SCIENTIFIC OPINION

Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents[1]

EFSA Panel on Plant Protection Products and their Residues (PPR)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority (EFSA) asked its Panel on Plant Protection products and their Residues to prepare a Guidance Document on pesticide exposure assessment for workers, operators, bystanders and residents. The Guidance Document would be for use in regulatory risk assessment for plant protection products, both to determine eligibility for inclusion in Annex 1 of Council Directive 91/414/EEC[4], and also to underpin the authorisation of products by individual Member States.

The starting point for the opinion was an outsourced project carried out jointly by the UK Pesticides Safety Directorate (PSD) and the University of Ghent (UG), who systematically reviewed and evaluated relevant sources of information. In addition, as a check that important data had not been overlooked, a draft of the opinion was made available via a public consultation in August 2009. In response to the comments received, various clarifications and amendments were made.

Council Directive 91/414/EEC requires that the residues of plant protection products (PPPs) applied in accordance with good plant protection practice must not have "any harmful effects on human or animal health". Currently, risk assessment for operators, workers, bystanders and residents uses a deterministic method, in which a check is made that reasonable upper estimates for daily systemic exposure are below a relevant toxicological reference value, the Acceptable Operator Exposure level (AOEL). Available data do not indicate any major flaws in the current methods of risk assessment for operators, workers, bystanders and residents.

1 On request of EFSA, Question No EFSA-Q-2008-261, adopted on 27 January 2010.

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4 During the preparation of this opinion, a new Regulation (EC) No. 1107/2009 replacing Council Directive 91/414/EEC was adopted by the European Parliament, and will come into force in June 2011.

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Nevertheless, the current method of risk assessment is not completely satisfactory. For some exposure scenarios, the empirical data underpinning exposure estimates are sparse, making the estimates less reliable statistically. For others, more than one model may be available with which to estimate exposures, and where this occurs, there can be inconsistency between the approaches adopted by regulatory authorities. Furthermore, exposure values based on 50th or 75th centiles of empirical datasets may substantially underestimate the maximum exposures that could reasonably occur in a single day, compromising margins of safety for PPPs that are acutely toxic.

Therefore, in developing the Guidance Document, the PPR Panel has proposed a number of changes to current practice. It is suggested that routine risk assessment for individual PPPs should continue to use deterministic methods, and that a tiered approach to exposure assessment remains appropriate. However, there are strong arguments for introducing an additional acute risk assessment for operators, workers and bystanders, where PPPs are acutely toxic. This will require the specification of a separate toxicological reference value, an "acute AOEL" ("AAOEL"), analogous to the Acute Reference Dose that is used in dietary risk assessment for acutely toxic PPPs. For acute risk assessments, exposure estimates should normally be based on 95th centiles of relevant data sets, whereas for longer term risk assessments, the starting point should be a 75th centile.

Furthermore, to allow for the statistical uncertainty in centiles of small datasets, it is proposed that as a default, the exposure value used for risk assessment should be the higher of: a) the appropriate centile in the relevant dataset; and b) a parametric estimate of the corresponding centile in the theoretical population of measurements from which the dataset was derived, under that the assumption that the overall distribution of measurements is log-normal. However, where there is convincing evidence that this assumption of log-normality is unreasonable, it should be open to the regulator to adopt an alternative approach on a case-by-case basis.

Applying the recommended approach, proposals are set out for standardised estimation of exposures in first tier risk assessments for each of the exposure scenarios most commonly encountered in regulatory practice. An element of risk management is implicit in any scheme of this sort. In framing its proposals, the PPR Panel has aimed for a level of precaution similar to or slightly greater than that currently applied. However, it is open to risk managers in the European Commission to modify the level of precaution if they wish (e.g. by changing the centiles on which exposure estimates are based).

The opinion also identifies those scenarios for which exposure estimates are least satisfactory, and makes recommendations for further research that would reduce current uncertainties.

Finally, in an appendix, the Panel has set out a draft format for a Guidance Document. It is suggested that once the final form of this Guidance Document has been agreed by risk managers, a paper should be produced showing how each parameter in the Guidance Document was derived, and a spreadsheet should be developed to facilitate the calculations that it requires.

KEY WORDS

Exposure, operator, worker, bystander, resident, estimation, guidance

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BACKGROUND

The production and revision of Guidance Documents to assist the implementation of Council Directive 91/414/EEC was originally the responsibility of the European Commission, but this remit has now been transferred to EFSA. In 2006, EFSA's PPR Unit consulted Member States on their priorities for development and for the revision of such Guidance Documents; in response, several Member States expressed a wish for a Guidance Document on pesticide exposure assessment for workers, operators, bystanders and residents.

Currently, there is no harmonised approach to pesticide exposure assessment for operators, workers, bystanders and residents. For the evaluation of active substances and plant protection products under Council Directive 91/414/EEC, models developed in the UK (UKPOEM) or Germany are normally used to assess the potential exposures of operators, but these models give somewhat different estimates for the same scenario. Worker exposures may be estimated using the EUROPOEM II model, or models developed in Germany or California. No well-standardised methods are available to assess the exposures of bystanders and residents, and different Member States follow different approaches.

When embarking on the development of this Guidance Document, the PPR Panel was aware of several recent activities that should be taken into account:

•In 2003, an international workshop took place in Brussels to assess the scope for probabilistic operator exposure assessment, from which a summary report was published by the organiser (ILSI-USA).

•The US agrochemical industry was developing a new "Agricultural Handlers Exposure Database" (AHED) from a large series of recently conducted operator exposure studies. In addition, a large series of re-entry worker exposure studies was being abstracted

•The European Crop Protection Association (ECPA) had carried out a series of operator and worker exposure studies in the recent past and these were to be included in a European version of AHED.

•The Seed Treatment Exposure Taskforce (SeedTropex) had carried out a series of seed treatment exposure studies to expand the range and depth of the scenarios included in their dataset.

In addition, other sources of relevant information needed to be systematically identified and evaluated. As a starting point, therefore, the collation and evaluation of relevant data and background information was outsourced. A Final Report of this outsourced project (CFP/EFSA/PPR/2007/01) was issued in October 2008. The Guidance Document was planned for adoption by the spring of 2010, 18 months after the Final Report by the beneficiary of the grant under Article 36 of Regulation (EC) No. 178/2002.

TERMS OF REFERENCE

The PPR Panel was asked to prepare a Guidance Document on pesticide exposure assessment for workers, operators, bystanders and residents for use in regulatory risk assessment of plant protection products.

ASSESSMENT

1. Introduction

As described above, the starting point for this opinion was an outsourced project carried out jointly by the UK Pesticides Safety Directorate (PSD) (now renamed the Chemicals Regulation Directorate (CRD)) and the University of Ghent (UG). The PSD/UG review indicated that relevant new data could be expected from several sources over the next five years. However, it was uncertain exactly when this new material would be available and, given the shortcomings of current approaches to exposure assessment (see Section 6 below), the PPR Panel concluded that it would be worth developing a Guidance Document for immediate use. If necessary, this could then be revised, as and when new data emerged.

The PPR Panel also took the view that its opinion would be most useful if it proposed draft text for the Guidance Document. Moreover, if the guidance was to be easy for risk assessors to follow and simple to apply, it would need to incorporate judgements on risk management (e.g. on the required level of confidence that the potential* exposures assumed in the risk assessment would not in practice be exceeded). In drafting the guidance, the Panel aimed for a level of precaution similar to, or somewhat higher than, that which is currently applied in risk assessment for operators, workers, residents and bystanders. However, it would be straightforward for risk managers in the European Commission to change the level of precaution if they wished, without major restructuring of the text.

It was also agreed that the opinion, including the draft Guidance Document, should be made available for external comment before it was finalised. This external consultation was conducted in August 2009. In response to the comments received, various clarifications and amendments were made.

The opinion starts by defining the scope of the Guidance Document (Section 2). It then reviews the legal requirements that underpin the relevant components of risk assessment for plant protection products (Section 3), describes the methods of risk assessment that are currently used (Section 4), and considers their adequacy and limitations (Sections 5 and 6). Next it proposes a revised approach to exposure and risk assessment for operators, workers, residents and bystanders, and gives the underlying rationale (Section 7). Most notable among the recommended changes is the introduction of an additional acute risk assessment for plant protection products (PPPs) that have significant potential to cause toxicity through exposures that might occur in a single day. Section 8 then builds on the PSD/UG review, setting out proposals for standard models and data sets that should be used as a default when estimating exposures for different scenarios, and giving reasons for choices where more than one option is available. Section 9 provides a link to the draft Guidance Document, which is set out in Appendix 1. Finally, there is a brief summary of conclusions and recommendations.

2. Scope

The Guidance Document that is the focus of this opinion is intended for use in relation to chemical PPPs, both to determine their eligibility for inclusion in Annex 1 of Council Directive 91/414/EEC[5], and also to underpin the authorisation of products by individual Members States. It does not apply to biocides, which are the subject of separate guidance (European Commission, 1998), or to biological pesticides.

* The word "potential" is used here in a non-technical sense. Throughout this opinion, "potential exposure" simply means exposure which could occur. "Potential dermal exposure (PDE)" has a specific technical meaning that is defined in the glossary.

[5] During the preparation of this opinion, a new Regulation (1107/2009) replacing Directive 91/414 was adopted by the European Parliament, and will come into force in June 2011.

Council Directive 91/414/EEC does not clearly define the three groups (operators, workers and bystanders) for which non-dietary exposure assessments are currently required. The new regulations that are proposed to update Council Directive 91/414/EEC refer also to a fourth non-dietary exposure group (residents), but again, definitions have not yet been formally agreed. For the purpose of this opinion, we have adopted the following definitions.

Operators are: persons who are involved in activities relating to the application of a plant protection product (PPP); such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the plant protection product, and emptying/cleaning the machinery/containers after use. Operators may be either professionals (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users).

Workers are: persons who, as part of their employment, enter an area that has previously been treated with a PPP or who handle a crop that has been treated with a PPP.

Bystanders are: persons who are located within or directly adjacent to the area where PPP application or treatment is in process or has recently been completed; whose presence is quite incidental and unrelated to work involving PPPs, but whose position might lead them to be exposed; and who take no action to avoid or control exposure.

Residents are: persons who live, work or attend school or any another institution adjacent to an area that is or has been treated with a PPP; whose presence is quite incidental and unrelated to work involving PPPs but whose position might lead them to be exposed; who take no action to avoid or control exposure; and who might be in the location for 24 hours per day.

These definitions are compatible with the proposed text for the replacement for Annex III of Directive 91/414/EEC, and with the draft Guidance Document on AOELs that is currently in use (European Commission, 2006).

In addition to the four categories of non-dietary exposure that are defined above, exposure to PPPs can occur through para-occupational routes. For example, members of an operator's family might be exposed to deposits on his clothes or skin when he comes home from work. Such exposures are not directly addressed in the current regulatory risk assessment for PPPs, and are not considered further in this opinion.

The main focus of the opinion is risk assessment for systemic toxicity, and it does not cover all the aspects of exposure that could be relevant to localised toxicity such as respiratory irritation. Nor does it provide guidance on the quantification of dermal absorption, which is currently the subject of a separate opinion that is being developed by the PPR Panel.

3. Legal requirements

Directive 91/414/EEC states that the residues of plant protection products applied in accordance with good plant protection practice must not have "any harmful effects on human or animal health". This has been taken to refer to toxic effects on health, and not to adverse effects from perceived exposure to plant protection products that occur through non-toxic, psychological mechanisms.

It is important to appreciate that there can never be an absolute guarantee of safety in toxicological risk assessment. The aim, therefore, in the case of PPPs must be for "adequate" reassurance of safety. What constitutes adequate reassurance is ultimately a decision for risk managers. As described in Section 1, in framing our proposals in this opinion, we have tried to maintain a level of precaution similar to, or somewhat greater than, that which is currently applied. However, it is open to risk managers to alter the level of precaution if they wish.

4. Current approach

Currently, risk assessment for operators, workers, bystanders and residents (in those countries where a separate risk assessment is carried out for residents) uses a deterministic method, in which a check is made that reasonable upper estimates for daily systemic exposure are below relevant toxicological reference values.

The reference value employed for all four categories of exposed person is the Acceptable Operator Exposure Level (AOEL). This is intended to define a level of daily exposure throughout a spraying season, year on year, below which no adverse systemic health effects would be expected. The AOEL is normally derived by applying an assessment factor (most often 100) to a No Observed Adverse Effect Level (NOAEL) (corrected if appropriate for incomplete absorption) from a toxicological study in which animals were dosed daily for 90 days or longer. Less often, the critical NOAEL comes from a study with a shorter dosing period (e.g. a developmental study).

The assessment of potential exposure is usually through application of a "model" that is deemed appropriate to the exposure scenario under consideration. Exposure models are based on empirical measurements of exposure, and are normalised to the amount of active substance applied, or to a suitable proxy (e.g. the amount of time an individual spends spraying). Typically, they do not adjust for many of the factors that might modify exposure levels in a given scenario (e.g. use of closed transfer systems for loading, the type of nozzle used for spraying), but instead, make conservative assumptions about these variables. Thus, they are expected, if anything, to overestimate the exposures that occur in practice. Where the conditions of approval for a pesticide include a requirement that operators or workers use specific personal protective equipment (PPE), and provided effective PPE is "readily obtainable" and its use is feasible, an appropriate offset is made to the estimated exposures of these groups. However, no allowance is made for use of PPE by non-professional operators, since they cannot necessarily be expected to use PPE effectively.

Where no satisfactory model is available for an exposure scenario, or the initial risk assessment using a conservative model gives inadequate reassurance of safety, the notifier may generate "higher tier" exposure estimates through an ad hoc study specific to the circumstances in which the pesticide will be used.

Where one of the routes of potential exposure is via the skin, as is normally the case, estimates of systemic exposure also take into account the rate of dermal absorption that can be expected when the pesticide (either as sold or after subsequent dilution) is deposited on the skin. As indicated in Section 2, guidance on dermal absorption is the subject of a separate PPR opinion.

5. Adequacy of current methods of risk assessment

As part of their review, PSD/UG compared measurements of operator and worker exposure from the peer-reviewed scientific literature with exposures for the same scenarios estimated by models that are currently used in risk assessment for plant protection products. While individual measured exposures were generally lower than those predicted by the models, this was not a universal finding. This indicates that the exposure models are not always conservative, perhaps because in practice, some operators do not adhere strictly to the prescribed precautions when they work with PPPs.

Another guide to the validity of current methods of exposure assessment comes from biomonitoring studies in operators and farm families. Interpretation of biomonitoring data is complicated because the concentration of a pesticide or its metabolite that is found in a body fluid is determined by the timing as well as the level of exposure. Nevertheless, interim findings from a review being carried out by the CRD in the UK indicate that current EU models predict higher operator exposures than those determined by biomonitoring (Byron et al., 2009). In another recent evaluation, agreement was found for a number of operator and re-entry scenarios between absorbed doses estimated by biomonitoring

and from passive dosimetry of the type that underpins currently used exposure models (Ross et al., 2008).

