générations FUTURES

RESIDENTS EXPOSED TO PESTICIDES: FAILURE IN RISK ASSESSMENT

SUMMARY

Context 3

What is a risk assessment? 6

Why are these assessments not protective enough? 7

Flaws in exposure assessment 8

Flaws in hazard assessment 16

Discussion 19

Conclusion and requests 22

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Générations Futures is a member association of the networks:
Pesticide Action Network and Europe Health and Environment Alliance

Acronyms and abbreviations

Buffer zone:	Untreated area
MA:	Marketing Authorization
EFSA:	European Food Safety Agency
ANSES:	French National Agency for Food, Environmental and Occupational Health Safety
CMR:	Products of most concern classified as carcinogenic, mutagenic or reprotoxic
AOEL:	Acceptable Operator Exposure Level
NOAEL:	No Observed Adverse Effect Level
MRL:	Maximum Residue Limit

CONTEXT

The proximity of homes to agriculture lands treated with pesticides is a significant source exposure to pesticides by inhalation and by skin contact, which comes on top of exposure through food. A review of the literature conducted by Santé Publique France in 2020[1] confirms that **studies show that residents living near treated plots are exposed to higher quantities of pesticides compared to people living far from fields.**

After years of inaction on the issue of risk for residents, France undertook in 2020 to apply safety distances – or buffer zones – between treated fields and residential areas. The breadth of these buffer zones can be set in two ways:

➔ **When available, the distances indicated on the Marketing Authorisation (MA) and on the product label must apply.** These distances are defined following a **risk assessment** specific to the product, carried out according to a European guideline drawn up by the **European Food Safety Agency (EFSA).** This guideline entered into force on January 1, 2016 and must therefore apply from this date to any new application for authorisation or renewal of authorisation for active substances and products. To date, only a small number of MAs issued by the French National Agency for Food, Environmental and Occupational Health and Safety (ANSES) contains this type of indication. The distances resulting from these risk assessments are 3, 5 or 10 meters for so-called "low" crops (e.g. cereals) and 10 meters for "high" crops (vineyards and orchards). These values correspond to the distances for which the risk is assessed. Indeed, the risk is only assessed at 3, 5 or 10 meters for low crops and only 10 meters for high crops.


GUIDANCE DOCUMENT

Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products

➔ **In the absence of a specific safety distance set by the marketing authorization (MA) for the product concerned, which is mostly the case to date, national provisions apply.** These provisions appear in the decree of May 4, 2017, amended by the decree of December 27, 2019 and more recently by the decree of January 25, 2022. The safety distances are set according to the dangerousness of the product and the type of crops treated:

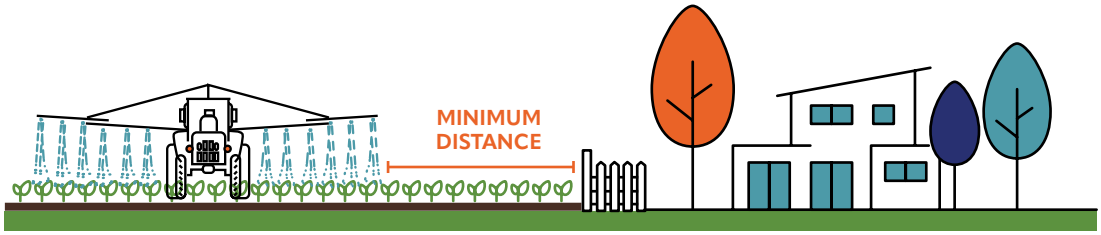
- For the products of greatest concern classified as proven (category 1A) or presumed (category 1B) carcinogens, mutagens or reprotoxics (CMR), products considered to be endocrine disruptors and products toxic or sensitizing by inhalation: the distance to be respected is of 20 incompressible meters. These most restrictive distances only concern a very limited number of products[2].

- For other products (including products classified as CMR category 2), the distance is set at 10 meters for all high crops and 5 meters for other crops. These distances can be reduced to 5 and 3 meters respectively if departmental charters have been signed between farmers and local residents, committing farmers to using drift reduction devices.

1. https://www.sciencedirect.com/science/article/pii/S0160412019314898?via%3Dihub

2. List available here: https://agriculture.gouv.fr/distances-de-securite-pour-les-traitements-phytopharmaceutiques-proximite-des-habitations

MINIMUM DISTANCES
between spreading areas and residential areas
Application date: January 1, 2020



For the most dangerous products

20 m
incompressible distance

For other plant protection products

10 m
For arboriculture, viticulture, trees and shrubs, forest, berries and ornamental crops over 50 cm in height, banana trees and hops

5 m
For other crops

Provided farmers have recourse to the most efficient in terms of the environment spraying equipment, and in the context of local charters, minimum distances can be reduced to:

- **Up to 5 meters for arboriculture,**
- **Up to 3 meters for viticulture and other crops.**

Source: https://landes.chambre-agriculture.fr/votre-chambre-40/toutes-les-actualites/detail-de lactualite/actualites/zones-non-traitement-nouveautes-a-partir-du-24-mars/

Following an appeal filed by several NGOs including Générations Futures, the Council of State issued a decision on July 26, 2021 in which it recognizes that **the safety distances provided for by these provisions are insufficient for the CMR2 classified products.** For these products, the Council of State recommends distances to be equal or above 10 meters for all products classified as CMR2, in the absence of a distance set by the MA, and therefore asks the State to revise the decree of December 27, 2019.

Following the opinion of the Council of State, the government therefore published the decree of January 25, 2022 in which, he asks manufacturers of products to supply, before October 1st, 2022, a risk assessment for any product classified as CMR 2. Thus, distances will be defined following the results of these

assessments. If none risk assessment is provided by the deadline set for October 1, 2022, the default distance of 10 meters will apply for all CMR2 classified products. This distance is the minimum distance recommended by the Council of State, which advocated ZNT at least equal to 10 meters.

Risk assessments therefore play a major role in determining safety distances:

- ➔ When they are carried out, **they always take precedence over national provisions,** even in the most risky situations. Let's take the hypothesis of a Category 2 carcinogen product, widespread near a school and for which the label indicates a safety distance of 3 meters. National provisions, in the absence of any indication on the label, would provide for a distance of 10 meters but as the label says 3 meters, it is well this distance, although smaller, which applies.

- ➔ In addition, these risk assessments will become increasingly important following **the decree of January 25, 2022, which requires that risk assessments be carried out for all CMR2 products** in order to set buffer zones according to the results of these assessments.

