*
***Exposure by the oral and dermal routes is not calculated for adults but is considered to be covered by exposure of children.*

PPP: CODIX

For this evaluation, the following parameters were used:

Body weight 60 kg (adult) and 15 kg (child)
Potential dermal exposure 0.1 mL at 8 m
Potential exposure by inhalation: 0.006 mL at 8 m
Atmospheric concentration: 1 µg/m^3/24h
Respiratory rate: 15.2 m^3 of air/day (adults) and 8.3 m^3 of air/day (children)
Drift: 1%

The risks for adult and child bystanders and residents for each category of exposure are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Dermal exposure	0.71	*
Exposure by inhalation	0.43	*
Total	1.14	*
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	0.11	0.25
Indirect exposure following deposition of spray drift		
Dermal exposure during contact with a surface	- **	0.015

deposit		
Hand-to-mouth transfer	- **	0.0055
Object -to-mouth transfer	- **	0.0014
Total oral contamination	- **	*0.0074*

**Exposure of children is covered by exposure of adults.*
***Exposure by the oral and dermal routes 'is not calculated for adults but is considered to be covered by exposure of children.*

3.3.4. Exposure and risks assessment according to the EFSA 2014 model[62]

PPP: FOLPAN SC

- **Risk assessment for bystanders**

For this assessment, the following parameters were used:

Body weight: 60 kg (adult) and 10 kg (child)	
Potential dermal exposure at 10 m: 12.9 mL (adults) and 3.7 mL (children)	
Potential exposure by inhalation at 10 m: 0.0044 mL (adults) and 0.0035 mL (children)	
Respiratory rate: 0.96 m^3 of air/kg/day (adults) and 4.56 m^3 of air/kg/day (children)	
Atmospheric concentration: 1µg/m^3	TC of surface deposits: 14,500 cm²/h (adults) and 5200 cm²/h (children)
Application rate: 0.015 mg/cm²	TC on re-entry: 1100 cm²/h (adults) and 330 cm²/h (children)
Drift: 1.23%	Duration of exposure: 15 minutes
Distance from spraying: 10 m	

For **1** application, risks for adult and child bystanders for each category of exposure are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Total dermal + inhalation	37	64
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	0.01	0.05
Indirect exposure following deposition of spray drift		
Dermal exposure following deposition of spray drift	0.01	0.01
Hand-to-mouth-transfer	-	0.046
Object-to-mouth transfer	-	0.092
Total oral contamination	-	*0.138*
Re-entry into treated crop areas		
Dermal exposure following re-entry	1.24	2.23

For **7** applications, risks for adult and child bystanders for each category of exposure are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Total dermal + inhalation	36.9	64.4
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	0.01	0.05
Indirect exposure following deposition of spray drift		
Dermal exposure following deposition of spray drift	0.02	0.04
Hand-to-mouth transfer		0.179
Object-to-mouth transfer		0.358
Total oral contamination		*0.54*

[62] Calculations are carried out on the basis of the EFSA calculator project submitted for a consultation phase. Depending on the elements collected during this phase, the calculator could be corrected, so it should not be ruled out that the results presented in this Opinion may be subject to change.

Re-entry into treated crops		
Dermal exposure following re-entry	4.84	8.65

- **Risk assessment for residents**

The parameters used are as follows:

Body weight: 60 kg (adult) and 10 kg (child)	
Potential dermal exposure at 10 m: 5.63 mL (adults) and 1.659 mL (children)	
Potential exposure by inhalation at 10 m: 0.0021 mL (adults) and 0.00164 mL (children) at the 75th percentile	
Atmospheric concentration: 1 µg/m^3	Drift: 1.02%
Respiratory rate: 0.23 m^3 of air/kg/day (adults) and 1.07 m^3 of air/kg/day (children)	TC of surface deposits: 7300 cm²/h (adults) and 2600 cm²/h (children)
Number of applications: 1 or 7	TC during re-entry: 1100 cm²/h (adults) and 330 cm²/h (children)
Application rate: 0.015 mg/cm²	Distance from spraying: 10 m