Ultimately, the best indicator of the effectiveness of current approaches to risk assessment for operators, workers, bystanders and residents is the frequency with which use of PPPs is associated with toxic effects. Data from the UK indicate that among operators, acute pesticide poisoning of sufficient severity to warrant hospital admission is extremely rare and usually attributable to an identifiable mishap, and that in workers, bystanders and residents, it is even less common (Leverton et al., 2007). Nor is there clear evidence of any longer term adverse health effects when PPPs are used in accordance with current conditions of approval. However, because of limitations in scientific methodology, it is not possible to confidently exclude a low frequency of chronic toxic effects or minor acute toxic effects.

In summary, therefore, available data do not indicate any major flaws in the current methods of risk assessment for operators, workers, bystanders and residents. While potential exposures may sometimes be underestimated by existing models, this does not appear to give rise to overt acute poisoning, perhaps because of compensatory conservatism in the toxicological reference values against which exposures are compared. The occurrence of longer term adverse health effects cannot be ruled out, but no such effects have been clearly demonstrated from PPPs as currently approved for use in the EU. Nevertheless, as described in the next Section, the current method of risk assessment is not completely satisfactory.

6. Problems with the current approach to risk assessment

There are several problems with the current method of risk assessment for operators, workers, bystanders and residents.

6.1. Limited data on exposures

For some exposure scenarios, especially for workers, bystanders and residents, but in some cases also for operators, the empirical data from which to estimate exposures are relatively limited. This shortcoming is addressed by the adoption of various conservative assumptions in the assessment of potential exposures, so that errors will tend to be on the side of safety. However, it would be preferable if more extensive data were available, from which to model and estimate exposures. A further limitation is that data sometimes come from trials conducted under unrepresentative conditions (e.g. where operators are all highly trained and using new personal protective equipment that is at its most efficient).

6.2. Inconsistency of methods

For some scenarios, more than one model is available with which to estimate exposures, and where this occurs, exposure estimates sometimes differ materially (i.e. such that one model indicates that potential exposure is below the relevant reference value while another does not). The discrepancies arise from:

- Differences in the structures of the models (for example, one approach may assume a single rate of penetration through clothing while another assumes different rates according to the level of contamination, or there may be differences in the area of crop that is assumed to be treated by a PPP in a single day)

- Differences in the empirical data underpinning the models (one model may be based on a different selection of measurements from another)

- The use of different cut-points within the underpinning empirical data to define what should be considered a reasonable upper estimate of daily exposure

The choice between alternative approaches is not currently standardised, and as a consequence, there is a lack of clarity and an inconsistency of decisions in risk management.

6.3. Variability within and between subjects

A particular challenge in exposure estimation is the wide variability (often over several orders of magnitude), between individual measurements of exposure associated with the same exposure scenario. Many factors are likely to contribute to this variability including, for example, differences in the packaging of the PPP (e.g. whether or not it is in a wide-necked container), the equipment used for its mixing, loading and application, the exact methods used by the operator, whether any unusual complications occur during application (e.g. the need to unblock a nozzle), and the meteorological conditions at the time of application. In addition, differences in experimental method and measurement techniques (e.g. use of dosimeter patches versus whole body dosimeters) may lead to systematic differences between studies in reported exposures for the same scenario. Where large data sets are available for the same scenario, the distribution of measured exposures often approximates to log-normal (Fenske and Day, 2004).

Few studies of pesticide application have entailed repeated measurements of exposure in the same subjects for the same scenario, but evidence from occupational exposure to other chemicals indicates that while there is often marked within-subject variability, there can also be systematic differences between workers, some having higher average exposures than others (Kromhout et al., 1993). It would be prudent to assume that the same applies in relation to pesticide application.

One implication of the substantial variability of pesticide exposures for a given scenario is that the 50th or 75th centile from a set of measured exposures might importantly underestimate some individual exposures on a single day. Where the critical determinant of toxic risk is average exposure over a longer period, this will not matter so much, especially if the 75th centile is used to allow for the possibility that some individuals tend to have consistently higher exposures than others (as was recommended in the first EUROPOEM report (EUROPOEM, 1996). However, the underestimation of exposure could be more important where toxic effects could result from acute exposure on a single day.

A second implication of the variability between exposures is that estimates of exposure from small data sets may be liable to major statistical uncertainty. This applies both to data underpinning models used in first tier assessments, and also to ad hoc data generated by notifiers for higher tier assessments.

6.4. Deterministic versus probabilistic risk assessment

Another limitation of the current method of risk assessment for operators, workers, bystanders and residents is that the deterministic approach, while having the merit of simplicity, does not always lend itself well to aggregate or cumulative risk assessments, in which account is taken of exposure to the same PPP through multiple pathways (e.g. as an operator and also in the diet) or to multiple PPPs. Such risk assessments are often better undertaken using probabilistic methods (EFSA, 2008).

7. Development of new guidance

In view of the problems outlined in the previous Section, there is a clear case for the development of refined guidance on exposure assessment for operators, workers, bystanders and residents. As the PSD/UG review identified, important new data on exposures should emerge from various projects that are currently ongoing. However, many of these new data are not expected to become available for some years, and in the mean time, it should be possible to standardise exposure assessments better

than at present, and at the same time to address at least some of the shortcomings that have been highlighted in current methodology. The guidance can subsequently be reviewed, and if appropriate revised, as and when new data become available.

Having considered the PSD/UG review, the PPR Panel believes that because of the limitations of data currently available, it would be better to persist with deterministic methods in routine risk assessment for individual PPPs, and that a tiered approach to exposure assessment remains appropriate. However, there is a strong argument that the method of risk assessment should be refined for pesticides that are acutely toxic.

7.1. Acute and longer term risk assessment for operators, workers, residents and bystanders

As described in Section 6.3, where toxicity could arise from acute exposure (over a single day) to a PPP, this has important implications for the method of risk assessment. Because exposures can vary substantially for a given scenario, it is necessary to take a high centile from a distribution of measured exposures in order to be confident that individual exposures on a given day will not be importantly underestimated. This concern does not apply to PPPs that do not have significant acute toxicity, since risk in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days.

We therefore propose that, as for dietary exposures, separate risk assessments should be carried out for operators, workers and bystanders where pesticides are acutely toxic (including those that might cause developmental toxicity through a single short exposure at a critical stage in development). As for dietary risk assessment, this will require the specification of a separate toxicological reference value, an "acute AOEL[*]" ("AAOEL"), derived from a relevant study or studies. In most cases, we would expect these to be the same studies that would be used to set an acute reference dose (ARfD) for the PPP under consideration (if necessary, with adjustment for incomplete absorption), although for PPPs that are not used on edible crops, suitable studies would need to be identified from first principles. This could normally be done from studies already conducted for the purposes of regulatory risk assessment, and should not require any additional use of experimental animals. Guidance on the derivation of ARfDs can be found in a paper by Solecki and colleagues (Solecki et al., 2005).

The AAOEL should be used as a reference for realistic upper estimates of exposure in a single day for operators, workers and bystanders, these estimates being derived as described in Section 7.2.1. The exposure assessment for bystanders should be such that it covers the maximum exposure that a resident could reasonably be expected to incur in a single day. Thus, any risk to residents from acute high exposures (i.e. within a single day) would be covered by the acute risk assessment for bystanders, and there would be no need for a separate acute risk assessment for residents.

Longer term exposures of operators, workers and residents should be assessed against standard AOELs as at present. Any longer term exposure of bystanders should be covered by the risk assessment for residents, and so there is no need for a separate longer term risk assessment for bystanders.

The revised scheme of risk assessments that we propose is summarised in Table 1.

[*] We have adopted the term "acute AOEL" here to be consistent with the terminology that is already in use in the assessment of risks from non-dietary exposures to PPPs. However, we recognise that the usage is unsatisfactory insofar as the reference value is applied to exposure groups other than just operators. We suggest that if our proposal is adopted, the nomenclature should be considered as part of a broader review of terminology in risk assessment, which is currently being undertaken by a Working Group of the EFSA Scientific Committee.

Table 1: Proposed scheme of risk assessment for operators, workers, bystanders and residents

Exposure group	Risk assessments that may be required[(a)]	
	PPPs with no significant potential for toxicity from exposure in a single day	**PPPs with significant potential for toxicity from exposure in a single day**
Operators	L	A L
Workers	L	A L
Residents	L	L
Bystanders		A

(a): A = acute, L = longer term

7.2. Methods of exposure assessment

Guiding principles

First tier exposure assessments should use standardised methods. Where available, a single, relevant, standard dataset of adequate quality should be identified for each exposure scenario. This should then be used to derive the exposure values that will be applied in the risk assessment. Where more than one possible dataset is available for a scenario, the choice of the standard dataset should be determined by the extent and quality of the alternative datasets. Where a first tier risk assessment gives inadequate reassurance of safety, or there is no suitable standard dataset for the exposure scenario, an ad hoc study may be used to generate higher tier exposure data.

Whether they are derived from a standard dataset or from an ad hoc study, exposure parameters should be normalised to the quantity of PPP applied or handled, and should be based on relevant centiles of the distribution of measured exposures. Normalisation to the quantity of PPP allows for the occurrence of higher exposures when larger quantities of a product are applied or handled. In practice, exposures tend to be rather less than directly proportional to the amount of PPP applied or handled, and normalisation therefore produces a more conservative risk assessment when larger quantities of PPP are being used.

Allowance for statistical variability in measurements

As described in Section 6.3, estimates of exposure derived from empirical data sets are subject to statistical uncertainty. By chance, this could lead to substantial underestimation of potential exposures, especially where the relevant centile from the exposure distribution is a high one, and the underpinning sample of exposure measurements is small. To address this statistical problem, we propose that, in addition to the relevant centile of the empirical data set, an estimate should be made of the corresponding centile in the theoretical population from which this sample of measurements was derived. This should be done with the assumption that the population has a log-normal distribution, using the formula:

$$\exp\left[\overline{x} + t_{n-1,a} * S * \sqrt{\left(1 + 1/n\right)}\right]$$

where $\overline{x}$ is the mean of the natural logarithms of the sample measurements, S is the standard deviation of the logarithms of the sample measurements, t_{n-1} is a t statistic with n-1 degrees of freedom (n being the number of measurements in the sample), and a is the relevant centile.

As a default, the exposure estimate for comparison with the relevant toxicological reference value would then be taken as the higher of the sample centile and this parametric estimate of the corresponding population centile. Where a notifier wished to argue that the assumption of a log-normal distribution was inappropriate, it would be open for them to do so by providing appropriate evidence. If the argument were accepted, the regulator could adopt an alternative approach on a case-by-case basis. This is similar to an approach followed by the Californian Department of Pesticide Regulation (Californian Department of Pesticide Regulation, 2001 and 2009),

To illustrate the way in which this method would work, Table 2 shows sample centiles and corresponding parametric population estimates for a selection of empirical data sets that were identified in the PSD/UG report.

Table 2: Sample centiles and corresponding parametric population estimates for a selection of data sets identified in the PSD/UG report

Exposure scenario	Number of studies	Number of exposure measure-ments	Statistical significance of deviation from log-normal distribution	75th centile exposure (mg/kg a.s. handled)		95th centile exposure (mg/kg a.s. handled)	
				Sample	Parametric estimate	Sample	Parametric estimate
Potential dermal exposure during ground boom application (EUROPOEM dataset)	19	104	>0.05	0.757	0.917	3.841	4.707
Dermal exposure (a) during ground boom application [German model dataset]	6	19	>0.05	5.955	6.826	18.97	62.206
Hand exposure during mix/loading hand held equipment [German model dataset]	3	30	>0.05	430.5	498.7	2114	1866
Head exposure during ground boom application [German model dataset]	6	19	≤0.05	0.4225	0.397	1.092	6.611

(a): Assuming T-shirt, shorts and shoes worn

In the first three scenarios, the sample of exposure measurements shows no statistically significant deviation from a log-normal distribution. Thus, for a given centile, the estimated exposure would be taken as the higher of the sample centile and the corresponding parametric estimate. In most cases, the parametric estimate is slightly higher than the sample measurement, although for the 95th centile in the second scenario, the difference is more marked (the parametric estimate is more than three times higher). The second scenario is based on relatively few measurements, and therefore the sample centiles are more liable to be unrepresentative by chance. Use of the higher parametric estimate would help to compensate for the resultant uncertainty.

In the fourth scenario, the distribution of sample measurements deviates significantly from log-normality. Here, the risk assessor would need to explore the distribution of sample measurements in more detail before deciding how to proceed. If parametric estimates assuming log-normality were less than or little higher than the corresponding sample centiles, then it might be appropriate to apply the standard default method. However, if a parametrically estimated centile were substantially higher than the corresponding sample centile, then an alternative approach could be adopted. For example, in deriving a 95th centile exposure value, one might use the parametrically estimated 95th centile if it was less than the maximum measured exposure in the dataset, but otherwise substitute the maximum measured value.

Acute exposure assessment

For acute exposure assessments, whether standard or generated ad hoc, we propose that a realistic upper estimate of exposure should normally be taken as the higher of: a) the 95th centile of the distribution of measurements in the relevant empirical data set; and b) a statistical estimate of the 95th centile for the theoretical population of measurements from which the empirical data set was derived, under the assumption that this population has a log-normal distribution. In deriving overall estimates of potential systemic exposure, it is necessary to sum components from each of several routes and/or circumstances of exposure (e.g. for an operator these would include inhalation exposure during mixing and loading, hand exposure during mixing, inhalation exposure during application, hand exposure during application, and body exposure during application). Taking each of these components as a 95th centile value, together with the likelihood that some of the underlying data relate to use under conditions outside current good practice, and of other conservative elements in the assessment (e.g. assuming exposure is linearly related to amount handled and the default values used for protection by clothing) (see Section 8.6), makes it less likely that the overall exposure estimate would in practice be exceeded. Thus, when used in conjunction with an AAOEL incorporating an appropriate uncertainty factor, the method should provide good reassurance of safety (overall, the risk assessment will at least be as precautionary as at present, since currently no acute risk assessment is carried out for operators, workers or bystanders). Furthermore, exposures measured in biomonitoring studies are generally below predicted levels and data from the UK indicate that among operators, acute pesticide poisoning of sufficient severity to warrant hospital admission is extremely rare and usually attributable to an identifiable mishap (Leverton et al., 2007). However, if risk managers in the European Commission wished to achieve a different level of precaution, an alternative centile could be used.

Longer term exposure assessment

For longer term risk assessments, whether standard or ad hoc, the realistic upper estimate of daily exposure over the course of a spraying season should normally be taken as the higher of: a) the 75th centile of the distribution of measurements in the relevant empirical data set; and b) a statistical estimate of the 75th centile for the theoretical population of measurements from which the empirical data set was derived, under the assumption that this population has a log-normal distribution. It can be expected, with this approach, that some people will have consistently higher exposures than others, and therefore, a long-term average exposure above the population mean or median. As explained above, the daily exposure estimates are considered to be conservative. The longer term assessment incorporates a number of additional conservative elements: it assumes that each day over a prolonged period, an operator applies the same pesticide, a worker handles or enters crops that have been treated with the same pesticide and a resident is exposed to nearby application of the same pesticide. Furthermore, estimates of dermal uptake may be conservative (Kissel and Fenske, 2000; Doran et al., 2003). Overall, it is expected that using the 75th centile provides a realistic upper estimate that will very rarely, if ever, be exceeded.