According to a search made on the Ephy[3] site listing all the products authorised in France and their instructions for use, it appears that the distances for use on low crops, when they appear on the labels, are most often 3 meters and sometimes 5 meters. To our knowledge, we do not have any products for which the label would indicate a safety distance of 10 meters for use on low crops.

Performing these risk assessments requested by the government will therefore lead, for uses on field crops, at the establishment of safety distances of 3 meters most often and 5 meters in a few cases.

The buffer zones set up following these assessments will therefore be smaller than those provided for by national provisions, in lack of risk assessment.

This approach is based on a postulate which turns out to be erroneous: the risk assessments would be reliable and protective, in particular towards the most vulnerable people. It is indeed considered by this policy that if the risk is deemed acceptable by the assessment, it is not necessary to apply extended buffer zones. Starting from this assumption is a serious mistake because it completely ignores the many **uncertainties and flaws inherent in risk assessments.**

This is why we have written this report, in order to shed light failures on these assessments. We will show that an "acceptable" risk in an assessment does not mean a total absence of risk, in particular for the most sensitive people. Consequently, **safety distances cannot be fixed on the sole basis of these assessments and the precautionary principle must apply.**

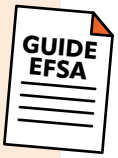
3. https://ephy.anses.fr/

WHAT IS A RISK ASSESSMENT?

To find out if the exposure of residents to pesticides may be harmful to their health, we proceed in 3 stages. These are the classic steps in any chemical risk assessment:

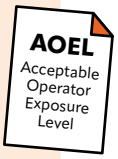
1

The exposure of residents is estimated by calculation. This modeling is done according to the recommendations of a European guidance written by the EFSA[4]. This guidance describes the assumptions made to **calculate the maximum level of exposure to the active substance expected under normal conditions of product use.** According to this guidance, the "worst case" exposure for a person is therefore calculated and expressed in milligrams of active substance per kilogram of body weight.



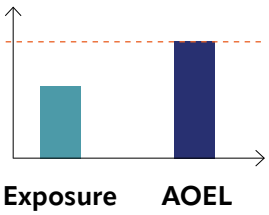
2

The intrinsic danger of the active substance is assessed and a **health value below which no adverse effects are expected is determined** from the results of available toxicology studies. This value is here called "AOEL" (for Acceptable Operator Exposure Level) and it is also expressed in milligrams of active substance per kilogram of body weight.

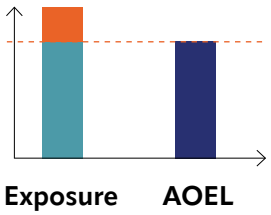


3

The risk assessment therefore consists of **comparing the estimated exposure to the health value without effect.** If the calculated exposure is lower than the AOEL, the risk is considered "acceptable". On the contrary, if the exposure is greater than the AOEL, the risk is considered unacceptable and the product, or a specific use of the product, may be prohibited.



ACCEPTABLE RISK



UNACCEPTABLE RISK

This method is carried out for each substance taken separately.

4. EFSA (European Food Safety Authority), Charistou A, Coja T, Craig P, Hamey P, Martin S, Sanvido O, Chiusolo A, Colas M and Istace F, 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, 134 pp. https://doi.org/10.2903/j.efsa.2022.7032

WHY ARE THESE ASSESSMENTS NOT PROTECTIVE ENOUGH?

In all the assessments made in the marketing files of which we are aware, the risk for residents is considered acceptable with or without the application of management measures, such as the obligation to use equipment reducing the spray drift.

But what does "acceptable" risk mean? Is it really protective, especially towards the most vulnerable people?

Actually, **the term "acceptable risk" is very misleading.** It should rather always be specified that the "risk is acceptable according to the risk assessment carried out according to the EFSA guidance", which is very different from the risk that there may be in reality! Indeed, these assessments contain many flaws and uncertainties, both for the exposure assessment and for the derivation of the health values. The model tends not to take into account the **"worst case"** exposure situation that could occur in reality, which leads to an underestimation of this exposure and a large uncertainty in the values. And at the same time, the hazard assessment that does not consider all the data nor the multiple possible exposures makes the assessment uncertain and can lead to underestimating the hazard and therefore overestimating the AOEL value.

Therefore, the result of the assessment is always in favor of authorising use even though it does not protect the entire population, in particular the most vulnerable people. This is what we will detail in the rest of this report.

FLAWS IN EXPOSURE ASSESSMENT

For the exposure assessment, the EFSA guidance and its calculator available online (OPEX) serve as a reference. They were published for the first time in 2014 and then recently revised in early 2022. Each time, a public consultation took place (in 2014 and 2021), during which stakeholders (industrials, authorities and NGOs) were able to comment and suggest modifications.

This modeling has the advantage of providing a common framework for all assessment dossiers and of estimating exposure from simple data on the products and their active substance. But this guidance has many flaws, most of which are recognized by the EFSA itself! After an analysis of this guidance as well as the comments received during the two public consultations in 2014 and 2021, we raised the following main shortcomings:

(a) Risk assessment and buffer zones for protecting residents do not apply to all products.

(b) Some routes of exposure are not taken into account.

(c) The studies included in the model are old, few in number, and the "worst case" values found in these studies are not used.

(d) The exposure durations considered in the model underestimate the real exposures.

(e) The meteorological conditions considered in the model underestimate the real exposures.

(f) The physical characteristics of people exposed according to the model are not realistic nor protective for the general population.

a

Risk assessment and buffer zones for protecting residents do not apply to all products

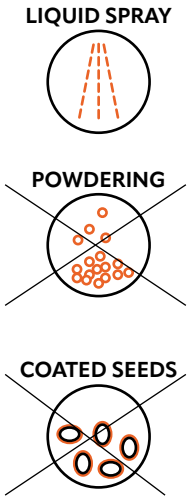
The risk assessment for residents is only carried out for spray applications of products in liquid form. Buffer zones for residents also only apply in French national provisions for products applied by spraying.

The other types of application, less currents, by dusting or the application of seeds coated with pesticides, are not subject to a risk assessment obligation for residents and no buffer zone is applied for these types of applications. Nevertheless, it is recognized that these modes of application can also lead to residents' exposure following the volatilisation of substances, wind erosion and uplift dust from contaminated soil, for example.