For **1** application, the risks for adult and child residents are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Total dermal + inhalation	16	28
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	0.23	1.07
Indirect exposure following deposition of spray drift		
Dermal exposure following deposition of spray drift	0.2	0.04
Hand-to-mouth transfer	-	0.14
Object -to-mouth transfer	-	0.076
Total oral contamination	-	*0.22*
Re-entry into treated crop areas		
Dermal exposure following re-entry	1.24	2.23
Total *	**12.12**	**20.48**

** Total resident exposure is calculated by adding the means of the exposure routes and not the 75th percentiles. However, the results for each exposure route are expressed using the 75th percentile for residents.*

Total systemic exposure of adult and child residents to the preparation FOLPAN SC containing folpet corresponds respectively to 12.12 % and 20.48 % of the AOEL of folpet.

For **7** applications, the risks for adult and child residents are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Total dermal + inhalation	16.15	28.31
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	0.23	1.07
Indirect exposure following deposition of spray drift		
Dermal exposure following deposition of spray drift	0.08	0.16
Hand-to-mouth transfer	-	0.564
Object -to-mouth transfer	-	0.29
Total oral contamination	-	*0.86*
Re-entry into treated crop areas		
Dermal exposure following re-entry	4.81	8.65
Total *	**15.75**	**27.48**

** Total resident exposure is calculated by adding the means of the exposure routes and not the 75th percentiles. However, the results for each exposure route are expressed using the 75th percentile for residents.*

PPP: CODIX

- **Risk assessment for bystanders**

For this evaluation, the following parameters were used:

Body weight: 60 kg (adult) and 10 kg (child)	
Potential dermal exposure at 10 m: 0.48 mL (adults) and 0.39 mL (children)	
Potential exposure by inhalation at 10 m: 0.00051 mL (adults) and 0.00076 mL (children)	
Atmospheric concentration: 1 µg/m^3	Drift: 1.9%
Respiratory rate: 0.96 m^3 of air/kg/day (adults) and 4.56 m^3 of air/kg/day (children)	TC: 14,500 cm²/h (adults) and 5200 cm²/h (children)
Application rate: 0.01 mg/cm²	Duration of exposure: 15 minutes
Distance from spraying: 10 m	

The risks for adult and child bystanders for each category of exposure are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Total dermal + inhalation	0.66	3.14
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	0.00	0.02
Indirect exposure following deposition of spray drift		
Dermal exposure following deposition of spray drift	0.0045	0.009
Hand-to-mouth transfer	-	0.02
Object-to-mouth transfer	-	0.041
Total oral contamination		*0.06*
Re-entry into treated crop areas		
Dermal exposure following re-entry	0.59	1.06

- **Evaluation of resident risks**

The parameters used are as follows:

Body weight: 60 kg (adult) and 10 kg (child)	
Potential dermal exposure at 10 m: 0.2 mL (adults) and 0.18 mL (children)	
Potential exposure by inhalation at 10 m: 0.00009 mL (adults) and 0.00013 mL (children)	
Atmospheric concentration: 1µg/m^3	Drift: 1.3%
Respiratory rate: 0.23 m^3 of air/kg/day (adults) and 1.07 m^3 of air/kg/day (children)	TC: 7300 cm²/h (adults) and 2600 cm²/h (children)
Number of applications: 1	Distance from spraying: 10 m
Application rate: 0.01 mg/cm²	

Risks for adult and child residents are as follows:

	% AOEL	
	Adult	Child
Exposure to spray drift at the time of application		
Total dermal + inhalation	0.28	1.36
Exposure to vapour after application		
Exposure by inhalation due to vapour drift	0.1	0.46
Indirect exposure following deposition of spray drift		
Dermal exposure following deposition of spray drift	0.01	0.024
Hand-to-mouth transfer	-	0.053
Object-to-mouth transfer	-	0.028
Total oral contamination	-	*0.08*
Re-entry into treated crop areas		
Dermal exposure following re-entry	0.59	1.06
Total *	**0.85**	**2.32**

** Total resident exposure is calculated by adding the means of the exposure routes and not the 75th percentiles. However, the results for each exposure route are expressed using the 75th percentile for residents.*

Total systemic exposure of adult and child residents to the preparation CODIX containing pendimethalin is respectively 0.85% and 2.32% of the AOEL of pendimethalin.