8. Proposed methods and standard data sets

This section proposes methods for estimating potential exposures in first tier risk assessments. It identifies the most appropriate standard dataset for each of the commonly encountered exposure scenarios, and where the distribution of measurements in a dataset deviates significantly from log-normal, it specifies how critical values (75th and 95th centile exposures) should be derived from the dataset. For most scenarios, only one suitable dataset could be found, but where there was more than one, the rationale for the choice is presented.

For some scenarios (e.g. worker re-entry to treated crops), directly measured exposure data are limited, but exposures can reasonably be estimated by combining data on the various determinants of exposure in a mathematical model. In these cases, the proposed model is described.

Where data on which to base exposure assessment are limited, this is highlighted as a priority for further research (see Conclusions and Recommendations).

In the case of operators and workers, the first requirement is to estimate exposure without any use of personal protective equipment (PPE). This demands an assumption about the clothing that operators or workers will wear when not using PPE. The Panel did not have information on operator and worker practices across Member States. In the absence of such information, and with the understanding that training and practices do vary, we propose that a first tier assessment of exposure should assume a poor standard of occupational hygiene, with an unprotected individual wearing shorts and a T-shirt and no PPE. However, where risk managers were confident that normal work wear would comprise trousers and a long sleeved shirt, this could be adopted as alternative assumption.

8.1. Operators

As a first tier, potential exposure of operators should be assessed using the datasets listed in Tables 3 and 4. Unless otherwise stated, exposures should be taken as the higher of the relevant centile in the dataset and a parametric estimate of the same centile in the population from which the sample of measurements was derived (see Section 7.2.2).

As highlighted in Tables 3 and 4, in a few of the datasets, the distribution of measurements deviates significantly ($p<0.05$) from log-normality. In none of these datasets was the parametric estimate of the 75th centile more than 30% greater than the sample 75th centile. Therefore, we propose that 75th centile exposures should nevertheless be derived by the default method. For the same datasets, all but one of the parametrically estimated 95th centiles were greater than the corresponding sample 95th centiles, and some exceeded the maximum measurement in the dataset. We propose that for the datasets that deviate from log-normality, 95th centile exposures be taken as the 95th centile of the underpinning dataset if higher than the parametrically estimated 95th centile, and otherwise as the lower of the parametrically estimated 95th centile and the maximum measurement in the underpinning dataset. The Tables indicate how this rule applies in each case.

For some scenarios, the most accessible source of information on potential exposures is a technical guidance document for biocides from 2002. This guidance does not provide full detail of the sample data from which exposures are characterised. As an interim approach, we propose that where they are available, relevant centile values should be taken as published in the biocides guidance. However, if no 95th centile is given in the guidance, the maximum value in the underpinning sample of measurements should be used as a proxy. Tables 3 and 4 indicate where this applies. In June 2007, a revision of the 2002 technical guidance document was endorsed by the Competent Authorities, and the data are now presented in two software programs (BEAT and CONSEXPO) rather than in the document. Data from these programs are not immediately available to the Panel. However, once the form of the guidance document is accepted, we propose that these databases should be used to derive the relevant centiles for the biocide datasets identified in Tables 3 and 4.

One other exception to the general rule for deriving centile values is the dermal exposure of the feet in certain application scenarios, where only 75th centiles are available. Exposures via the feet are smaller than by other routes, and in this particular circumstance, it is proposed that in the absence of further information, the 75th centile may be used as a proxy for the 95th centile in acute risk assessments. Component exposures for each relevant activity and route of exposure should be summed to give an overall estimate of potential exposure.

We recognise that for some scenarios that have been studied less extensively, and for which fewer data are available, the proposed exposure values are likely to be highly conservative. Nevertheless, we think that they can reasonably be used as first-tier estimates.

Table 3: Choices of standard models and underpinning data sets for first tier estimation of exposures in operators when mixing and loading

Scenario		Formulation	Sources of data	
			Dermal exposure	Inhalation exposure
		SOLIDS		
1 a (i)	Large scale (e.g. tractor-mounted) equipment	WP, SP	German model (PDE) [German model has most robust dataset]	PHED [PHED has larger and more robust data set than EUROPOEM and German model]
(ii)		GR, FG	PHED (ADE) [PHED has larger and more robust data set than EUROPOEM] [Data for exposure to body not log-normal, use parametric estimate for 95th centile]	PHED [PHED has larger and more robust data set than EUROPOEM] [Data not log-normal, use parametric estimate for 95th centile]
(iii)		WG, SG	German model (PDE) [Data sets from German model and EUROPOEM are of similar size and quality, but German model is more protective]	EUROPOEM [EUROPOEM dataset is larger and more robust than German model] [Data not log-normal, use parametric estimate for 95th centile]
1 b (i)	Medium scale (e.g. professional hand-held) equipment	WP, SP	Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002, Spraying Model 1 (based on HSE surveys 1992-3, IOM study on PPE, 1996) *NB This dataset gives exposures for the combination of mixing and loading with application by compression sprayers or dusting applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards. However, it provides a conservative estimate of exposure during mixing/loading that can be combined with a separate estimate of exposure during application.*	German model [More extensive and robust data set than EUROPOEM and PHED]
(ii)		GR, FG	PHED (ADE) [PHED has larger and more robust data set than EUROPOEM] [Data for hand and body exposure are not log-normal, use sample maximum for 95th centile in each case]	PHED [PHED has larger and more robust data set than EUROPOEM] [Data not log-normal, use parametric estimate for 95th centile]
(iii)		WG, SG	German model (PDE) [German model has larger and more robust data set than EUROPOEM]	German model [German model has slightly larger dataset than EUROPOEM and is more protective] [Data not log-normal, use sample maximum for 95th centile]

Scenario		Formulation	Sources of data	
			Dermal exposure	Inhalation exposure
1 c (i)	Small scale (e.g. home garden) equipment	WP, SP	For exposure to hands use Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held dusting applicator pack for crack and crevice [Biocides Guidance does not allow derivation of 95th centile, so use maximum value as a proxy] [Exposures to legs, feet and face can be ignored]	Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held dusting applicator pack for crack and crevice
(ii)		GR, FG	For exposure to hands, use surrogate data from Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held dusting applicator pack for crack and crevice [No directly relevant data are available] [Exposures to legs, feet and face can be ignored]	Use surrogate data from Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held dusting applicator pack for crack and crevice [No directly relevant data are available.]
(iii)		WG, SG	For exposure to hands use surrogate data from: Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held dusting applicator pack for crack and crevice [No directly relevant data are available] [Exposures to legs, feet and face can be ignored]	Use surrogate data from: Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held dusting applicator pack for crack and crevice [No directly relevant data are available]

Scenario		Formulation	Sources of data
		LIQUIDS	**Dermal exposure** **(For mixing and loading liquid formulations, there is no need to consider inhalation exposure because it is much lower than dermal exposure)**
2 a	Large scale (e.g. Tractor mounted) equipment	SC, EC etc.	EUROPOEM [Large and robust dataset. Data set for German model is smaller. UK model does not provide data normalised to amount of active substance] [Data not log-normal, use parametric estimate for 95th centile]
b	Medium scale (e.g. Professional hand-held) equipment		German model [German model has larger dataset and is more protective]
c	Small scale (e.g. home garden) equipment		UK POEM – taking into account whether cap is used for measurement or another measuring device [Only suitable data set] [Data not log-normal for use of another measuring device rather than cap, use parametric estimate of 95th centile]

WP	=	Wettable powder	SP	=	Soluble powder
GR	=	Granules	FG	=	Fine granules
WG	=	Wettable granules	SG	=	Soluble granules
SC	=	Soluble concentrate	EC	=	Emulsifiable concentrate
PDE	=	Potential dermal exposure	ADE	=	Actual dermal exposure

N.B. For PPPs packaged in water-soluble bags, exposure during mixing and loading is considered negligible.

A comprehensive list of exposure models is given in the report (EFSA, 2008b). The racionale for selecting the most suitable one per scenario is given in Table 3. The underlying datasets for each scenario will be presented in a separate report after the proposed format of Guidance Document is accepted.

Table 4: Choices of standard models and underpinning data sets for first tier estimation of exposures in operators during application

Scenario			Source of exposure data **(It is proposed that for each application scenario, the same source of data would be used for dermal and inhalation exposure)**
1 a. Outdoor spray/spreading/placement applications, downward spraying			
i	Tractor-mounted equipment	Boom sprayers	EUROPOEM Use Ground Boom subset as defined in EUROPOEM II report Table 12.1 [Most comprehensive and representative data set]
ii	Manual equipment	1. Knapsack sprayers	EUROPOEM Use Hand Held Low Level Target subset as defined in EUROPOEM II report Table 14.1 [No suitable alternative data set is available] [Data for dermal exposure of hands not log-normal, use sample maximum for 95th centile; data for inhalation exposure not log-normal, use parametric estimate for 95th centile]
		2. Controlled droplet application/Rotary disc ULV sprayers – spot treatment	Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Fogging and misting, Misting Model 1 (Based on HSE Survey 1999) Misting at low level using CDA wand (CDA low level sprayer). No mixing or loading. [Most relevant dataset] [For 95th centiles use sample maxima from Biocides Guidance where available; for dermal exposure of feet use 75th centile]
		3. Trigger sprayers	Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held trigger spray [Most relevant dataset] [For 95th centiles use sample maxima from Biocides Guidance]

Scenario			Source of exposure data **(It is proposed that for each application scenario, the same source of data would be used for dermal and inhalation exposure)**
		4.Pre-pressurised aerosol spray can	Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Pre-pressurised aerosol spray can [Most relevant dataset] [For 95th centiles use sample maxima from Biocides Guidance]
1 b. Outdoor spray/spreading/placement applications, upward spraying			
i	Tractor-mounted equipment		EUROPOEM Use Broadcast Air-Assisted subset as defined in EUROPOEM II report Table 13.1 [EUROPOEM based on larger data set than German model] [Data for dermal exposure of hands not log-normal, use sample maximum for 95th centile; data for inhalation exposure not log-normal, use parametric estimate for 95th centile]
ii	Manual equipment	1. Knapsack sprayers (including motorised knapsack mistblowers)	EUROPOEM Use Hand Held High Targets subset as defined in EUROPOEM II report Table 14.5 [Highest quality and most representative European dataset] [Data for dermal exposure of body not log-normal, use parametric estimate for 95th centile]
		3. Hand-held lances	EUROPOEM Use Hand Held High Targets subset as defined in EUROPOEM II report Table 14.5 [No suitable alternative dataset available] [Data for dermal exposure of body not log-normal, use parametric estimate for 95th centile]
1 c. Outdoor spray/spreading/placement applications, application of granules			
i	Tractor-mounted equipment		PHED (ADE) [PHED has larger and more robust data set than EUROPOEM] [Data for dermal exposure of hands not log-normal, use parametric estimate for 95th centile; data for inhalation exposure not log-normal, use sample 95th centile]

Scenario			Source of exposure data **(It is proposed that for each application scenario, the same source of data would be used for dermal and inhalation exposure)**
ii	Manual equipment	Medium scale	PHED (ADE) *NB These data are for the combination of loading and application. For this application scenario, there is no need to assess exposures during mixing separately.* [No suitable alternative dataset] [Data for dermal exposure of hands not log-normal, use sample maximum for 95th centile; data for dermal exposure of body not log-normal, use sample maximum for 95th centile; data for inhalation exposure not log-normal, use parametric estimate for 95th centile]
		Small scale (e.g. home garden)	Use surrogate data for powders from Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (HSL 2001) Hand-held dusting applicator pack for crack and crevice [Conservative alternative in the absence of any directly relevant data] [For 95th centiles use sample maxima from Biocides Guidance]
1 d. Outdoor spray/spreading/placement applications, stem and stump treatments			
i	Manual equipment	1. Stump treatment - paintbrush	Assume no inhalation exposure. For dermal exposure, use surrogate data for paintbrush application from Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product painting Model 2 (Ann. Occ. Hyg. 41(3):97-312, 1997) Hand-held dusting applicator pack for crack and crevice [Most suitable surrogate data] [For 95th centiles, use sample maxima from Biocides Guidance]
		2. Stem injection	Use EUROPOEM data for knapsack application. [Conservative alternative in the absence of any directly relevant data] [Data for dermal exposure of hands not log-normal, use sample maximum for 95th centile; data for dermal exposure of body not log-normal, use parametric estimate for 95th centile; data for inhalation exposure not log-normal, use parametric estimate for 95th centile]

Scenario			Source of exposure data **(It is proposed that for each application scenario, the same source of data would be used for dermal and inhalation exposure)**
1 e. Outdoor spray/spreading/placement applications, weed wipers			
i	Tractor-mounted equipment		Use surrogate data from EUROPOEM for boom sprayers. [Conservative alternative in the absence of any directly relevant data]
ii	Manual equipment		Assume no inhalation exposure For dermal exposure, use surrogate data for paintbrush application from Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product painting Model 2 (Ann. Occ. Hyg. 41(3):97-312, 1997) Laboratory studies - lattice fence painting, water-based/solvent based product [Conservative alternative in the absence of any directly relevant data] [For 95th centiles, use sample maxima from Biocides Guidance]
2 a. Indoor spray/spreading/placement applications, spraying downward			
i	Manual equipment	1. Knapsack sprayer	EUROPOEM Use Hand Held Low Level Target subset as defined in EUROPOEM II report Table 14.1 [No suitable alternative data set is available] [Data for dermal exposure of hands not log-normal, use sample maximum for 95th centile; data for inhalation exposure not log-normal, use parametric estimate for 95th centile]
		2. Hand-held lance	EUROPOEM Use Hand Held Low Level Target subset as defined in EUROPOEM II report Table 14.1 [No suitable alternative data set is available] [Data for dermal exposure of hands not log-normal, use sample maximum for 95th centile; data for inhalation exposure not log-normal, use parametric estimate for 95th centile]
ii	Automated equipment	1. Gantry sprayer	It would normally be assumed that operators are not present.
		2. Ultra-low volume sprayers	It would normally be assumed that operators are not present.