This lack of obligation to assess the risk for residents for these solid products is in total contradiction with the requirements for risk assessment for ecosystems. Indeed, according to the European regulation 284/2013 setting out requirements the requirements for the assessment of phytopharmaceutical products, a risk assessment relative to the drift of dust that occurs after the application of products in solid form must be provided for all non-target species.

Why is such an obligation not mentioned in the European regulations for the assessment of the risks for residents?! EFSA argues that at the time current, data is still missing to develop a model that would allow to perform this kind of assessment. Nevertheless, models do exist to estimate the dust drift after application of products in solid or seed form, allowing to assess the risks for the environment.
So why is no model available for resident risk assessment for? Why does it take so long to generate this data?

As a precaution, pending that such models exist, the buffer zone should therefore also apply to solid products and to treated seeds and not only liquid products applied by spraying.



Regulation 284/2013, section 9, 2: "For solid plant protection products, treated and coated seeds there shall be an assessment of the risk from dust drift on to non-target species during application or sowing. Until agreed dust dissipation rates are available, then likely exposure levels shall be determined using a range of application techniques, suitable dust measurement methodology and, where appropriate, mitigation measures."

b

Some routes of exposure are not taken into account

For liquid products applied by spraying, 4 exposure scenarios for adults and 5 for children are considered in the model:

Exposure scenarios	Route of exposure	Exposure time considered
Spray drift at the time of application	Inhalation Skin contact	No duration specified (exposure via spray drift occurs just after application)
Volatilisation after application	Inhalation	For 24 hours
Deposition of droplets on surfaces	Skin contact	2 hours
Entry into a treated crops	Skin contact	15 minutes
Hand-to-mouth transfer of contaminated objects (for children over one year only)	Oral route	

The contamination of the air by droplets resulting from the spraying and by volatilisation as well as the contamination of surfaces following the deposition of droplets have an important part in the model. But the model forgets a significant scenario: **the inhalation of contaminated dust.**

These contaminated dusts can be found in dwellings in two ways: first, by the lifting by the wind of dust from the treated ground on which the substances has been adsorbed; then, by the adsorption on the dust of substances contained in the air following volatilization.

A literature review carried out by researchers from Santé Publique France and Inserm highlights several publications showing that **the concentrations of contaminated dust are 4 times higher in houses located near fields than in more distant houses**[5]. A recent Dutch study also points to the importance of dust in the exposure of residents[6]. However, this route of exposure, considered minor compared to the other scenarios, is not taken into account in the risk assessment for residents.

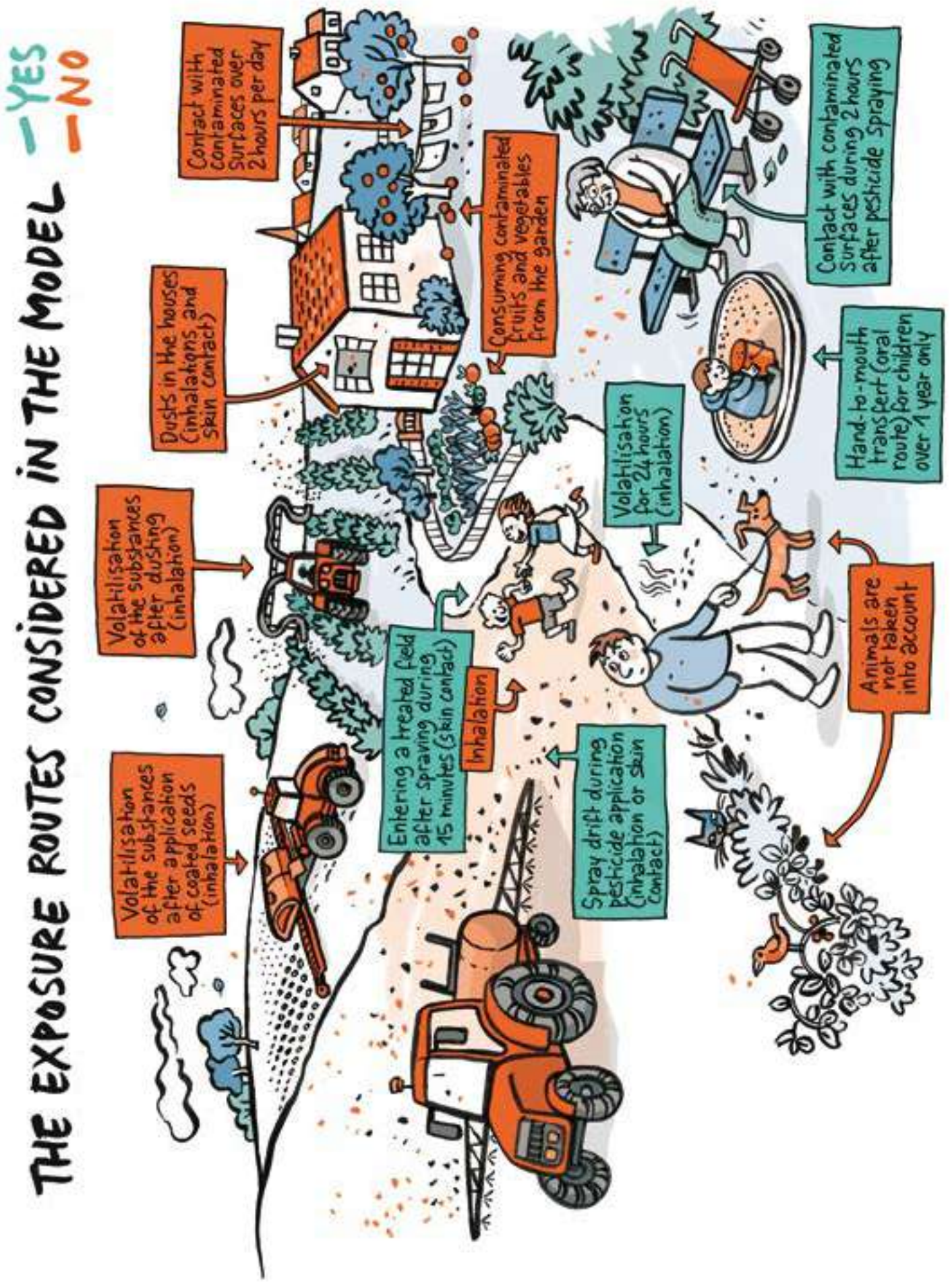
These criticisms have already been made to EFSA during both public consultations of 2014 and 2021. Each time, EFSA recognizes that the model does not effectively include all possible modes of exposure but that data are still missing to incorporate them into the model[7]. Between 2014 and 2021, therefore, no progress has been made on this issue.