3.3.5. Presentation and analysis of the comparison of the risk assessments carried out with the different methodologies

- **Risk assessment for bystanders**

The following tables summarise the risk assessments for bystanders obtained according to the different models.

PPP: FOLPAN SC

	%AOEL							
	ANSES		Martin, 2008		BREAM*		EFSA 2014	
	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Exposure by the dermal and inhalation routes through spray drift during application	6.7	-	1.90	1.55	57	-	37	64
Exposure by inhalation due to product vaporisation	-	-	-	-	3.8	8.3	0.01	0.05
Dermal exposure following deposition	-	-	-	-	-	1.69	0.01/ 0.02**	0,01/0.04**
Oral contamination in children	-	-	-	-	-	1.35	-	0.14/ 0.54**
Re-entry	-	-	-	-	-	-	1.24/4.84**	2.23/ 8.65**

In this methodology, the estimated exposures of bystanders and residents are overlaid to provide a single estimate covering both sub-populations. Each category of exposure including bystanders and residents is taken into account separately in the evaluation.
*** 1 / 7 applications.*

pPPP: CODIX

	%AOEL							
	ANSES		Martin, 2008		BREAM*		EFSA 2014	
	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Exposure by the dermal and inhalation routes through spray drift during application	0.5	-	0.21	0.17	1.14	-	0.66	3.14
Exposure by inhalation due to product vaporisation	-	-	-	-	0.11	0.25	0.00	0.02
Dermal exposure following deposition	-	-	-	-	-	0.015	0.005	0.009
Contamination of children by the oral route	-	-	-	-	-	0.0074	-	0.06
Re-entry	-	-	-	-	-	-	0.59	1.06

In this methodology, the estimated exposures of bystanders and residents are combined and provide a single estimate covering both sub-populations. Each category of exposure including bystanders and residents is taken into account separately in the evaluation.

- **Risk assessment for residents**

The following tables summarise the risk assessments for residents obtained according to the different models.

PPP: FOLPAN SC

	% AOEL							
	ANSES		Martin, 2008		BREAM*		EFSA 2014	
	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Exposure by the dermal and inhalation routes through spray drift during application	-	-	-	-	57	-	16	28
Exposure by inhalation due to product vaporisation	1.6**	2.1**	0.27	0.51	3.8	8.3	0.23	1.07
Dermal exposure during contact with a surface deposit by spray drift	-	-	0.14/ 0.72#	0.18/ 0.95#	-	1.69	0.02/ 0.08#	0.04/ 0.16#
Contamination of children by the oral route	-	-	-	0.28/ 1.53#	-	1.35	-	0.22/ 0.86#
Re-entry	-	-	-	-	-	-	1.24/ 4.81#	2.23/ 8.65#
Total	1.6**	2.1**	0.41/0.99**	0.97/ 2.99#	-	-	12.12/ 15.74#, §	20.48/27.48#,§

In this methodology, the estimated exposures of bystanders and residents are overlaid to provide a single estimate covering both sub-populations. Each category of exposure including bystanders and residents is taken into account separately in evaluations.

*** Exposure by the respiratory route of people residing near spraying areas was estimated, on the basis of measured values, at 1.6% and 2.1% of the substance's ADI respectively for adults and children.*

*** 1 / 7 applications.*

§ Final exposure taken into account for residents is the sum of the mean values of each potential route of exposure.