Scenario			Source of exposure data **(It is proposed that for each application scenario, the same source of data would be used for dermal and inhalation exposure)**
2 b. Indoor spray/spreading/placement applications, spraying upward (crops and building fabric)			
i	Manual equipment	1. Knapsack sprayer - crops	EUROPOEM Use Hand Held High Targets subset as defined in EUROPOEM II report Table 14.5 [No suitable alternative dataset available] [Data for dermal exposure of body not log-normal, use parametric estimate for 95th centile]
		2. Knapsack sprayer – structural treatments	Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Spraying Model 2 (Based on HSE survey 1988, BPCA 1990, ECoS 1996, IOM study on PPE, 1996) [For 95th centile dermal exposure of feet use 75th centile]
		3. Hand-held lance – crops	EUROPOEM Use Hand Held High Targets subset as defined in EUROPOEM II report Table 14.5 [No suitable alternative dataset available] [Data for dermal exposure of body not log-normal, use parametric estimate for 95th centile]
		4. Hand-held lance – structural treatments	Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Spraying Model 2 (Based on HSE survey 1988, BPCA 1990, ECoS 1996, IOM study on PPE, 1996) [For 95th centile dermal exposure of feet use 75th centile]
2 c. Indoor spray/spreading/placement applications, dust applications			
i	Manual equipment		Use surrogate data from Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Consumer product spraying and dusting Model 2 (Based on HSL 2001) Hand-held dusting applicator pack for crack and crevice [Best available surrogate data] [For 95th centiles, use sample maxima from Biocides Guidance]

Scenario			Source of exposure data **(It is proposed that for each application scenario, the same source of data would be used for dermal and inhalation exposure)**
2 d. Indoor spray/spreading/placement applications, granule applications			
i	Manual equipment		Use PHED data for same methods of application outdoors *NB These data are for the combination of loading and application. For this application scenario, there is no need to assess exposures during mixing separately.* [Best available surrogate data] [Data for dermal exposure of hands not log-normal, use sample maximum for 95th centile; data for dermal exposure of body not log-normal, use sample maximum for 95th centile; data for inhalation exposure not log-normal, use parametric estimate for 95th centile]
3 a. Treatments of seed, seedlings, bulbs , tubers etc., dipping			
i	Mechanical		Use surrogate data from Biocides Technical Guidance 2002 version: TNsG Human Exposure 2002 Handling Model 1 (Based on HSE surveys 1989, 1993, 1996, AEAT survey 1997-8) Data for water based Assume one cycle is typically 180 minutes [Best available surrogate data] [For 95th centile dermal exposure of feet use 75th centile]
ii	Manual		Assume no inhalation exposure. For dermal exposure, use data from: Brouwer,D.H., Brouwer,E.J., van Hemmen,J.J., 1992. Assessment of dermal and inhalation exposure to zineb/maneb in the cultivation of flower bulbs, *Ann. Occup. Hyg.* 36, pp. 373-384. Assume one basket contains 35 kg of bulbs [Use sample maximum for 95th centile]

A comprehensive list of exposure models is given in the report (EFSA, 2008b). The racionale for selecting the most suitable one per scenario is given in Table 4. The underlying datasets for each scenario will be presented in a separate report after the proposed format of Guidance Document is accepted.

8.2. Workers

Exposure of workers must be estimated for activities that involve significant contact with treated crops. Such contact may occur when workers re-enter treated areas after application of a PPP, e.g. for crop inspection/harvesting activities. In addition, worker exposure can arise from other activities such as packaging, sorting and bundling.

8.2.1. General considerations

The main routes of exposure during post-application activities are dermal and by inhalation. The sources of exposure are contact with foliage (used here to include fruit as well as leaves), soil and possibly dust. Oral exposure may occur secondarily to dermal exposure, through hand to mouth transfer. However, for workers, maximum potential exposure by this route is generally assumed to be negligible in comparison with that via the skin and by inhalation.

Most crop maintenance and harvesting activities entail frequent contact with the foliage of the crop. Therefore, dermal exposure is considered to be the most important exposure route during these re-entry activities. The level of resultant exposure (for a given activity) depends on the amount of residue on foliage, the intensity of contact with the foliage, and the duration of contact.

Inhalation exposure may be to vapour and/or airborne aerosols (including dust). After outdoor application of PPPs, there will be more rapid dissipation of vapour and aerosols, leading to lower inhalation potential than from indoor treatments, such as those made to protected crops grown in glasshouses.

Some scenarios involving exposure to plant protection products (or relevant metabolites, degradation and reaction products) through dislodgeable foliar residues (DFR) or turf transferable residues (TTR) may also entail exposure to soil-borne residues. For example harvesting leeks or weeding in a leafy crop may entail contact with such residues. In these situations, the estimate of dermal exposure should include any exposure through soil contact as well as that arising from contact with foliage.

There are also some re-entry situations where exposure to soil-borne residues occurs in the absence of contact with treated foliage – for example, workers using compost treated with an insecticide, or during manual harvesting of root crops.

In general, workers cannot be expected to routinely use personal protective equipment. Therefore, in assessment of their potential exposures, allowance for use of such equipment should only be made where the risk assessor can be reasonably confident that it would be used (e.g. because it was necessitated by other aspects of the task being undertaken).

Relatively few measurements of worker exposure to PPPs are available, and it is therefore proposed that exposure estimates in first tier risk assessments will best be derived by application of suitable mathematical models, parameters for which are based on empirical data. It is proposed that the exposure estimates obtained in this way will be suitable for both acute and longer term risk assessments. However, where ad hoc higher tier exposure estimates were made, separate values would normally be derived for acute and longer term risk assessment.

In both first and higher tier risk assessments, the exposures estimated for each relevant source and route of exposure should be summed to give an overall estimate of potential exposure in workers.

8.2.2. Dermal exposure

Contact with foliage may deposit residues of a PPP onto the clothing and skin of a worker. The exposure is assumed to depend on the application rate, the foliage density, the time of re-entry activities after application, the transfer from foliage to worker, and the task duration.

Exposure should be estimated as the product of the dislodgeable foliar residue (DFR, µg/cm^2), the transfer coefficient (TC, cm^2/h) (from Table 5 below), and the task duration (T, h/day) (EUROPOEM, 2002):

Potential dermal exposure (PDE) µg/day = DFR µg/cm^2 x TC cm^2/h x T h/day

The default value for time of exposure should be taken as 8 hours for harvesting and 2 hours for crop inspection.

8.2.2.1. Dislodgeable foliar residue

The amount of residue deposited on foliage depends on several factors, including the application rate, application efficiency (how much reaches and is retained on the target), crop type and the amount of foliage (leaf area index). Dissipation of residues on crop foliage over time depends on the physical and chemical properties of the applied PPP, and also on environmental conditions. Where experimentally determined dislodgeable foliar residue data are not available, a worst case assessment of the initial DFR (DFR0), in a first tier assessment, should assume 3 µg active substance/cm^2 of foliage/kg a.s. applied/ha (EUROPOEM, 2002).

If no data are available on the degree of dissipation (decay) over time, the worst-case approach would be to assume that no dissipation occurs. In this case DFR0 would be used for calculations, i.e. the residue available directly after application. However, for active substances that are organic chemicals for which there is evidence of breakdown by photolysis or hydrolysis in soil or water, available data indicate that it would be reasonable to assume, as a default, that dissipation occurs exponentially, with a half-life of 30 days[6] (USDA Natural Resources Conservation Service, 2006; Willis and McDowell, 1987). Where sequential applications of an active substance were made on the same crop, the dissipation would then be taken into account by application of multiple application factors (MAFs), calculated from the assumed half-life.

A realistic worst-case is to consider re-entry after the final treatment has been made to a crop. Therefore, where approval is sought for multiple treatments, the assessment should consider the potential accumulation of DFR from successive treatments.

8.2.2.2. Transfer coefficient

The transfer of residues from the plant surface to the clothes or skin of the worker should be taken into account, regardless of the product applied, the level of exposure depending on the intensity and duration of contact with the foliage. This is determined by the nature and duration of the activity during re-entry. Therefore, it is possible to group various crop habitats and re-entry activities. The indicative TC values in Table 5, taken from EUROPOEM (EUROPOEM II, 2002), should be used in first tier assessments of potential dermal exposure for the four harvesting scenarios specified. Two sets of TC values are given, according to whether or not it can be assumed that the worker will wear clothing that covers the arms, body and legs. In both cases, it is assumed that harvesting is performed with bare hands.

[6] This value differs from that proposed in the birds and mammals opinion (EFSA, 2008c) because the approach for human risk assessment is more precautionary.

Table 5: Transfer coefficients

Crop	Nature of task	Main body parts in contact with foliage	Transfer Coefficient (cm2 / hr) assuming arms, body and legs covered	Transfer Coefficient (cm2 / hr) total potential exposure
Vegetables	**Reach / Pick**	**Hand and body**	2500	5800
Tree fruits	**Search / Reach / Pick**	**Hand and body**	4500	22500
Strawberries	**Reach / Pick**	**Hand and forearm**	3000	3000
Ornamentals	**Cut / Sort / Bundle / Carry**	**Hand and body**	5000	14000

These TC values may be extrapolated to other re-entry scenarios, where the intensity and duration of contact with the foliage is judged to be similar.

8.2.3. Inhalation exposure

Potential exposure from a volatile PPP decreases with time, as the concentration of the active ingredient is reduced, either by absorption into the plant, degradation, or loss to the environment. Although in many cases inhalation exposure will contribute less to total potential exposure than that by the dermal route, task-specific inhalation factors should be used for first tier exposure assessments relating to harvesting of ornamentals and to re-entering greenhouses within 8-16 hours after treatment (van Hemmen *et al* 2002). Inhalation exposure for this re-entry scenario should be predicted as:

Potential inhalation exposure (mg a.s./hr inhaled) = Application rate (kg/a.s./ha) x Task Specific Factor (ha/hr x 10^{-3})

where Task Specific Factors are as set out in Table 6.

Table 6: Indicative inhalation Task Specific Factors for protected crops

Task	Task Specific Factor (ha/hr x 10^{-3})
Cutting ornamentals	0.1
Sorting and bundling ornamentals	0.01
Re-entering greenhouses after low-volume-mist application	0.03
Re-entering greenhouses after roof fogger application	0.15

The default value for time of exposure should be taken as 8 hours for harvesting and 2 hours for crop inspection.

This approach may be used for pesticides with low and moderate volatility (< 100 mPa), where levels of inhalation exposure (vapour and dust) would be expected to be low in comparison with dermal exposure. Products applied as aerosols and more volatile pesticides may require further data/information, if exposure is judged to be potentially significant (i.e. not negligible compared to the AOEL).

8.2.4. Residues in Soil / Compost

In most situations the contribution of soil residues to total exposure is expected to be significantly less than that from dislodgeable foliar residues. For example, in a study carried out in Florida (Stamper et al., 1987), measurements of DFR levels on strawberry leaves were 1-3 μg/cm^2, while the concurrent soil residues ranged from trace levels to 25 ppm. Thus, where there is concomitant exposure to foliar residues, the contribution to exposure from contact with soil residues can reasonably be ignored.

For situations where exposure to soil-borne residues occurs in the absence of contact with treated foliage, an estimate of potential (dermal) exposure may be derived by considering the concentration in the treated soil, together with soil dermal adherence data. Field studies investigating dermal exposure to soil by direct gravimetric measurements (Kissel et al., 1996) suggest that an appropriate hand soil loading for a worker would be 0.44 mg/cm^2 (geometric mean peak value for farmers involved in hand weeding). Inhalation exposure can be estimated by using field data on personal exposure levels to soil dust during relevant operations. For example, data from California (Nieuwenhuijsen et al., 1998), where there is a dry-climate situation likely to produce a high level of dust, suggest a total inhalation dust exposure when discing (cultivating) on a vehicle not fitted with a cab of 98.6 mg/m^3.

Concentrations in treated soil should be estimated as follows: For handling of compost after admixture treatment, the concentration in compost should be derived from the label-recommended application rate for the admixture of product with compost. For other situations, soil concentration values should be sought from the fate and behaviour evaluation. For acute exposure assessment, the highest initial PEC Soil value should be used. For assessment of chronic exposures, an appropriate time weighted average (TWA) value may be used. Where values are not available from the fate and behaviour evaluation, soil concentrations for field applications should be estimated assuming: the distribution is limited to the top 5 cm layer; or 20 cm when cultivation follows the application; soil density is 1.5 g/cm^3; and 100% of the applied dose reaches the soil surface. In the case of home garden exposures, the more protective assumption that the material is distributed through the uppermost 1 cm should be used.

8.3. Residents

For exposure through treatment of nearby crops, four pathways of exposure should be considered, and the potential exposures from each relevant pathway summed:

1) Spray drift

Calculations should use 75th centile values from data on potential dermal and inhalational exposures, with correction for incomplete dermal absorption using the dermal absorption percentage for the in-use dilution of the PPP. For arable crops, the best available dataset is that reported by Lloyd and Bell for "standard" F110/1.18/3.1 (11003) nozzles applying 165 litres/ha application (these are representative nozzles, and give higher exposures than the other three nozzles in the report) (Lloyd and Bell, 1983). For orchard crops and vines, the most appropriate dataset is that for D5 25 hollow cone nozzles applying 470 litres/ha, from a 1987 report by Lloyd and colleagues (Lloyd et al., 1987). This gave the highest exposures in that report. Moreover, the data form a significant part of those included in EUROPOEM for this scenario, and are preferred to the others as they were generated under more representative conditions. Some of the other measurements in the EUROPOEM dataset were collected in the absence of any tree or bush target, which will have increased the potential for exposure.

The exposure values derived from the publication by Lloyd and Bell (1983) for tractor-mounted boom-spraying relate to exposures at a distance of 8 m downwind from a passing sprayer. To account for additional more distant passes of a sprayer, and for the possibility of closer proximity than 8 m, we propose that the dermal values be increased by a factor of 10. Limited empirical data suggest that this is a reasonable adjustment (ACP, 2003; Butler Ellis and Miller, 2009). However, if risk managers in

the European Commission wished to apply a different level of adjustment, that could easily be accommodated in the Guidance Document. From currently available data, there does not appear to be a need for similar adjustment of exposures by inhalation. Nor do we propose any adjustment to the exposure values for orchard crops and vines, since the measurements in the 1987 report by Lloyd and colleagues (Lloyd et al., 1987) related to application across an entire orchard, and the design of orchards and vineyards makes it much less likely that a resident would be less than 8 m from a passing sprayer.

While airborne concentrations will tend to be higher in the breathing zones of children than of adults (because they are closer to the ground), children have lower inhalation rates (in m^3/hr) and a smaller surface area than adults. Thus, their total inhalation and dermal exposures are expected to be less than those of adults, and provided appropriate correction is made for the lower body weights of children, use of adult exposure values should provide an adequately protective first tier assessment for children.

2) Vapour

Exposures to vapour should be estimated using the method that has been developed in the UK (CRD, 2008) and Germany (Martin et al., 2008), based on the highest time-weighted average exposure for a 24-hour period, according to the volatility of the active substance.

3) Surface deposits

Exposure to surface deposits in children aged less than 1 year and 1 to < 3 years should be calculated as the sum of components from dermal absorption, hand to mouth transfer and object to mouth transfer.

Dermal exposure should be estimated as:

Application rate (mg/cm^2) x Drift percentage x Turf transferable residues percentage x Transfer coefficient (cm^2/hour) x Exposure duration (hours) x Dermal absorption percentage.

Hand to mouth transfer should be estimated as:

Application rate (mg/cm^2) x Drift percentage x Turf transferable residues percentage x Saliva extraction percentage x Surface area of hands x Frequency of hand to mouth activity (events/hour) x Exposure duration (hours) x Oral absorption percentage.

Object to mouth transfer should be estimated as:

Application rate (mg/cm^2) x Drift percentage x Dislodgeable residues percentage x Ingestion rate for mouthing of grass per day (cm^2) x Oral absorption percentage.