Another important overlooked route of exposure is the oral route, with the possibility of consuming drift-contaminated garden fruits and vegetables. EFSA replies that this route of exposure is covered by the risk assessment made for consumers with the derivation of maximum residue limits (MRLs), and therefore does not constitute a specific risk for residents. This completely ignores the fact that spray drifts can settle on fruit or vegetables that have already reached maturity, whereas the MRLs are calculated for applications to plants at a less advanced stage of development, while the fruits are not already developed!

5. Dereumeaux et coll., Pesticide exposures for residents living close to agricultural lands: A review. Environment international, 2020 https://www.sciencedirect.com/science/article/pii/S0160412019314898?via%3Dihub

6. Figueiredo et coll., OBOMod - Integrated modelling framework for residents' exposure to pesticides. Science of the total environment, 2022. https://www.sciencedirect.com/science/article/pii/S0048969722008907?via%3Dihub

7. Extract of public consultation of 2014, EFSA's answer: "As for exposure to dust this exposure pathway is not covered by the present assessment, however it is Working Group opinion that the expected worst case exposure has been covered by the other main significant exposures. Nevertheless, the Working Group recommends to further collect/produce data on exposure pathways other than the ones considered in order to produce more realistic scenarios."
Extrait consultation publique 2022, réponse de l'EFSA: " The guidance is based on the assessment of available data. A limited number of scenarios is covered; therefore, the submission of new relevant data is encouraged for the next developments of the guidance."


THE EXPOSURE ROUTES CONSIDERED IN THE MODEL
YES
NO
Contact with contaminated surfaces over 2 hours per day
Dusts in the houses (inhalations and skin contact)
Consuming contaminated fruits and vegetables from the garden
Contact with contaminated surfaces during 2 hours after pesticide spraying
Hand-to-mouth transfert (oral route) for children over 1 year only
Volatilisation for 24 hours (inhalation)
Volatilisation of the substances after dusting (inhalation)
Entering a treated field after spraying during 15 minutes (skin contact)
Inhalation
Animals are not taken into account
Volatilisation of the substances after application of coated seeds (inhalation)
Spray drift during pesticide application (inhalation or skin contact)

C

The studies included in the model are old, few in number, and the "worst case" values found in these studies are not used

The exposure values integrated into the model, in particular the values related to spray drift, are taken from studies carried out in the field. The greater the number of studies and "real" data integrated into the model, the more robust it is. However, for the calculation of exposure resulting from spray drift, there are very few "field" data: in particular, for exposure following an application of products on so-called "high" crops (orchards and vines) **a single study dating from 1987 (Lloyd et al., 1987[8]), which is not accessible to the general public, is used to feed the model.** EFSA itself recognizes that additional data is needed.

Moreover, the values resulting from studies integrated into the model are not the most conservative. As the values measured at a given distance are not all uniform in the studies, a distribution of these values is made. The value used in the model is the 75th percentile of this distribution. The 75th percentile means that 75% of the values measured in the study are below the 75th percentile and 25% of the measurements are above. In other words, a value is used that theoretically represents a "worst case", knowing that in 25% of cases, the real exposure measurements proved to be higher. This 75th percentile is used to estimate exposure related to spray drift taken separately. When the total exposure is calculated, considering the 4 (or 5 for children) possible exposure scenarios, the 50th percentile is used!

Using the 50th or 75th percentiles would not be a problem if their values were close to the value represented by the 95th percentile, considered as a more protective value. However, in the case of the study by Lloyd et al., 1987, used to estimate exposure near vineyards and orchards, there is a considerable difference between these values:

Exposure by skin contact at 5 and 10 meters from orchards treated with an airblast sprayer (in mL of diluted product/person)

	Adults	Children
50th percentile	3.68	1.11
75th percentile	5.63	1.69
95th percentile	12.9	3.87

The values taken into account to calculate the total exposure (50th percentile) are more than 50% lower than the more protective value represented by the 95th percentile.

It is therefore difficult to say that the assessment covers the "realistic worst cases".

Faced with these criticisms expressed during the two public consultations, **the EFSA disclaims all responsibility and relies on the "risk managers"**, therefore the health authorities, for any dispute and questioning of these values.[9]

8. 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.

9. Extract of public consultation 2021, EFSA answer: "The choice of which percentile of exposure to use is a risk management decision and there is outside the remit of EFSA. However, the use of the 75th and 95th percentiles follows the PPR opinion (2010) as agreed with risk managers for the first guidance (EFSA, 2014). This has clearly been accepted by risk managers and it would be their role to ask for this to be reconsidered."

d

The exposure durations considered in the model underestimate the real exposures

For exposure following skin contact with contaminated surfaces, 2 hours is arbitrarily considered to be a worst case. Using this short duration does not take into account all situations that may lead to longer exposure, such as wearing clothes that were drying outdoors during the spraying, for instance.

e

The meteorological conditions considered in the model underestimate the real exposures

The wind speed at the time of spraying is an essential factor for the estimation of spray drift. However, it is very difficult to know what the real wind speed was during the course of the studies feeding the EFSA model.

As the study is not available, it is not possible to know the wind speed during the study by Lloyd et al., 1987, which remains the only study used to estimate exposure following an application of pesticides on high crops.

For low crops, the EFSA model uses data from the British BREAM project which uses a maximum wind speed of 2.7 m/s, equivalent to just under 10 km/h, i.e. force 2 over the Beaufort scale.

In short: exposures are estimated either for a wind speed unknown to the general public, for tall crops, or for a maximum speed of 2.7 m/s for low crops.

However, in France, the spreading of pesticides is authorised up to a wind speed of 5.2 m/s (i.e. 19 km/h or 3 Beaufort).