Preparation: CODIX

	% AOEL							
	ANSES		Martin, 2008		BREAM*		EFSA 2014	
	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Exposure by the dermal and inhalation routes to spray drift during application	-	-	-	-	1.14	-	0.28	1.36
Exposure by inhalation due to product vaporisation	0.0013**	0.0017 **	0.12	0.22	0.11	0.25	0.1	0.46
Dermal exposure during contact with a surface deposit by spray drift	-	-	0.015	0.02	-	0.015	0.01	0.024
Contamination of children by the oral route	-	-	-	0.02	-	0.0074	-	0.08
Re-entry	-	-	-	-	-	-	0.59	1.06
Total	0.0013**	0.0017 **	0.135	0.26	-	-	0.85§	2.32§

In this methodology, the estimated exposures of bystanders and residents are overlaid to provide a single estimate covering both sub-populations. Each category of exposure including bystanders and residents is taken into account separately in evaluations.

*** Exposure by the respiratory route of people residing near spraying areas was estimated, on the basis of measured values, at 0.0013% and 0.017% of the substance's ADI respectively for adults.*

§ Final exposure taken into account for residents is the sum of the mean values of each potential route of exposure.

The estimations carried out show that, irrespective of the methodology employed, exposure of bystanders and residents is in most cases related to dermal exposure and inhalation of spray drift during application.

The evaluation methodologies presented are based on the same principle, except for the one used by ANSES to estimate resident exposure by the respiratory route, which takes measured environmental values into account. The differences between the estimated levels of exposure based on these methodologies can

be explained by the experimental measurements used, which may have been taken under different conditions, and also by the choice of exposure scenarios. The results obtained in terms of percentages of AOEL are highest for the methodology proposed by EFSA 2014, mainly because of the statistical processing of the data concerning drift for bystanders and the fact that a greater number of exposure situations were taken into account.

On the basis of a comparison of the results from applying different methodologies to the products FOLPAN SC and CODIX, the results obtained by the methodology followed by ANSES are not called into question in terms of acceptability of risks according to Regulation (EC) No.1107/2009. It should be noted that, considering the uses and properties of the substances, estimated exposures represent some of the most serious potential exposure situations in field crops and in perennial crops with high directed applications. Furthermore, if the spray dilution contains a sensitising substance, a complementary evaluation may be necessary; its relevance will be analysed on a case-by-case basis.

The EFSA 2014 project is currently the most complete and up-to-date methodology for estimating exposure and risk for bystanders and residents. This project could nonetheless be subject to modification depending on the comments received during the public consultation phase. Concerning spray drift from airblast sprayers in orchards and vineyards, it should be noted that the exposure values were measured experimentally only at a distance of 8 m. ANSES therefore considers that, in the absence of further information, and for the purpose of this evaluation, a value at a distance of 8 m or 10 m[63] should be used. If the results of a study recently published by Van De Zande *et al.* (2014) on spray drift in orchards are used, other distances could be incorporated[64]. Additional experimental work could also make it possible to specify certain parameters and to take different ways of reducing drift into account.

4. THE AGENCY'S CONCLUSIONS AND RECOMMENDATIONS

In response to the request by the Ministry of Agriculture for a re-assessment of the regulatory provisions in force for protecting bystanders and residents in areas treated with plant protection products, the Agency analysed all applicable European and French regulatory requirements and, more specifically, the risk assessment methodologies currently available in Europe for residents and bystanders, and compared the results obtained using these different methodologies.

On the basis of this study, ANSES can express the following conclusions and recommendations:

- Concerning risk assessment before products are placed on the market

Regulation (EC) No. 1107/2009 requires an estimate of exposure and a risk assessment for bystanders and residents and establishes acceptability criteria on this basis, as a part of the process for granting marketing authorisations. Risk assessment is based on different models used in Europe which are not yet fully harmonised.

The exposures taken into account in this assessment, on the basis of current knowledge, are exposure by inhalation and by the dermal route due to spray drift at the time of the product's application, exposure related to vapour after application or due to vapour drift, exposure related to the deposit of vapour drift, oral contamination by hand-to-mouth or object-to-mouth transfer in children, and exposure by re-entering treated crop areas.

The assessments currently practised by ANSES, in the absence of a harmonised methodology, take into account the exposure of bystanders and residents. Risk assessment for residents by the respiratory route takes into account measured environmental values, when these are available.