For older children and adults, only dermal exposure (calculated according to the same formula) needs to be considered.

Default values for parameters should be applied as follows:

Turf Transferable Residues percentage: for products applied in liquid sprays 5% and for products applied as granules 1% (These values come from data obtained using the Modified Californian Roller Method (Rosenheck et al., 2001), and represent the upper end of the range from a number of studies with different compounds).

Transfer coefficient: 1800, 2300, 3100, 4300, 6400 cm^2/hour in children aged <1, 1 to < 3, 3 to <6, 6 to <11, 11 to <16 years old respectively[7], and 7300 cm^2/hour in adults. These values come from data measured in adults that were considered by the USA EPA (EPA 2001), and are adjusted for children using the ratio of body surface areas (EPA 2001, EPA 2007, EPA 2008).

Exposure duration: 2 hours

Saliva extraction percentage: 50% (This refers to the fraction of pesticide extracted from a hand/object via saliva. It is a median value from a study by Camman and colleagues on the fraction of pesticide extracted by saliva from hands (Camman et al., 1995).

Surface area of hands mouthed: 20 cm^2

Frequency of hand to mouth activity: 9.5 events/hour

Dislodgeable residues percentage: 20%

Ingestion rate for mouthing of grass per day: 25 cm^2

Dermal and oral absorption percentages should be taken from the toxicological evaluation. For the dermal absorption percentage, the higher of the values for the undiluted product and the in-use dilution should be used.

Values for Drift percentage (expressed as % areic mass)[8] should be derived from data on spray drift collated by Rautman according to the type of crop (Rautman et al., 2001). However, as there are indications that these data may in some circumstances underestimate drift for ground boom sprayers (for example, see van de Zande, 2002), we propose that values for these applications be increased by a factor of 10. For products applied as granules, a value of 3% should be used (EFSA, 2004).

4) Entry into treated crops

For entry into crops, only dermal exposure need be considered. The method used should be the same as for workers, taking the same values for DFR and transfer coefficient as for workers, and assuming 15 minutes exposure per day.

For entry onto treated lawns, exposures should be calculated as for surface deposits (see above) but taking the drift percentage as 100%.

Although it is possible that someone might sunbathe on a treated lawn or contaminated surface for longer than two hours in a day, the average levels of transfer when sunbathing for prolonged periods are likely to be lower than those assumed above.

For children, all of the above pathways are relevant. For adults, object-to-mouth and hand-to-mouth transfer of surface deposits are considered negligible, and can be ignored.

An additional possible pathway of exposure for residents, not covered under the four headings listed above, is through consumption of home-grown fruit and vegetables that have been contaminated by spray drift from neighbouring land. Currently, data to predict residues in crops growing adjacent to treated areas are not available, and therefore the potential for exposure by this pathway cannot be reliably assessed. However, if risk managers in the European Commission wished to take it into account in the future, relevant data could be generated through a research project.

[7] Children below 1 year old, from 1 to below 3, from 3 to below 6, from 6 to below 11 and from 11 to below 16 years.

[8] Drift expressed as % areic mass indicates the deposition of a substance per unit receiving (non target) surface and is expressed as a percentage of the amount applied per unit area target surface. For example, at 1% drift, the deposition per square metre surface water is 1 mg when the dosage is 1 kg per ha (100 mg per square metre).

8.4. Bystanders

Exposures for bystanders should be assessed in the same way as for residents, except that dermal and inhalation exposures to spray drift should be taken as the 95th centile values derived from the underpinning datasets. For inhalation exposure during orchard/broadcast air assisted applications, the dataset deviates significantly from log-normality, but the 95th centile of the dataset is greater than that estimated parametrically, and can therefore be used.

For surface deposits, the above transfer coefficients should be replaced with 3600, 4600, 6100, 8600, 12,600 cm^2/hour for children aged <1, 1 to <3, 3 to <6, 6 to <11, 11 to <16 years old , respectively, and 14,500 cm^2/hour for adults, and the frequency of infant hand to mouth activity should be 20 events/hour.

8.5. Scale of use

Where an assumption must be made about scale of use to estimate operator exposure, we propose as a pragmatic choice, that the area of crop treated in a single day should, as a default, be taken as 20 hectares for field crops, 8 hectares for orchards, and 1 hectare for medium-scale hand-held application by professional operators (including use in greenhouses). These assumptions are in line with those currently applied in the German model. In practice the treated area will depend on the type of equipment used. With relatively simple equipment, of the type used in the derivation of most of the available exposure data, the areas treated per day are not expected to exceed those proposed. With use of more sophisticated equipment, exposure per unit area treated is likely to be lower. For small-scale application by amateur users, the potential scale of use should be decided on a case-by-case basis.

8.6. Allowance for engineering/technical controls and personal protective equipment (PPE)

In first tier exposure assessments, the following levels of penetration should be assumed for use of engineering/technical controls, clothing and PPE (provided, as Directive 91/414/ EEC stipulates, “effective” PPE is “readily obtainable” and its use is “feasible”) (Gerritsen-Ebben et al., 2007, van Hemmen, 2008):

For broadcast air-assisted (orchard) applications, closed cabs with positive air pressure and functioning filtration units (the default data set was generated using only cabless vehicles) – dermal and inhalation exposure are reduced to 10%. (However, the availability of closed cabs that fulfil the conditions of positive air pressure and functioning filtration units is limited (Gerritsen-Ebben *et al.,* 2007). Therefore, assurance about the availability of such equipment should be provided to support the use of closed cabs as an exposure mitigation recommendation.)

Coveralls (whole body) or a single layer of work clothing (covering arms, body and legs) – for operators 10% (data on the additional protection from coated coveralls are not available)

Single layer of coveralls or work clothing (covering arms, body and legs) - for workers 20%

Gloves – 10% for liquids and 5% for solids – for operators (NB these values refer to chemical-resistant gloves. Workers would not be expected to use chemical-resistant gloves for extended periods, and therefore these values should not be applied in worker exposure assessments)

Respiratory protective equipment (RPE) – it is proposed to use the “assigned protection factors” (APF) as deduced by the BSI (British Standards Institution) and ANSI (American National Standards Institute). Since these values are not in full agreement and since in agricultural settings efficient control and proper training with respect to RPE is generally absent, a precautionary approach is proposed, with use of the lowest value cited for each type of mask. It should be noted that, even with appropriate training, it is not feasible to wear most RPE for extended periods. Therefore reliance

should not normally be placed on RPE to control worker exposures. The proposed protection factors are given in Table 7.

Table 7: Recommended 'Protection Factors' for RPE

Mask type	Filter type	Protection Factor
Filtering half masks	**FP1**	25%
	FFP2	10%
	FFP3	10%
Half or quarter mask and filter	**P1**	25%
	P2	10%
	Gas	10%
	GasXP3	10%
	P3	10%
Filtering half masks without inhalation valves	**FMP1**	25%
	FMP2	10%
	FMGasX	10%
	FMGasXP3	10%
	FMP3	10%
Valved filtering half masks	**FFGasXP1**	25%
	FFGasX 10 10	10%
	FFGasXP2	10%
	FFGasXP3	10%
Full face masks and filter	**P1**	25%
	P2	10%
	Gas	5%
	GasXP3	5%
	P3	2.5%
Powered filtering devices incorporating helmets or hoods	**TH1 all types**	10%
	TH2 all types	5%
	TH3 (semi) hood/blouse	2,5%
Power assisted filtering devices incorporating full, half or quarter masks	**TM1 all types**	10%
	TM2 all types	5%
	TM3 (half face) particle, gas or combined filters	5%
	TM3 (half face) gas or combined filters	2.5%

8.7. Dermal absorption factors

These will be provided in a separate guidance document that is currently being revised (Sanco/222/2000 rev. 7, adopted in 2004).

8.8. Standard body weights

When deriving exposures per unit body weight, it is proposed that the body weight of an adult should be taken as 60 kg, and those for children aged 10 to <12 months, 1 to <3 years, 3 to <6 years, 6 to <11 years, and 11 to <16 years, as 8.7, 12.3, 17.5, 28.7 and 50.2 kg respectively (derived from data published by ECETOC (2001) and Prud'homme de Lodder (2006)).

8.9. Breathing rates

Where values for inhalation exposure are given as concentrations per cubic metre of air, an assumption must be made about the person's breathing rate in order to derive a systemic exposure. For this purpose, it is proposed that representative values for breathing rates should be taken from the latest analysis of relevant data (US EPA, 2009). For longer term exposures (e.g. of residents to vapours), the daily inhalation breathing rate should be taken as:

Age Group	Daily Inhalation Rate, Adjusted for Body Weight (m^3/day/kg)
<1 year	1.14
1 to <3 years	1.07
3 to <6 years	0.70
6 to <11 years	0.44
11 to <16 years	0.27
Adults	0.23

For exposures which could occur predominantly over a shorter period, typically less than 30 minutes in duration, during which activity was more intense, higher values should be assumed corresponding to high activity as follows:

Age Group	High Intensity Hourly Inhalation Rate, Adjusted for Body Weight (m^3/hour/kg)
<1 year	0.196
1 to <3 years	0.190
3 to <6 years	0.120
6 to <11 years	0.0820
11 to <16 years	0.0550
Adults	0.0400

9. Proposed Guidance Document

Appendix A sets out wording for a Guidance Document, based on the methods that we have proposed above. We believe that application of this guidance would result in a level of precaution similar to, or somewhat higher than, that which is currently applied. Increased precaution arises from the introduction of an additional acute risk assessment for PPPs that have significant potential to cause toxicity from exposure in a single day, and from use of parametric estimates of population exposure centiles, if they are higher than corresponding sample centiles. If risk managers in the EC required a different level of precaution, that could be achieved, for example, by changing the centiles of exposure distributions that have been used in the models.

The methods set out in the Guidance Document would cover more commonly occurring exposure scenarios. Other scenarios, including special local circumstances in individual Member States, would need to be addressed by the risk manager on a case by case basis.

It should be noted that the numerical parameters in Appendix A are for illustration and would require independent checking before being used. If our proposed format is accepted, and once the required level of precaution is agreed, we suggest that a revised draft of the Guidance Document should be prepared, together with a separate report setting out how each parameter in the Guidance Document was derived, and also a spreadsheet to assist exposure calculations according to the guidance.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The PPR Panel concludes that a tiered approach should continue to be applied in exposure assessment for operators, workers, residents and bystanders.

For assessment of potential longer term exposures, estimates should normally be based on 75th centiles of relevant exposure distributions.

For PPPs which might cause toxicity through exposures on a single day, a separate acute risk assessment should be carried out, comparing estimated potential exposures with an "acute acceptable operator exposure level" (AAOEL). For this purpose, estimates of potential exposure should normally be based on the 95th centiles of relevant exposure distributions. Performance of an acute risk assessment in this way would guard against the possibility of toxicity from unusually high exposure in a single day, and parallels the approach that is already used for dietary exposure to acutely toxic residues.

Because there can be substantial statistical uncertainties in the estimation of higher centiles of exposure distributions, especially when based on relatively small samples of measurements, there is a strong case for deriving parametric estimates of relevant centiles with a default assumption that measured exposures come from a log-normal distribution. A precautionary approach would then be to take the estimated potential exposure for the risk assessment as the higher of a) the relevant centile of measured exposures for the scenario under consideration and b) the corresponding parametric estimate of that centile.

Based on a review of available data for estimating exposures in different scenarios, the Panel has identified a single preferred dataset or model for first tier exposure assessment in relation to each commonly occurring scenario. Where several possible datasets were available for a scenario, we have selected that which was based on what we judge to be the most robust. We did not attempt to merge datasets because in many cases there will have been overlap in the studies from which they were compiled, and without recourse to all of the original study reports, it would not be possible to assess this and eliminate possible double-counting. We did not have the time or resources to undertake an investigation of this sort, although it could, if desired, be undertaken in the future as a commissioned, outsourced project.

The Panel has also made proposals for default assumptions regarding body weight, scale of use and allowance for PPE.

Adopting these proposals, the Panel has set out a draft format for a guidance document on assessment of exposure for operators, workers, residents and bystanders in risk assessment for plant protection products. It should be noted that the numerical parameters in Appendix A are for illustration and would require independent checking before being used. The Panel recognises that the draft guidance incorporates decisions in risk management, such as the choice of centiles from exposure distributions.

However, the text is worded in such a way that if risk managers in the European Commission wished to adopt a different level of precaution, the necessary modifications could easily be made.

For some scenarios, the available data on exposures are particularly limited, and there would be value in further research to improve the knowledge base. Worker exposure is a particular priority. The transfer coefficients that are currently available cover only a few scenarios, and the conservative default value that we have proposed for DFR could usefully be refined with further data. It would also be helpful to carry out worker exposure studies for crop inspection scenarios, especially for cereals, and for post-harvest activities such as packing vegetables.

With regard to operator exposures, the main need is for exposure data that relate directly to certain, generally less common, scenarios, especially seed treatments, roller table/conveyor type treatments, dipping and drenching treatments, stem injections and spot treatments.

In addition, more work is needed to establish the reductions in exposure to PPPs from clothing and use of PPE under representative field conditions

Other gaps in knowledge are being addressed in work that is already ongoing. Thus, for example, the proposed method for estimating exposures of residents to vapours is likely to give substantial overestimates for many pesticides. However, there should be scope for refinement when data become available from the ongoing BREAM study in the UK.

Meanwhile, in the absence of better data, the Panel has indicated methods of exposure estimation that would provide reassurance of safety comparable to that for scenarios that have been studied more extensively.

RECOMMENDATIONS

The PPR Panel recommends that a new guidance document on exposure assessment for operators, workers, residents and bystanders should be adopted along the lines of that set out in Appendix A. If risk managers in the European Commission wish to vary the level of precaution that is applied, the guidance should be modified accordingly.

In order to finalise the Guidance Document rapidly, we ask that the Commission give a timely response to our opinion.

Once the exact format for the guidance document has been agreed by risk managers, it should be published with a supporting spreadsheet to enable easy application by notifiers and regulatory authorities, and also a separate document detailing the derivation of specified exposure values from underlying datasets.

The Guidance Document should thereafter be reviewed periodically, as and when relevant new data become available, and if appropriate, be revised.

If the case is accepted for an additional acute risk assessment for PPPs that could plausibly cause toxicity through exposures on a single day, we recommend that the nomenclature for the toxicological reference value that would be used should be considered as part of a review of terminology in risk assessment that is currently being undertaken by a Working Group of the EFSA Scientific Committee, and that guidance be developed on the derivation of the new reference value.

Further research could usefully be conducted on:

- Transfer coefficients for worker exposure scenarios that have not yet been investigated
- Dislodgeable foliar residues
- Worker exposures in different crop inspection scenarios (especially for cereals) and during post-harvest activities such as packing vegetables
- Operator exposures in less common scenarios, especially seed treatments (we understand that data on exposures associated with the treatment of seed have been collected, but they need to be collated and placed in the public domain), roller table/conveyor type treatments, dipping and drenching treatments, stem injections and spot treatments
- The reductions in exposure to PPPs from clothing and use of PPE under representative field conditions
- The potential for residential exposure through consumption of home-grown fruit and vegetables that have been contaminated by spray drift from neighbouring land
- Development of appropriate exposure data and methods to conduct cumulative and aggregate risk assessment.