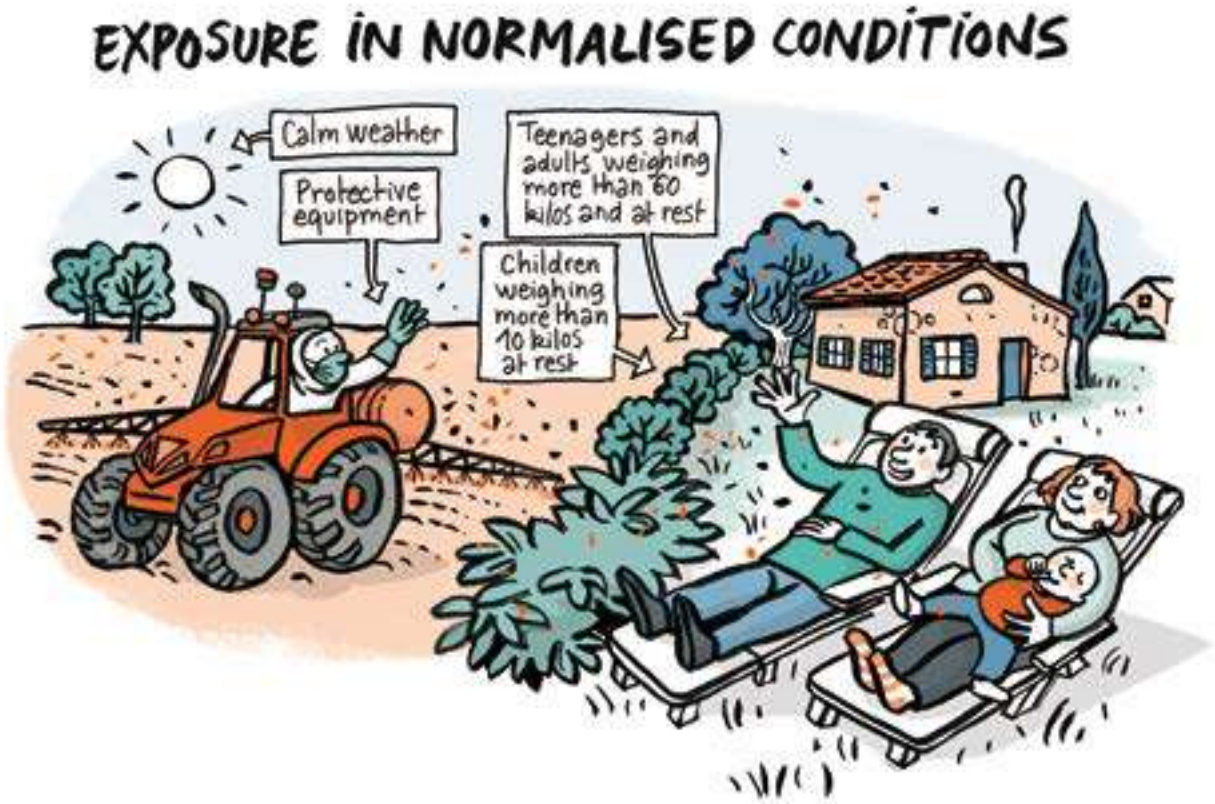
The exposure of residents when a product is spread on a windy day between 10 and 19 km/h is therefore not evaluated. This raises questions about how much pesticides can drift, and how far they drift under these conditions. **By underestimating the wind force that can occur in real conditions, the risk assessment greatly underestimates the exposure of residents.** We are therefore very far from the worst realistic exposure conditions boasted by the model!

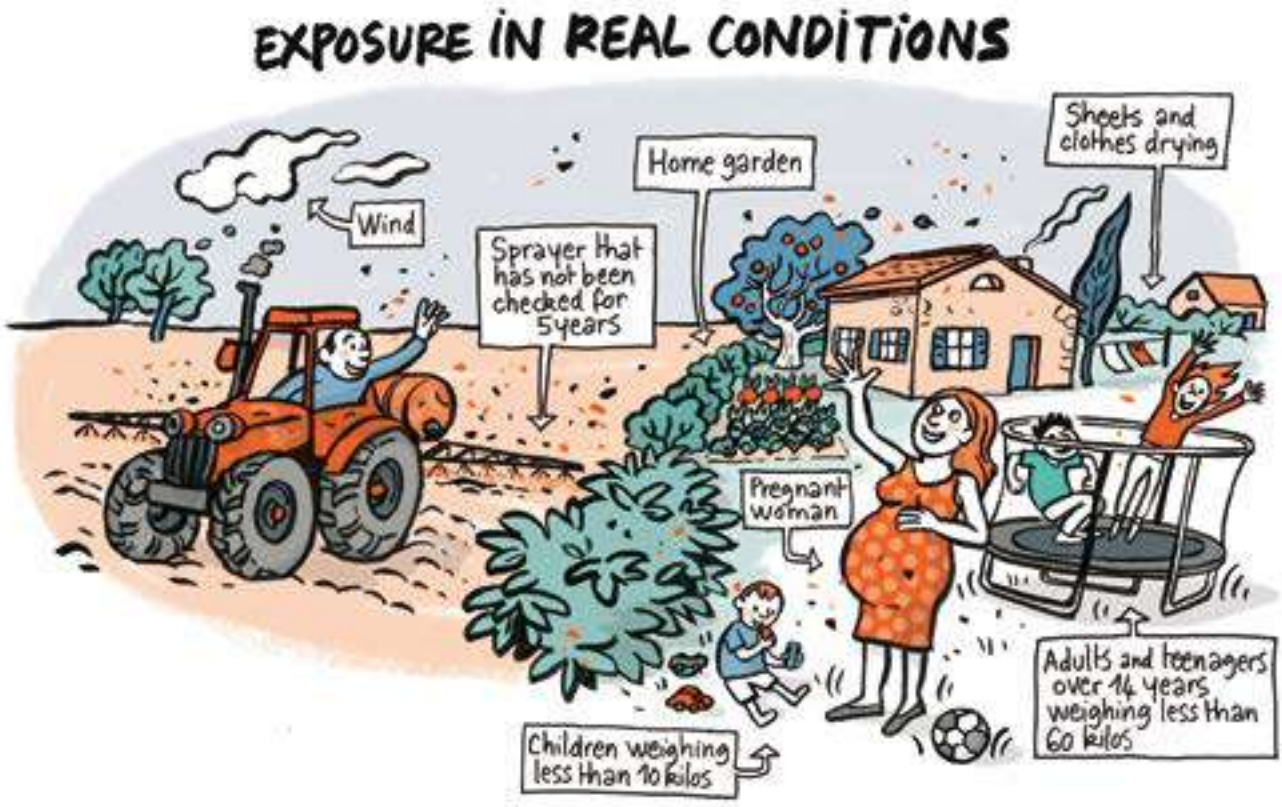
The Dutch authorities (RIVM and CTGB) pointed out to EFSA that the wind speed considered in the model was lower than the wind speed that could occur in real conditions[10]. EFSA did not respond to this comment.

Moreover, these conditions of "good agricultural practices" prohibiting in France the spraying by more than 3 Beaufort would not always be respected according to numerous testimonies collected[11].