The results of the work carried out by ANSES to compare the various methodologies applied in different European countries and the proposal developed by EFSA lead to the conclusion that the latter takes into account the largest number of exposure situations and is the most sophisticated methodology for assessing

[63] Distance presented in the EFSA Guide document, in line with the distances proposed for boom sprayers.

[64] Spray drift and bystander risk from fruit crop spraying. J C VAN DE ZANDE, M C BUTLER ELLIS, M WENNEKER, P J WALKLATE and M KENNEDY. *Aspects of Applied Biology 122, 2014.*

risk for bystanders and residents. Consequently, **ANSES recommends implementing this methodology, developed by EFSA, as rapidly as possible once it has been adopted at European level.**

The draft methodology presented in the EFSA document should enable an estimation of exposure for bystanders and residents at distances of 2-3, 5 and 10 m for field crops with a boom sprayer and at a distance of 8 m for orchards and vineyards with an airblast sprayer (upward spraying). Non-treated areas could be defined by taking these distances into account. Regarding other methods of application, specific evaluation methodologies should be used.

Exposure of bystanders and residents is essentially caused by dermal exposure and by inhalation related to spray drift during application. In addition to the available studies and data, **the Agency recommends that additional metrological studies be launched to produce improved documentation about exposure** and to further improve the robustness of risk assessment.

In particular, ANSES considers that, regarding spraying using an airblast sprayer on high-growing crops, it is necessary to set up experiments providing data on drift at a variety of distances, including different parameters influencing drift and its reduction: over row sprayers (widely used in vineyards), drift reduction nozzles, spray volume, spraying directed towards the inside of fields for the outside rows, tractor speed during application, and wind speed. The results of these measurements could be used to improve risk assessment and also recommendation for use.

Furthermore, **ANSES will undertake a cumulative risk assessment for bystanders and residents once harmonised evaluation methodology has been adopted at European level**. ANSES emphasises the need for harmonising this evaluation methodology as rapidly as possible and is actively participating in ongoing European methodology work on this topic. The Agency already uses a cumulative risk assessment methodology for operators, which could be used for bystanders and residents who may potentially be directly exposed to spray drift.

Regarding exposure by inhalation, this can be estimated using either default values (which are often maximised) or modelling tools. In order to improve knowledge of exposures by this route, and also to improve their quantification through better appreciation of the representativeness of the exposure of populations, **ANSES recommends undertaking atmospheric measurement campaigns.** For this purpose, substance toxicities (the lowest AOELs), properties affecting their potential for volatilisation, and the extent of their use in space and time, must all be taken into account. As part of these measurement campaigns, care should be taken to ensure that the sampling protocols and analytical methods are correctly described and provided.

ANSES will also employ the biomonitoring data analysis of residents developed in the United Kingdom, which should be available at the end of 2014. Depending on these results, ANSES may be obliged to revise some of the elements in this Opinion.

- ***Concerning general risk management measures***

In France, government orders already set general rules for risk management independently of the results of the health risk assessments for each individual product. In particular, these regulations impose restrictions of use for products depending on their classification and the rules concerning their conditions of application.

Statements received by ANSES from local residents and bystanders some of which mention symptoms potentially related to exposure, suggest that in a number of cases the conditions of application of products have resulted in the product drifting outside the field or area treated, contrary to the provisions of the Order of 12 September 2006.

As a result, in addition to the provisions related to the results of the risk assessments based on the application of good agricultural practice, these deviations observed on the ground may justify new regulatory provisions laying down risk management measures, independently of case-by-case risk assessments. However, considering the influence of several parameters on the exposure of bystanders and residents and the varied toxicological profiles of the products used, it is not possible to specify relevant general measures on a purely scientific basis.

Lastly, ANSES emphasises the importance of training programmes for farmers in good agricultural practice and wishes to reiterate that it is indispensable to strictly follow the conditions of use of products associated with their marketing authorisations, in order to reduce exposure and especially that of residents and bystanders.

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KEY-WORDS
Residents, bystanders, plant protection products.