DOCUMENTATION PROVIDED TO EFSA

1. Background and Terms of Reference for the Guidance Document on pesticide exposure assessment for workers, operators, bystanders and residents.
2. Final Report of 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 (CFP/EFSA/PPR/2007/01).

REFERENCES

Advisory Committee on Pesticides (UK), 2003. Bystander exposure assessment, ACP 9 (297/2002), 16 January 2003.

Advisory Committee on Pesticides (UK), 2007. Reports in Bystander exposure measurements during application to arable crops, ACP 13 (325/2007), 15 may 2007.

Butler E M and Miller P, 2009. Summary of the Current Status of the Bystander and Resident Exposure Assessment Model, ACP 9/3 (338/2009), June 2009 (available on request from CRD, UK).

Byron N, Morgan N and Wilder J, 2009. Review of biological monitoring exposure studies reported in the open literature. Interim report. CRD, York.

California Department of Pesticide Regulation, 1998. Position Paper: Standard reference values and availability of exposure factors handbook (1997), HSM 98/014.

Californian Department of Pesticide Regulation, 2001. Approximating the 95th Percentile and the 90 % Confidence Limit for Exposure Estimates from the Pesticide Handlers Exposure Database (PHED v1.1). HSM-01010, August 23, 2001.

Californian Department of Pesticide Regulation, 2009. Method for Calculating Short-term Exposure Estimates, HSM-09004, February 13 2009.

Camann D E, Majumadar T K and Geno P, 1989. Determination of Pesticide Removal Efficiency from Human hands Wiped with Gauze Moistened with Three Salivary Fluids. Final Report to EPA by ManTech under Contract 68-D5-0049

CRD (The Chemical Regulation Directorate, UK), 2008 online. Bystander Exposure Guidance, available at: http://www.pesticides.gov.uk/applicant_guide.asp?id=1246&link=%2Fuploadedfiles%2FWeb%5FAssets%2FPSD%2FBystander%2520exposure%2520guidance%5Ffinal%2520version%2Epdf.

Doran E M, Fenske R, Kissel J C, Curl C L, Simcox N J, 2003. Impact of dermal absorption factors in occupational exposure assessment: comparison of two models for agricultural re-entry workers exposed to azinphosmethyl. Applied Occupational and Environmental Hygiene 18(9):669-677.

ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals), 2001. Exposure Factors Sourcebook for European Populations (with Focus on UK Data), Technical Report No. 79.

EC (European Commission), 1991. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991).

EC (European Commission), 1998. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placement of biocidal products on the market. O J Eur Comm L123/23.

EC (European Commission), 2006. Draft guidance for the setting and application of acceptable operatior exposure levels (AOELs). SANCO 7531 rev 10.

EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS sw scenarios. The EFSA Journal (2004)145, 1-31.

EFSA (European Food Safety Authority), 2008. Scientific Opinion of the Panel on Plant Protection Products and their Residues (PPR Panel) on a request from the EFSA to evaluate the suitability of existing methodologies and, if appropriate, the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005. The EFSA Journal (2008) 704, 1-84.

EFSA (European Food Safety Authority), 2008b. 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

EFSA (European Food Safety Authority), 2008c. Scientific Opinion of the Panel on Plant protection products and their Residues on a request from the EFSA PRAPeR Unit on risk assessment for birds and mammals. The EFSA Journal (2008) 734, 1-181.

EPA (U.S. Environmental Protection Agency), 2001. Science Advisory Council for Exposure, Policy Number 12, Recommended Revisions to the Standard Operating Procedures (SOPs)

for Residential Exposure Assessments. Office of Pesticide Programs, Health Effects Division. Washington D.C

EPA (U.S. Environmental Protection Agency), 1997. Exposure Factors Handbook (Final Report) 1997. U.S. Environmental Protection Agency, Washington, DC, EPA/600/P-95/002F a-c, 1997.

EPA (U.S. Environmental Protection Agency), 2008. Child-Specific Exposure Factors Handbook (2008). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-06/096F, 2008.

EPA (U.S. Environmental Protection Agency), 2009. Metabolically derived human ventilation rates: a revised approach based on oxygen consumption rates. National Center for Environmental Assessment, Washington DC; EPA/600/R-06/129F.

EUROPOEM, 1996. The development, maintenance and dissemination of a European Predictive Operator Exposure Model (EUROPOEM Database) Draft Final Report, December 1996, AIR3 CT91-1370.

EUROPOEM II, 2002. The development, maintenance and dissemination of generic European databases and predictive exposure models to plant protection products: a EUROPOEM operator exposure database: A EUROPOEM bystander exposure database and harmonised model; a EUROPOEM re-entry exposure database and harmonised model; an evaluation of the nature and efficacy of exposure mitigation methods; a tiered approach to exposure and risk assessment, FAIR3 CT96-1406.

Fenske R A and Day E W, 2005. Assessment of exposure for pesticide handlers in agricultural, residential and institutional environments. Eds Franklin C A and Worgan J P Occupational and residential exposure assessment for pesticides. Wiley 1-32.

Gerritsen-Ebben R M G, Brouwer D H, van Hemmen J J, 2007. TNO report V7333, Effective Personal Protective Equipment (PPE). Default setting of PPE for registration purposes of agrochemical and biocidal pesticides.

Kissel J, Richter K and Fenske R, 1996. Field measurements of dermal soil loading attributable to various activities: implications for risk assessment. Risk Anal. Feb 16(1), 115-125

Kissel, J and Fenske R, 2000. Improved estimation of dermal pesticide dose to agricultural workers up re-entry. Applied Occupational and Environmental Hygiene 15(3):284-290.

Kromhout H, Symanski E and Rappaport S M, 1993. A comprehensive evaluation of within- and between-worker components of occupational exposure to chemical agents. Ann Occup Hyg, 37, 253-270.

Leverton K, Cox V, Battershill J and Coggon D, 2007. Hospital admission for accidental pesticide poisoning among adults of working age in England, 1998 - 2003. Clinical Toxicology, 45, 594-597.

Lloyd G A and Bell G J, 1983. Hydraulic nozzles: comparative spray drift study, Agricultural Development and Advisory Service, Ministry of Agriculture Fisheries and Food, UK.

Lloyd G A, Bell G J, Samuels S W, Cross J V, Berry A M, 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.

Martin S, Westphal D, Erdtmann-Vourliotis M, Dechet F, Schulze-Rosario C, Stauber F, Wicke H, Chester G, 2008. Guidance for exposure and risk evaluation for bystanders and residents exposed to plant protection products during and after application J. Verbr. Lebensm. 3 (2008): 272 – 281.

Nieuwenhuijsen M J, Krusize H and Schenker M B, 1998. Exposure to dust and its particle size distribution in California agriculture, Am. Ind. Hyg. Assoc. J. 58:34-38.

Prud'homme de Lodder L C H, Bremmer H J, van Engelen J G M, 2006. Assessment of secondary exposure to lawn pesticides, SIR report 09709A00, RIVM, P.O. Box 1, 3720 BA Bilthoven, The Netherlands.

Rautmann D, Streloke M, 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.

Rosenheck L, Cowell J, Mueth M, Eberhart D, Klonne D, Norman C and Ross J, 2001. Determination of a Standardized Sampling Technique for Pesticide Transferable Turf Residues.Bull Environ Contam Toxicol 67:780-786.

Ross J, Chester G, Driver J, Lunchick C, Holden L, Rosenheck L and Barnekow D, 2008. Comparative evaluation of absorbed dose estimates derived from passive dosimetry measurements to those derived from biological monitoring: validation of exposure monitoring methodologies. J Expo Sci Environ Epidemiol, 18, 211-230.

Solecki R, Davies L, Dellarco V, Dewhurst I, van Raaij M and Tritscher A, 2005. Guidance on setting of acute reference dose (ARfD) for pesticides. Food and Chemical Toxicology, 43, 1569–1593.

Stamper J H, Nigg H N and Queen R M, 1987. Dislodgeable captan residues at Florida strawberry farms. Chemosphere 16: 1257-1271.

USDA (United States Department of Agriculture) Natural Resources Conservation Service, 2006, online. Pesticide properties database (PPD), available at: http://www.wsi.nrcs.usda.gov/products/W2Q/pest/winpst.html#pst%20ppd.

van de Zande J C, Michielsen M G P, Stallinga H, Porskamp H A J, Holterman H J, Huijsmans J F M, 2002. Environmental risk control. Aspects of Applied Biology, 66 165 – 176.

van Hemmen J J, 2008. Addendum to the TNO Report V7333: Effective Personal Protective Equipment (PPE). Default setting of PPE for registration purposes of agrochemical and biocidal pesticides. Covering the literature published in the period 2005 to early 2008., TNO Quality of Life, TNO Chemistry, Food & Chemical Risk Analysis, Chemical Exposure assessment, Zeist, The Netherlands.

van Hemmen J J, Chester G, Hamey P, Kangas J, Kirknel E, Maasfeld W, Perkins J, Phillips J, and Schulze-Rosario C, 2002. Post-Application Exposure of Workers to Pesticides in Agriculture, Report of the Re-entry Working Group, EUROPOEM II Project, FAIR3-CT96-1406, December 2002.

Willis G H and McDowell L L, 1987. Pesticide persistence on foliage. Reviews of Environmental Contamination and Toxicology, 100, 23-73

APPENDICES

APPENDIX A PROPOSED FORMAT OF GUIDANCE DOCUMENT

GUIDANCE ON THE ASSESSMENT OF EXPOSURE FOR OPERATORS, WORKERS, RESIDENTS AND BYSTANDERS IN RISK ASSESSMENT FOR PLANT PROTECTION PRODUCTS

1. INTRODUCTION

This Guidance Document is designed to assist risk assessors and notifiers when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products (PPPs). It is based on an initial draft that was presented as part of a published opinion of the EFSA PPR Panel (reference to be added when available), and readers are referred to that opinion for an explanation of the rationale underlying the methods that it describes.

It is not mandatory to follow the guidance. However, any departure from the procedures described should be justified by sound scientific arguments.

The aim of exposure assessment in this context is to generate realistic upper bounds for potential systemic exposure that can be compared with appropriate toxicological reference values.

Risk assessments must be carried out for all scenarios of exposure to operators, workers, residents and bystanders that can be expected to occur as a consequence of the proposed uses of a PPP. Most exposure scenarios will fall into a category for which a standardised first tier exposure assessment can be applied as described in this document. For unusual scenarios that are not covered by these standardised methods, the risk assessor will need to follow an ad hoc approach that is judged to be the most appropriate.

An ad hoc, higher tier, exposure assessment may also be used for exposure scenarios that are covered by a standardised first tier method. However, this should only be done where the risk assessor has good grounds for concluding that the ad hoc method will provide a more reliable realistic upper bound for potential exposure than the standard method. This conclusion must take into account the quality and quantity of data underpinning the ad hoc as compared with the standard method, and also the closeness with which the data relate to the exposure scenario under consideration. Where a non-standardised higher tier exposure assessment is adopted, the justification should be clearly documented.

2. Definitions of exposed groups

For the purpose of this guidance, the following definitions have been adopted.

a. Operators are: persons who are involved in activities relating to the application of a plant protection product (PPP); such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the plant protection product, and emptying/cleaning the machinery/containers after use. Operators may be either professional (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users).

b. Workers are: persons who, as part of their employment, enter an area that has been treated previously with a PPP or who handle a crop that has been treated with a PPP.

c. Bystanders are: persons who are located within or directly adjacent to the area where PPP application or treatment is in process or has recently been completed; whose presence is quite incidental and unrelated to work involving PPPs, but whose position might lead them to be exposed; and who take no action to avoid or control exposure.

d. Residents are: persons who live, work or attend school or any another institution adjacent to an area that is or has been treated with a PPP; whose presence is quite incidental and unrelated to work involving PPPs but whose position might lead them to be exposed; who take no action to avoid or control exposure; and who might be in the location for 24 hours per day.

3. Overall approach

Step one: Identification of risk assessments that are required

The first step is to establish the risk assessments that will be required. This will depend upon who can be expected to incur exposure as a consequence of the proposed use of the PPP (operators, workers, residents, bystanders), and also on whether the PPP has significant potential for systemic toxicity from exposure in a single day. The answer to this second question will be determined as part of the toxicological evaluation (it will normally be relevant also to whether an acute dietary risk assessment is needed).

Depending on the exposed groups and potential for toxicity from acute exposures, risk assessments will be required as set out in Table 1 below.

Table 1: Risk assessments required

Exposure group	Risk assessments that may be required[(a)]	
	PPPs with no significant potential for toxicity from exposure in a single day	**PPPs with significant potential for toxicity from exposure in a single day**
Operators	L	A L
Workers	L	A L
Residents	L	L
Bystanders		A

(a): A = acute, L = longer term

Step two: Use standardised first tier methods of exposure assessment where available

For each risk assessment that is deemed necessary, potential daily exposures should if possible be assessed using standardised methods as set out in Section 4 below. These methods have been defined for the more commonly occurring exposure scenarios, which are specified in terms of:

The category of person exposed – operator, worker, resident or bystander.

The nature of the PPP – e.g. whether it is formulated as a solid or a liquid.

The operations that will be carried out with the PPP and the equipment that will be used – e.g. mixing and loading for application by tractor-mounted equipment, outdoor application with a knapsack sprayer.

In some cases it may be necessary to combine exposures from two or more scenarios to obtain a figure for the total potential daily exposure – for example, an operator might have components of exposure from mixing and loading and also from spraying.

In the case of professional operators and workers, it may be determined that there is scope to reduce exposures effectively through a regulatory requirement for use of personal protective equipment (PPE). If so, the exposures of these groups should where possible be assessed both with and without the proposed PPE. The multiplying factors by which PPE can be assumed to reduce exposures are also set out in Section 4.

Step three: Use appropriate ad hoc methods where standardised first tier methods of exposure assessment are not available.

Where no standardised first tier method of exposure assessment is available, it will be necessary to apply an appropriate ad hoc method. This will normally be based on a sample of exposure measurements.

For risk assessments in relation to acute exposures (i.e. those that could occur in a single day), exposure estimates should as a default be derived as the higher of: a) the 95th centile of the distribution of measurements in the sample; and b) a statistical estimate of the 95th centile for the theoretical population of measurements from which the sample was derived, under the assumption that this population has a log-normal distribution.

For risk assessments in relation to longer term exposures, exposures should as a default be derived as the higher of: a) the 75th centile of the distribution of measurements in the sample; and b) a statistical estimate of the 75th centile for the theoretical population of measurements from which the sample was derived, under the assumption that this population has a log-normal distribution.