10. Extract of public consultation 2021, RIVM's comment: "Also, the wind speed parameter 'Wind speed 2.7 m/s' is not worst case as in some EU countries a maximum wind speed of 5 m/s at 2 m height or 1 m above the crop canopy is the maximum wind speed spraying allowed (within Good Agricultural Practice)."

11. https://vic-times-pesticides.fr/


EXPOSURE IN NORMALISED CONDITIONS
Calm weather
Protective equipment
Teenagers and adults weighing more than 60 kilos and at rest
Children weighing more than 10 kilos at rest


EXPOSURE IN REAL CONDITIONS
Wind
Sprayer that has not been checked for 5 years
Home garden
Sheets and clothes drying
Pregnant woman
Adults and teenagers over 14 years weighing less than 60 kilos
Children weighing less than 10 kilos

f

The physical characteristics of people exposed according to the model are not realistic nor protective for the general population

The calculated exposure values are "internal" exposures, after passage of the substance into the blood by skin absorption and after inhalation. They are expressed in milligrams of substance per kilogram of body weight. **The physical characteristics of people, and in particular their weight, are therefore important factors for calculating exposure.** The higher the weight of the people, the lower the calculated concentrations will be.

To facilitate and limit the number of calculations, two groups of people are considered in the assessment of the exposure of residents: one group representing children aged 0 to 14 and another representing people aged 14 and over. Each of these groups is represented by an "average" weight considered protective for the group as a whole.

For the group of children, EFSA assumed that children aged 1 to 3 years, with an estimated average weight of 10 kg, represent the "worst case" group. Indeed, their low weight and their behavior imply that they are likely to be more exposed, especially through the skin, than the other groups. In particular, it is considered that 0-1 year old children are not concerned by the scenario of re-entry into the fields and consequently that they would

be less exposed than older children. The risk for the 1-3 year old group is thus the only one assessed and "covers" the risks for the other 0–1-year old and 3-14 year old groups.

This approach is indeed protective for the 3–14-year old group. But what about the 0–1-year old group? Their greater sensitivity to chemical pollutants, in particular to endocrine disruptors, their low weight (well below 10 kg for newborns), their behavior (walking on 4 legs, putting objects in the mouth, etc.) would not be enough to consider them as the "worst case" group?!

Studied group	Considered body weight
0-1 YEAR 1-3 YEARS 3-14 YEARS **CHILDREN** (group 1-3 years old covering 0-14 years old)	**10 kg**
ADULTS (14 years and over)	**60 kg**

The hypothesis taken here is very risky and absolutely not based on scientific considerations. **Newborns and babies under 1 year old are therefore not covered by this assessment!**

In addition, considering a weight of 10 kg for 1-year old babies is also an erroneous and non-protective assumption: according to the weight curves drawn up by the French Association of Ambulatory Pediatrics (AFPA) and appearing in the health records of French people, 50% of boys and 75% of girls aged 1 year weigh less than 10 kg[12].

The same problem arises for the group of adults: 60 kg is the weight considered "protective" for men and women from the age of 14[13] ! However, still according to the growth curves of the AFPA[14], **almost 80% of girls and 76% of boys aged 14 weigh less than 60 kg**. At 18, this percentage is still 60% for girls and 25% for boys. How can the EFSA say that this weight is protective for girls and boys aged 14 to 18?! **The exposure of teenagers aged 14 to 18 is therefore largely underestimated according to these figures.**

Another major parameter for estimating exposure by inhalation is the inhalation rate, meaning the volume of air inhaled by a person per hour (rate expressed in m^3/h). In the assessment, the inhalation rates considered for residents are average daily values for people carrying out normal, low-intensity activity. **This hypothesis is therefore not always protective and does not cover the many situations during which people make a physical activity**, responsible for an increase of their breathing rate.

These moments of more intense physical activity can however occur over several hours during a day and be responsible for a greater absorption of substances by inhalation. This is the case, for example, of children playing in their garden or schoolyard.

12. *file:///C:/Users/Utilisateur/Downloads/Courbes-Poids-garcons-1-mois-3-ans-AFPA-CRESS-Inserm-CGM-2018.pdf file:///C:/Users/Utilisateur/Downloads/Courbes-Poids-filles-1-mois-3-ans-AFPA-CRESS-Inserm-CGM-2018.pdf*

13. *Extrait du guide EFSA: "a default body weight value of 60 kg is proposed in this guidance to be protective for the non-dietary risk assessment of all adults, including females and teenagers from 14 to 18 years."*

14. *file:///C:/Users/Utilisateur/Downloads/Courbes-Taille-et-Poids-filles-1-18-ans-AFPA-CRESS-Inserm-CGM-2018.pdf*

FAILURES IN HAZARD ASSESSMENT

In parallel to the exposure assessment, the hazard assessment of substances and the derivation of health values (AOEL) also have several flaws, the main ones of which are summarized here:

a. The database of studies used to derive AOEL is often incomplete.

b. Genotoxic and carcinogenic effects are not always covered by AOELs.

c. The co-formulants present in the product are not taken into account.

d. The cocktail effect is not taken into account.

a

The database of studies used to derive the AOEL is often incomplete

The results of the toxicology studies are the starting point for the derivation of the AOELs: among all the available studies, only one study will be retained. The study that will serve as the basis for deriving the AOEL will be the one showing an adverse effect appearing at the lowest exposure dose among all the doses tested in all available studies. Thus, **the dose retained is the dose below which no harmful effect appears in all the toxicology studies considered.** This dose is called NOAEL (No Observed Adverse Effect Level). A safety factor of 100 is then applied to this NOAEL to take into account the uncertainties linked to the extrapolation of data from animals to humans and to take into account inter-individual variations.

AOEL = NOAEL / 100

To be sure that the NOAEL used to derive the AOEL is indeed the lowest, in other words, to be sure that no other effect appears at doses lower than the selected NOAEL, the database of studies used must be as broad as possible, in order to cover the maximum possible toxicological effects.

What about the toxicological studies considered for the substance authorisation?

The toxicology studies used to derive health values (AOEL) come almost exclusively from industry. The other available data, from the independent scientific literature, is largely ignored because these studies are not conducted according to the standards described by the OECD and thus are not considered reliable. The regulatory system for evaluating the dangers of substances, by considering only the OECD studies as reliable and usable, is therefore disconnected from the whole state of science available from independent research. In consequence, a certain number of toxic effects are not or badly covered by

the regulatory assessment and its OECD standards. In particular endocrine disrupting effects, for which the available OECD standardised tests do not cover all possible effects[15], but also neurotoxic or immunotoxic effects are underestimated by the regulatory science. **Many other toxic effects are not covered by these regulated studies,** such as toxic effects on the mitochondria (intracellular organelle responsible for cell respiration) or the effects of substances on the microbial flora, for example.

The emblematic example of this system based on these so-called "regulatory" studies is obviously glyphosate, for which the assessment is based exclusively on industry studies, despite the existence of many studies from independent research[16]. This is how the authorities miss the genotoxic and neurotoxic character and miss its effects on the microbial flora, among others.

Another emblematic example is that of bisphenol A. After taking into account new data from independent scientific literature, and in particular studies on the immune system (effect poorly studied by OECD studies), EFSA proposed to considerably reduce the tolerable daily intake of bisphenol A from 4 µg/kg bw/day to 0.04 ng/kg bw/day, i.e. a reduction by a factor of 100,000![17]

Thus, until all toxicological effects have been explored, **there will always be an uncertainty regarding the reliability of health values. This uncertainty must be taken into account by the authorities when managing risks.**

b

Genotoxic and carcinogenic effects are not always covered by AOELs

Most of the time, genotoxic and carcinogenic effects are said to be "non-threshold": this means that, in theory, effects can appear from the lowest exposure. Of course, the higher the exposure dose, the greater the likelihood that these effects will indeed appear. However, it is not possible for these non-threshold effects to define a safe dose like the AOEL.

15. https://www.generations-futures.fr/wp-content/uploads/2022/03/version-finale-rapport-pe-thyroide-vol2.pdf

16. https://www.generations-futures.fr/wp-content/uploads/2021/11/evaluation-du-glyphosate-un-rapport-biaise-v4.pdf

17. https://www.efsa.europa.eu/fr/news/bisphenol-efsa-draft-opinion-proposes-lowering-tolerable-daily-intake

This aspect is widely accepted in all chemical regulations and also in the reference document used for the derivation of AOELs[18]. For these non-threshold effects, the classic quantitative risk assessment approach (comparing exposure to a no-effect dose) is therefore not possible. In these cases, a qualitative risk assessment is carried out, which consists of ensuring that all the necessary measures have been taken to limit exposure as much as possible.

Thus for category 2 carcinogens and mutagens, **these types of non-threshold hazards are not covered by the AOEL.** The result of the risk assessment therefore covers other effects, but not carcinogenic or mutagenic effects. It is therefore totally wrong to assert that the risk is acceptable for this type of substance and product when, in reality, the risk has not been assessed!

The EFSA justifies itself saying that residents are exposed for a maximum of 90 days in the year, during the spreading season and therefore not chronically. Thus, there would in any case be no possible carcinogenic risk with this exposure time. This unfortunately overlooks the fact that residents are exposed to this type of product every year, often to a mixture of products from different plots, and that these emissions can occur over a much longer period due to the re-volatilization of substances in particular!

c

The co-formulants present in the product are not taken into account and the chronic toxicity of the products is not evaluated

Product risk assessments are based solely on the active substance(s) contained in the product. **Adjuvants as well as the effects of the mixture itself are not considered or even ever assessed.** Indeed, chronic toxicity studies carried out with the mixture itself are not required by the regulation. However, in some cases, it has been proven, via the scientific literature, that the mixture is much more toxic than the active substance(s) taken separately. This is particularly the case for glyphosate-based products, which are found to be more toxic in genotoxicity and carcinogenicity studies than glyphosate itself[19]. **This failure to take into account the co-formulants and the toxicity of the mixture adds additional uncertainty to the assessment.** However, residents are actually exposed to the products and not to the substance alone.

d

The cocktail effect is not taken into account

More generally, the risk assessment done substance by substance **fails to take into account the cocktail effect linked to multiple exposures to several substances and products,** although this type of exposure is very frequent for residents. However, it is widely accepted and recognized that substances in a mixture have potentially more toxic effects than substances taken separately[20]. The European Commission takes this subject very seriously[21] and taking this "cocktail" effect into account is under discussion in other European regulations. In particular, the introduction of a Mixture Assessment Factor (MAF) aimed at better protecting populations and the environment from these multiple exposures is proposed by the Commission as part of the revision of the REACH regulation.

When will cocktail effect be taken into account in phytopharmaceutical regulations and in measures aimed at protecting residents implemented?

18. SANCO 7531 - rev.10, 07 July 2006 "An AOEL cannot be established for an active substance that is genotoxic in vivo and/or carcinogenic unless a threshold mechanism has been demonstrated."

19. Expertise collective Inserm 2022.

20. https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_mixtures.pdf et https://chemtrust.org/wp-content/uploads/Chemical-cocktails_CHEMTrust-report_March-2022.pdf

21. https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_mixtures.pdf

DISCUSSION

The risk assessment is therefore tainted with many uncertainties, on these two aspects which are the exposure assessment and the hazard assessment.

Regarding the exposure assessment, some assumptions in the modeling are wrong (for example, the weight of the people exposed) or not representative of the real conditions under which the products can be applied (for example the force of the wind). Thus, they do not represent the "worst case" exposure situation, especially for vulnerable people such as young children and pregnant women. Concerning the hazard assessment, the failure to consider all the available studies, the chronic effects of the products as well as the cocktail effects make the assessment unreliable.

Thus, the statement "acceptable risk" made in marketing authorizations is misleading and should not be taken at face value. This is why it is imperative to apply the precautionary principle and to widen the buffer zone in order to protect the whole population.

Using one parameter rather than another may seem trivial when the model has several dozens. However, it is at this level that the result of the risk assessment is played out, in particular for the most toxic substances: on one or two parameters! When the risk ratio (the ratio between exposure and AOEL) is close to 1 (this ratio must be less than 1 to show an "acceptable" risk), the use of a single more protective parameter may be sufficient to tip the scales towards an unacceptable risk. For example, using the 75th percentile instead of the 50th, using a weight of 50 kg, which is more representative of women's weight, instead of 60 kg, could change the conclusions of an assessment. Thus, the choice of exposure model parameters plays an important role in product authorisation and should not be taken arbitrarily as is the case for some. By using more protective parameters, some products, or at least certain uses of these products, could be prohibited for their risk for residents, in theory…

In practice, no product is or has been, to our knowledge, prohibited because of an unacceptable risk for residents. When the result of the assessment shows an unacceptable risk, management measures are applied. In the model, the use of anti-drift nozzles is taken into account and allows the exposure values resulting from the spray drift to be reduced by half. Thus, the risk is still acceptable with these management measures and the products can be authorized.