Statistical estimates of centiles for the theoretical populations from which samples were derived can be made using the formula:

$$\exp\left[\overline{x} + t_{n-1,a} * S * \sqrt{\left(1 + 1/n\right)}\right]$$

where $\overline{x}$ is the mean of the natural logarithms of the sample measurements, S is the standard deviation of the logarithms of the sample measurements, t_{n-1} is a t statistic with n-1 degrees of freedom (n being the number of measurements in the sample), and a is the relevant centile.

The reason for including the statistical estimates of population parameters is that sample centiles may by chance be unrepresentatively low, especially when the sample is relatively small and it is a high centile that is being estimated. However, it would be reasonable to depart from this default method if, for example, there were good evidence that the assumption of an underlying log-normal distribution was inappropriate (e.g. a demonstration that the sample measurements deviated significantly (in statistical terms) and importantly (not just because of a single outlying value) from log-normality).

Where only a small sample of relevant exposure measurements is available, a decision must be made as to whether the dataset is adequate to support a valid risk assessment. If it is used, it may be necessary to make additional allowance for uncertainty in centile estimates (e.g. by using upper confidence limits for parametrically estimated centiles, or a higher than normal centile from the sample of measurements).

Step four: Higher tier exposure assessment

Ad hoc methods may also be used for higher tier exposure assessment where risk assessments using standardised methods give inadequate reassurance of safety. However, this should be done only where there is convincing evidence that the ad hoc method will be more reliable than the standardised method. The methods for higher tier exposure assessment should follow the same approach as described in Step 3 above.

BODY WEIGHTS

In all calculations, it should be assumed as a default that adults have a body weight of 60kg, and that body weights for children aged 10 to <12 months, 1 to <3 years, 3 to <6 years, 6 to <11, and 11 to <16 years, are 8.7, 12.3, 17.5, 28.5 and 50.2 kg respectively.

BREATHING RATES

Where values for inhalation exposure are given as concentrations per cubic metre of air, an assumption must be made about the person's breathing rate in order to derive a systemic exposure.

For longer term exposures (e.g. of residents to vapours), the daily inhalation breathing rate should be taken as:

Age Group	Daily Inhalation Rate, Adjusted for Body Weight (m^3/day/kg)
<1 year	1.14
1 to <3 years	1.07
3 to <6 years	0.70
6 to <11 years	0.44
11 to <16 years	0.27
Adults	0.23

For exposures which could occur predominantly over a shorter period, typically less than 30 minutes in duration, during which activity was more intense (e.g. of bystanders to spray drift), higher values should be assumed as follows:

Age Group	High Intensity Hourly Inhalation Rate, Adjusted for Body Weight (m^3/hour/kg)
<1 year	0.196
1 to 2 years	0.190
3 to <6 years	0.120
6 to <11years	0.082
11 to <16 years	0.055
Adults	0.040

SCALE OF USE

Where an assumption must be made about scale of use, the area of crop treated in a single day should, as a default, be taken as 20 hectares for field crops, 8 hectares for orchards, and 1 hectare for medium-scale hand-held application by professional operators. For small-scale application by amateur users, the potential scale of use should be decided on a case-by-case basis.

4. Methods for first tier exposure assessment

The guidance set out in this section relates to estimation of exposures to active substances with vapour pressures less than 10^{-2} Pa. For active substances with vapour pressures $\geq 10^{-2}$ Pa, an ad hoc approach will be required.

4.1. Operator exposure

Exposure is estimated for the recommended conditions of use of the plant protection product. This is normally done separately for the mixing/loading task and the application tasks. Both dermal and inhalation exposures are considered.

The estimated exposures from defined work tasks are assumed to depend on the amount of active substance handled in the tasks. The estimated exposure is the product of the specific exposure in mg exposure/kg a.s. handled (from Table 2 or 3 as appropriate), the area treated (ha/day) (from Table 4), and the recommended amount of active substance applied (kg/ha).

Dermal exposures are converted into systemic doses using appropriate dermal absorption percentages from the assessment of toxicological data. Inhalation exposures are assumed to be completely absorbed. The exposures for individual tasks are the sums of the dermal exposures and the inhalation exposures. Where an operator can be expected to engage in both mixing/loading and application, exposures from these tasks are summed (in a few cases, as indicated in Table 2, specific exposures cover a combination of mixing/loading and application, in which case this summation exercise is not required). The total exposure is divided by a standard body weight of 60 kg and then compared with the AOEL or AAOEL as appropriate.

Where specific exposures do not assume the use of PPE, the unprotected individual is assumed to wear shorts and a T-shirt. Where the risk assessor is confident that normal work wear will comprise trousers and a long sleeved shirt this can be used as alternative assumption. Where PPE will be used, exposures can be modified to reflect this, by multiplying the appropriate values in Tables 2 and 3 by the protection (i.e. per cent penetration/transfer) factors shown in Table 5

EXAMPLE

An acute exposure assessment for a wettable powder (WP) formulation product containing 500 g a.s./kg recommended to be applied at 1.5 kg product/ha in 200 litres water/ha on wheat, where dermal absorption has been determined as 1% for the product and 10% for the spray dilution.

Amount handled/applied = Area treated/day [20 ha/day] x Application rate of product [1.5 kg/ha] x Concentration of active substance in product [0.5 kg a.s./kg] = 15 kg a.s./day

Estimated exposure during mix/loading without PPE

Dermal exposure = Specific dermal (hand) exposure [48.0 mg/kg a.s. handled] x Amount handled [15 kg a.s./day] = 720 mg/day

Inhalation exposure = Specific inhalation exposure [0.973 mg/kg a.s. handled] x Amount handled [15 kg a.s./day] = 14.6 mg/day

Systemic exposure during mix/loading = Dermal exposure [720 mg/day] x Dermal absorption for product [1%] + Inhalation exposure [14.6 mg/day] = 21.8 mg/day

Estimated exposure during application without PPE

Dermal exposure (hands) = Specific dermal exposure [10.6 mg/kg a.s. applied] x Amount handled [15 kg a.s./day] = 159 mg/day

Dermal exposure (body) = Specific dermal exposure [4.71 mg/kg a.s. applied] x Amount handled [15 kg a.s./day] = 70.65 mg/ day

Inhalation exposure = Specific inhalation exposure [0.0781 mg/kg a.s. applied] x Amount handled [15 kg a.s./day] = 1.17 mg/ day

Systemic exposure during application = {Dermal exposure (hands) [159 mg/day] + Dermal exposure body [70.65 mg/day]} x Dermal absorption for spray dilution [10%] + Inhalation exposure [1.17 mg/kg] = 24.1 mg/day

Total systemic exposure

Total systemic exposure = Exposure during mix/loading [21.8 mg/day] + Exposure during application [24.1 mg/day] = 45.9 mg/day

Standard body weight exposure = 45.9 mg/day/60 kg = 0.77 mg/kg bw/day

Allowance for personal protective equipment (PPE)

Suppose that gloves and RPE (a disposable filtering facepiece, FFP3) are worn during mixing and loading, and a coverall is worn during application, along with gloves when handling contaminated surfaces. The exposure with PPE is estimated as follows:

Estimated exposure during mix/loading with PPE

Dermal exposure = Specific dermal (hand) exposure [48.0 mg/kg a.s. handled] x Amount handled [15 kg a.s./day] x Factor for use of gloves [5%] = 36.0 mg/day

Inhalation exposure = Specific inhalation exposure [0.973 mg/kg a.s. handled] x Amount handled [15 kg a.s./day] x Factor for RPE [10%] = 1.46 mg/day

Systemic exposure during mix/loading = Dermal exposure [36.0 mg/day] x Dermal absorption of product [1%] + Inhalation exposure [1.46 mg/day] = 1.82 mg/day

Estimated exposure during application with PPE

Dermal exposure (hands) = Specific dermal exposure [10.6 mg/kg a.s. applied] x Amount handled [15 kg a.s./day] x Factor for gloves [10%] = 15.9 mg/day

Dermal exposure (body) = Specific dermal exposure [4.71 mg/kg a.s. applied] x Amount handled [15 kg a.s./day] x Factor for coverall [10%] = 7.07 mg/ day

Inhalation exposure = Specific inhalation exposure [0.0781 mg/kg a.s. applied] x Amount handled [15 kg a.s./day] = 1.17 mg/ day

Systemic exposure during application = {Dermal exposure (hands) [15.9 mg/day] + Dermal exposure (body) [7.07 mg/day]} x Dermal absorption for spray dilution [10%] + Inhalation exposure [1.17 mg/day] = 3.47 mg/day

Total systemic exposure

Total systemic exposure = Exposure during mix/loading [1.82 mg/day] + Exposure during application [3.47 mg/day] = 5.29 mg/day

Standard body weight exposure = 5.29 mg/day/60 kg = 0.089 mg/kg bw/day

Table 2: Specific exposures during mixing/loading (potential exposures except where indicated otherwise)

Scenario		Formulation	Standard 75th and 95th Specific Exposure Centiles (mg exposure/kg a.s. mixed/loaded, excepted where stated otherwise)			
			Dermal exposure		Inhalation exposure	
		SOLIDS	75th Centile	95th Centile	75th Centile	95th Centile
1 a (i)	Large scale (e.g. Tractor mounted) equipment	WP, SP	Hands 13.5	Hands 48.0	0.248	0.973
(ii)		GR, FG	Hands under protective gloves 0.00145 Body under coverall 0.00198	Hands under protective glove 0.00688 Body under coverall 0.036	0.0146	0.0784
(iii)		WG, SG	Hands 3.52	Hands 9.20	0.0332	0.140
1 b (i)	Medium scale (e.g. Professional hand-held) equipment	WP, SP	Hands under protective gloves 10.7 mg in-use preparation/min	Hands under protective gloves 39.4 mg in-use preparation/min	1.53	4.06
(ii)		GR, FG	Hand under protective gloves 38.6 Body under coverall 42.1	Hand under protective gloves 94.4 Body under coverall 253	0.260	1.53
(iii)		WG, SG	Hands 56.5	Hands 298	0.039	0.0628
1 c (i)	Small scale (e.g. home garden) equipment	WP, SP	Hands 2.83 mg formulation/min (legs, feet and face can be ignored)	Hands 18 mg formulation/min (legs, feet and face can be ignored)	1.78 mg formulation /m^3	8.01 mg formulation/m^3
(ii)		GR, FG	Hands 2.83 mg/min [legs, feet and face can be ignored]	Hands 4.18 mg/min [legs, feet and face can be ignored]	1.78 mg/m^3	8.01 mg/m^3
(iii)		WG, SG	Hands 2.83 mg/min [legs feet and face can be ignored]	Hands 4.18 mg/min [legs feet and face can be ignored]	1.78 mg/m^3	8.01 mg/m^3

Scenario		Formulation	Standard 75th and 95th Specific Exposure Centiles (mg exposure/kg a.s. mixed/loaded, excepted where stated otherwise)			
			Dermal exposure		Inhalation exposure	
		LIQUIDS	75th Centile	95th Centile	For mixing and loading liquid formulations, there is no need to consider inhalation exposure because it is much lower than dermal exposure	
2 a	Large scale (e.g. Tractor mounted) equipment	SC, EC etc.	Hands 21.7	Hands 118		
b	Medium scale (e.g. Professional hand-held) equipment		Hands 498	Hands 1866		
c	Small scale (e.g. home garden) equipment		Hands when measure using cap 0.03 ml formulation/operation Hands when measure using device other than cap 0.0021 ml formulaiotn/operation	Hands when measure using cap 0.533 ml formulaiton/operation Hands when measure using device other than cap 0.0126 ml formulation/operation		

N.B. For products packaged in water-soluble bags, exposure during mixing and loading is considered negligible.

Table 3: Specific exposures during application

Scenario			Standard 75th and 95th Specific Exposure Centiles (mg exposure/kg a.s. applied, excepted where stated otherwise)			
			Dermal exposure		Inhalation exposure	
			75th Centile	95th Centile	75th Centile	95th Centile
1 a. Outdoor spray/spreading/placement applications, downward spraying						
i	Tractor mounted equipment	Boom sprayers	Hands 0.730 Body 0.917	Hands 10.6 Body 4.71	0.0107	0.0781
ii	Manual equipment	1. Knapsack sprayers	Hands 611 Body 1777	Hands 2856 Body 10949	0.783	5.99
		2. Controlled droplet application/Rotary disc ULV sprayers – spot treatment	Hands inside protective gloves 0.12 mg in-use preparation/min Body 8.08 mg in-use preparation/min Feet inside shoes 0.05 mg in-use preparation/min	Hands inside protective gloves 0.98 mg in-use preparation/min Body 13.8 mg in-use preparation/min Feet inside shoes 0.76 mg in-use preparation/min	24 mg in-use preparation/m^3	26 mg in-use preparation/m^3
		3. Trigger sprayers	Hands 36.1 mg in-use preparation/min Feet legs and face 9.7 mg in-use preparation/min	Hands 68.2 mg in-use preparation/min Feet legs and face 12.4 mg in-use preparation/min	10.5 mg in-use preparation/m^3	19.5 mg in-use preparation/m^3
		4. Pre-pressurised aerosol spray can	Hands 64.7mg formulation/min Feet, legs and face 35.7 mg formulation/min	Hands 156 mg formulation/min Feet, legs and face 45.2 mg formulation/min	35.9 mg formulation/m^3	49.5 mg formulation/m^3
1 b. Outdoor spray/spreading/placement applications, upward spraying						
i	Tractor mounted equipment		Hands 12.3 Body 45.8	Hands 68.3 Body 211	0.0350	0.0946

Scenario			Standard 75th and 95th Specific Exposure Centiles (mg exposure/kg a.s. applied, excepted where stated otherwise)			
			Dermal exposure		Inhalation exposure	
			75th Centile	95th Centile	75th Centile	95th Centile
ii	Manual equipment	1. Knapsack sprayers (including motorised knapsack mistblowers)	Hands 172 Body 645	Hands 1338 Body 2926	0.465	4.21
		2. Hand-held lances	Hands 172 Body 645	Hands 1338 Body 2926	0.465	4.21
1 c. Outdoor spray/spreading/placement applications, application of granules						
i	Tractor-mounted equipment		Hands inside protective gloves 0.000313 Body inside coverall 0.00490	Hands inside protective gloves 0.00115 Body inside coverall 0.0150	0.00110	0.00438
ii	Manual equipment	Medium scale	Hand under protective gloves 38.6 Body under coverall 42.1 [NB these specific exposures include loading as well as application]	Hand under protective gloves 94.4 Body under coverall 253 [NB these specific exposures include loading as well as application]	0.260 [NB this specific exposure includes loading as well as application]	1.53 [NB this specific exposure includes loading as well as application]
		Small scale (e.g. home garden)	Hands 2.83 mg formulation/min Legs, feet and face 2.15 mg formulation/min	4.18 mg formulation/min Legs, feet and face 6.56 mg formulation/min	1.78 mg formulation /m^3	8.01 mg formulation/m^3