However, **several questions arise regarding the effectiveness of these risk management measures.** Indeed, a recent scientific peer reviewed study[22] suggests that "while drift mitigation measures contributed some reduction in pesticide contamination, they were not sufficient to eliminate substantial risks to human health and the environment in nontarget areas". Therefore, do anti-drift nozzles halve drift every time as claimed in regulatory risk assessment? Are they always well applied? Are application material checks carried out on a regular basis?

The uncertainties raised in this report were largely recognized by EFSA already during the public consultation in 2014. However, **no improvement of the model for residents was included in the update of the model published at the beginning of 2022.** EFSA still recognizes that additional data are needed, in particular to better characterize drift after application on high crops, exposure due to dust after application of treated seeds or to better take into account the cocktail effect. **EFSA thus reminds dozens of times during the two public consultations that its role is limited to proposing a model and returns the ball to the "risk managers", the competent health authorities of each country, for taking modeling flaws into account and proposing appropriate risk management measures**. This message does not seem to have been heard by the authorities who, instead of taking additional precautionary measures related to these uncertainties, blindly trust the risk assessments and propose safety distances based solely on the results of these

22. *http://dx.doi.org/10.1016/j.scitotenv.2022.158814*

assessments. **It's as if each party, EFSA and authorities, passed the buck for the choice of safety distances!** And in the middle, there are the local residents, whose ever-increasing number of testimonies show that concern on this subject is growing.

In France, ANSES and Santé Publique France initiated a vast study in 2021, called **Pestiriv**[23], aimed at better characterizing the exposure of residents. Certain exposure pathways not taken into account in the EFSA model will be studied with measurements of pesticides in dust as well as in the garden fruits and vegetables of certain participants. The first results of the study are only expected in 2024. In addition, it is not guaranteed that these results will be integrated into the exposure model, both the **requirements necessary for a study to be included in the model are important.** This aspect partly explains why the residents' exposure model has not been improved between 2014 and 2022. It is important to keep in mind that **these models and the studies incorporated into them are largely developed and financed by manufacturers themselves**, in a totally non-transparent way.

We will cite as an example the model that will be used to estimate exposure following the application of treated seeds, a scenario not currently taken into account, whether for residents or farmers, due to a lack of available data. A consortium of industrialists grouped together under the name "SeedTropex Taskforce" and three health agencies, including ANSES, are involved in the development of this model. NGOs and other stakeholders are totally excluded from the discussions and are not made aware of progress. However, we learned during a workshop organised by EFSA that the exposure of local residents following the application of treated seeds will still not be integrated into this model and therefore still not evaluated. However, EFSA has clearly pointed out this shortcoming since 2014!

The evolution of the model and the integration of new data is therefore very long. Thus, **it is not possible to count on a rapid improvement of these models to apply more protective safety distances.** So, it is necessary to act immediately to protect residents!

23. https://www.santepubliquefrance.fr/etudes-et-enquetes/pestiriv-une-etude-pour-mieux-connaitre-l-exposition-aux-pesticides-des-personnes-vivant-en-zones-viticoles-et-non-viticoles

CONCLUSION AND REQUESTS

On the basis of this report, Générations Futures is asking the French Government and ANSES to make the following progress:

1

REQUEST

Safety distances to protect residents must be set according to the precautionary principle and not according to the results of regulatory risk assessments.

An "acceptable" risk in a risk assessment does not mean an absence of risk given all the uncertainties and flaws in the assessment models. It is not acceptable to blindly trust these ratings!

2

REQUEST

Safety distances must be extended for all products, and at least for products classified as CMR2 and/or classified for their chronic toxicity.

In order to take into account all the uncertainties mentioned in this report, the precautionary principle must apply, especially for substances and/or products classified as CMR2 and substances and/or products classified for their chronic toxicity. In addition, this request is shared by the French Council of State, which requires greater safety distances for CMR2 products.

3

REQUEST

Spreading must be prohibited when the wind is greater than 10 km/h (2.7 m/s), i.e. force 2 on the Beaufort scale.

Spreading is authorised in France up to 19 km/h (Force 3 Beaufort) while the risk for residents is no longer assessed beyond 10 km/h.

4

REQUEST

Residents must be informed in a clear and effective manner about the time and nature of spreading.

In order to take all possible precautions, this information should be provided to residents, for example, by the systematic sending of SMS and by its materialisation with posters near the fields in order to avoid entering the fields after the spreading.

5

REQUEST

More human and financial resources must be allocated to the French Biodiversity Office (OFB)

to ensure the control of application and drift reduction equipment as well as to verify compliance with good agricultural practices.

6

REQUEST

The phyto-pharmacovigilance system must be improved in order to give residents a real possibility of reporting their alerts in a simple and coordinated way.

7

REQUEST

The Government must commit to a real pesticide reduction policy.

The most dangerous pesticides must be substituted, as required by European regulations.

générations FUTURES

A RECOGNIZED ASSOCIATION

Générations Futures is an association for the defense of the environment recognized as being of general interest, created in 1996 and approved by the Ministry of Ecology since 2008 (renewal obtained in 2014). The association carries out actions (surveys, conferences, legal actions, awareness campaigns, etc.) to inform about the risks of various types of pollution (chemical substances in general and pesticides in particular) and to promote alternatives to these products that threaten health and the environment (particularly during the Week for alternatives to pesticides). It participates in many official committees within the Ministries of Health, Environment, Agriculture and the National Food Safety Agency (Anses).

WHO ARE WE?

The association currently has on its Board of Directors a retired specialist teacher, a retired agronomist, a retired communication officer, a retired doctor, an organic certifier, an organic farmer, an organic breeder, a CEO of an SME that does organic milling and an animal osteopath.

It relies in its work on hundreds of active volunteers and on its salaried team of four people. In 2016, the association set up a scientific committee, bringing together doctors, biologists, toxicologists, teacher-researchers... Similarly, since the end of 2015 it has been able to count on local volunteer relays spread over the whole of the territory in order to disseminate its work and relevant information on the subject of pesticides, dangerous chemicals and their alternatives to as many people as possible. In addition, the association is an active member of recognized European networks such as the Pesticide Action Network Europe (PAN Europe) and the Health and Environment Alliance (HEAL).

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