Scenario			Standard 75th and 95th Specific Exposure Centiles (mg exposure/kg a.s. applied, excepted where stated otherwise)			
			Dermal exposure		Inhalation exposure	
1 d. Outdoor spray/spreading/placement applications, stem and stump treatments			75th Centile	95th Centile	75th Centile	95th Centile
i	Manual equipment	1. Stump treatment – paintbrush	Hands Water-based 6.32 mg formulation/min Solvent-based 19.5 mg formulation/min	Hands Water-based 17 mg formualtion/min Solvent-based 87.3 mg formulation/min	Inhalation exposure may be ignored	Inhalation exposure may be ignored
			Body Water-based 13.8 mg formulation/minute Solvent-based 30.2 mg formulation/min	Body Water-based 28.1 mg formulation/minute Solvent-based 133 mg formulation/min		
		2. Stem injection	Hands 611	Hands 2856	0.783	5.99
			Body 645	Body 2926		
1 e. Outdoor spray/spreading/placement applications, weed wipers						
i	Tractor mounted equipment		Hands 0.730	Hands 10.6	0.0107	0.0781
			Body 0.917	Body 4.71		
ii	Manual equipment		Hands Water-based 6.32 mg formulation/min Solvent-based 19.5 mg formulation/min	Hands Water-based 17 mg formulation/min Solvent-based 87.3 mg formulation/min	Inhalation exposure may be ignored	Inhalation exposure may be ignored
			Body Water-based 13.8 mg formulation/min Solvent-based 30.2 mg formulation/min	Body Water-based 28.1 mg formulation/min Solvent-based 133 mg formulation/min		

Scenario			Standard 75th and 95th Specific Exposure Centiles (mg exposure/kg a.s. applied, excepted where stated otherwise)			
			Dermal exposure		Inhalation exposure	
2 a. Indoor spray/spreading/placement applications, spraying downward			75th Centile	95th Centile	75th Centile	95th Centile
i	Manual equipment	1. Knapsack sprayer	Hands 611 Body 1777	Hands 2856 Body 10949	0.783	5.99
		2. Hand-held lance	Hands 611 Body 1777	Hands 2856 Body 10949	0.783	5.99
ii	Automated equipment	1. Gantry sprayer	It would normally be assumed that operators are not present.			
		2. Ultra-low volume sprayers	It would normally be assumed that operators are not present.			
2 b. Indoor spray/spreading/placement applications, spraying upward (crops and building fabric)						
i	Manual equipment	1. Knapsack sprayer – crops	Hands 172 Body 645	Hands 1338 Body 2926	0.465	4.21
		2. Knapsack sprayer – structural treatments	Hands inside protective gloves 7.8 mg in-use preparation/min Body 222 mg in-use preparation/min Feet inside shoes 5.4 mg in-use preparation/min	Hands inside protective gloves 191 mg in-use preparation/min Body 2100 mg in use preparation/min Feet inside shoes 260 mg in-use preparation/min	76 mg in-use preparation/m^3	198 mg in-use preparation/m^3
		3. Hand-held lance – crops	Hands 172 Body 645	Hands 1338 Body 2926	0.465	4.21
		4. Hand-held lance – structural treaments	Hands inside protective gloves 7.8 mg in-use preparation/min Body 222 mg in-use preparation/min Feet inside shoes 5.4 mg in-use preparation/min	Hands inside protective gloves 191 mg in-use preparation/min Body 2100 mg in-use preparation/min Feet inside shoes 260 mg in-use preparation/min	76 mg in-use preparation/m^3	198 mg in-use preparation/m^3

2 c. Indoor spray/spreading/placement applications, dust applications			75th Centile	95th Centile	75th Centile	95th Centile
I	Manual equipment		Hands 2.83 mg formulation/min Legs, feet and face 2.15 mg formulation/min	Hands 4.18 mg formulation/min Legs, feet and face 6.56 mg formulation/min	1.78 mg formulation/m^3	8.01 mg formulation/m^3
2 d. Indoor spray/spreading/placement applications, granule applications						
I	Manual equipment		Hand under protective gloves 38.6 Body under coverall 42.1 [NB these specific exposures include loading as well as application]	Hand under protective gloves 94.4 Body under coverall 253 [NB these specific exposures include loading as well as application]	0.260 [NB this specific exposure includes loading as well as application]	1.53 [NB this specific exposure includes loading as well as application]
3 a. Treatments of seed, seedlings, bulbs , tubers etc., dipping						
I	Mechanical		Hands inside protective gloves 1080 mg in-use preparation/cycle Body 8570 mg in-use preparation/cycle Feet inside shoes 501 mg in-use prepartion/cycle (NB 1 cycle typically 180 minutes)	Hands inside protective gloves 2410 mg in-use preparation/cycle Body 32200 mg in-use preparation/cycle Feet inside shoes 2670 mg in-use prepartion/cycle (NB 1 cycle typically 180 minutes)	1.9 mg in-use preparation /m^3	5.5 mg in-use preparation /m^3
Ii	Manual		Hands 1.46 mg/basket [Assuming one basket contains 35 kg bulbs]	Hands 4.1 mg/basket [Assuming one basket contains 35 kg bulbs]	Inhalation exposure may be ignored	Inhalation exposure may be ignored

Table 4: Area treated per day

	Low crops		High crops	
	Hand-held equipment	**Vehicle mounted equipment**	**Hand-held equipment**	**Vehicle mounted equipment**
Area treated per day (ha/day)	1	20	1	8

Table 5: Engineering/technical controls and personal protective equipment (PPE)

Technical control/PPE item		**Protection factor (by which exposure in absence of protection should be multiplied)**	**Specific exposure value affected**
Closed cabs with positive air pressure and functioning filtration units		10%	Broadcast air-assisted applications only Dermal and inhalation exposure
Protective (chemical resistant) gloves		Operators Liquids 10% Operators Solids 5%	Dermal exposure – hands only
Long sleeved shirt and trousers		Operators 10%, Workers 20%	Dermal exposure – body only
Protective coverall		Operators 10% Workers 20%	Dermal exposure – body only
RPE mask type	**Filter type**		
Filtering half masks	**FP1**	25%	Inhalation exposure
	FFP2	10%	Inhalation exposure
	FFP3	10%	Inhalation exposure
Half or quarter mask and filter	**P1**	25%	Inhalation exposure
	P2	10%	Inhalation exposure
	Gas	10%	Inhalation exposure
	GasXP3	10%	Inhalation exposure
	P3	10%	Inhalation exposure
Filtering half masks without inhalation valves	**FMP1**	25%	Inhalation exposure
	FMP2	10%	Inhalation exposure
	FMGasX	10%	Inhalation exposure
	FMGasXP3	10%	Inhalation exposure
	FMP3	10%	Inhalation exposure
Valved filtering half masks	**FFGasXP1**	25%	Inhalation exposure

Table 5: Engineering/technical controls and personal protective equipment (PPE) (cont.)

Technical control/PPE item	Protection factor	Specific exposure value affected	Technical control/PPE item
	FFGasX	10%	Inhalation exposure
	FFGasXP2	10%	Inhalation exposure
	FFGasXP3	10%	Inhalation exposure
Full face masks and filter	**P1**	25%	Inhalation exposure
	P2	10%	Inhalation exposure
	Gas	5%	Inhalation exposure
	GasXP3	5%	Inhalation exposure
	P3	2.5%	Inhalation exposure
Powered filtering devices incorporating helmets or hoods	**TH1 all types**	10%	Inhalation exposure
	TH2 all types	5%	Inhalation exposure
	TH3 (semi) hood/blouse	2.5%	Inhalation exposure
Power assisted filtering devices incorporating full, half or quarter masks	**TM1 all types**	10%	Inhalation exposure
	TM2 all types	5%	Inhalation exposure
	TM3 (half face) particle, gas or combined filters	5%	Inhalation exposure
	TM3 (half face) gas or combined filters	2.5%	Inhalation exposure

4.2. Worker exposure

Exposure should be estimated for activities that could entail significant contact with treated crops, either through re-entry of a treated area soon after application (e.g. for crop inspection/harvesting activities) or through other activities such as packaging, sorting and bundling.

The main routes of exposure during post-application activities are dermal and inhalation, and the sources of exposure are contact with foliage (here used to include fruit as well as leaves), soil and possibly dust. Oral exposure may occur secondarily to dermal exposure, through hand to mouth transfer. However, for workers, maximum potential exposure by this route is generally assumed to be negligible in comparison with that via skin and inhalation.

Most crop maintenance and harvesting activities include frequent contacts with the foliage of the crop. Therefore, dermal exposure is considered to be the most important exposure route during these re-entry activities. The level of resultant exposure (for a given activity) depends on the amount of residue on foliage, the intensity of contact with the foliage and the duration of contact.

Inhalation exposure may be to vapour and/or airborne aerosols (including dust). After outdoor application of PPPs, there will be more rapid dissipation of vapour and aerosols, leading to lower inhalation potential than from indoor treatments, such as those made to protected crops grown in glasshouses.

Some scenarios involving exposure to PPPs (or relevant metabolites, degradation and reaction products) through dislodgeable foliar residues (DFR) may also entail exposure to soil-borne residues (e.g. harvesting leeks or weeding in a leafy crop). In these situations, estimates of dermal exposure should include any exposure through soil contact as well as that arising from contact with foliage.

There are also some re-entry situations where exposure to soil-borne residues occurs in the absence of contact with treated foliage – for example, workers using compost treated with an insecticide, or during manual harvesting of root crops.

When the first tier methods described in this section are applied, the same estimates of worker exposure are used for both acute and longer term risk assessment. However, if worker exposures are estimated from ad hoc data, then the exposure estimates used for acute and longer term risk assessments will normally be different (see Section 3, Step Three).

To derive a total estimate of worker exposure, it is necessary to sum the components of exposure from each relevant source and route. The methods for estimating exposures assume that the worker will wear shorts and a T-shirt. Where the risk assessor is confident that normal work wear will comprise trousers and a long sleeved shirt, this can be used as alternative assumption. If it is considered that workers can be expected reliably to use personal protective equipment, then allowance for this can be made in exposure estimation by application of protection factors as specified in Table 5.

Dermal exposure

Dermal exposure from contact with residues on foliage should be estimated as the product of the dislodgeable foliar residue (DFR) (see below), the transfer coefficient (TC) (from Table 6 below), and the task duration (T):

Potential dermal exposure (PDE) in µg/day = DFR [µg/cm^2] x TC [cm^2/h] x T [h/day]

The default value for time of exposure should be taken as 8 hours for harvesting and 2 hours for crop inspection.

The amount of residue on foliage depends on several factors, including the application rate, application efficiency (how much reaches and is retained on the target), crop type and the amount of foliage (leaf area index). Dissipation of residues on crop foliage over time depends on the physical and chemical properties of the applied PPP, and also on environmental conditions. Where experimentally determined dislodgeable foliar residue data are not available, the initial DFR (DFR0) in a first tier assessment should assume 3 µg active substance/cm^2 of foliage/kg a.s. applied/ha.

Allowance may be introduced for dissipation (decay) of the active substance on the foliage if the exact nature of the dissipation over time is known. If no data are available on the degree of dissipation, it may be assumed that active substances which are organic chemicals, and for which there is evidence of breakdown by photolysis or hydrolysis in soil or water, will dissipate with a half-life of 30 days. For other categories of active substance DFR0 (i.e. the residue available directly after application (when dry)) should be used for calculations.

A realistic worst-case is to consider re-entry after the final treatment has been made to a crop. Therefore, where approval is sought for multiple treatments, the assessment should consider the potential accumulation of DFR from successive treatments. Where an active substance is assumed to dissipate with a half-life of 30 days, the dissipation should be taken into account by application of an appropriate multiple application factor (MAF), examples of which are given in Table 6.

Table 6: Multiple application factors, assuming a dissipation half-life of 30 days

Interval between applications (days)	Number of applications											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
7	1.0	1.9	2.6	3.2	3.7	4.2	4.5	4.9	5.1	5.4	5.6	5.7
10	1.0	1.8	2.4	2.9	3.3	3.6	3.9	4.1	4.2	4.4	4.5	4.5
14	1.0	1.7	2.2	2.6	2.9	3.1	3.2	3.3	3.4	3.5	3.5	3.5

To convert estimated dermal exposures to corresponding systemic exposures, they should be multiplied by a dermal absorption factor, derived from the toxicological assessment. The value used for the dermal absorption factor should be the higher of the values for the product, and for the in-use dilution.

Transfer coefficient

The transfer of residues from the plant surface to the clothes or skin of the worker is assumed to be independent of the product applied, the level of exposure depending on the intensity and duration of contact with the foliage. This is determined by the nature and duration of the activity during re-entry. Therefore, it is possible to group various crop habitats and re-entry activities. The indicative TC values in Table 7 should be used in first tier assessments of potential dermal exposure for the four harvesting scenarios specified. The TC values in the third column of Table 7 assume that harvesting is performed with bare hands, and that dermal exposure to the body is reduced ten-fold by clothing covering the arms, body and legs. In situations where T-shirts and/or shorts are worn, exposures may be higher than these estimates, and potential exposure should be estimated using the values in the fourth column of the Table.

Table 7: Transfer coefficients

Crop	Nature of task	Main body parts in contact with foliage	Transfer Coefficient (cm^2 / hr) assuming arm, body and legs covered	Transfer Coefficient (cm^2 / hr) total potential exposure
Vegetables	**Reach / Pick**	**Hand and body**	2500	5800
Tree fruits	**Search / Reach / Rick**	**Hand and body**	4500	22500
Strawberries	**Reach / Pick**	**Hand and forearm**	3000	3000
Ornamentals	**Cut / Sort / Bundle / Carry**	**Hand and body**	5000	14000

These TC values may be extrapolated to other re-entry scenarios, where the intensity and duration of contact with the foliage is judged to be similar.

Inhalation exposure

Potential exposure from a volatile PPP decreases with time as the concentration of the active ingredient is reduced, either by absorption into the plant, degradation, or loss to the environment. Although in many cases inhalation exposure will contribute less to total potential exposure than that by the dermal route, task-specific inhalation factors should be used for first tier exposure assessments relating to harvesting of ornamentals and to re-entering greenhouses within 8-16 hours after treatment. Inhalation exposure for this re-entry scenario may be predicted by the following:

Potential inhalation exposure [mg a.s./hr inhaled] = Application rate [kg a.s./ha] x Task Specific Factor [ha/hr x 10^{-3}]

where Task Specific Factors are as set out in Table 8.

Table 8: Indicative inhalation Task Specific Factors for protected crops

Task	Task Specific Factor (ha/hr x 10^{-3})
Cutting ornamentals	0.1
Sorting and bundling ornamentals	0.01
Re-entering greenhouses after low-volume-mist application	0.03
Re-entering greenhouses after roof fogger application	0.15

This approach may be used for non-volatile pesticides, where levels of inhalation exposure (vapour and dust) would be expected to be low in comparison with dermal exposure. Additional data may be required to estimate inhalation exposures for products applied as aerosols and for volatile pesticides.

Residues in Soil / Compost

In most situations the contribution of soil residues to the total exposure is expected to be significantly less than that from dislodgeable foliar residues. Where there is concomitant exposure to dislodgeable foliar residues, exposure from contact with soil residues can be ignored.

For situations in which exposure to soil-borne residues occurs in the absence of contact with treated foliage, an estimate of potential (dermal) exposure may be derived by considering the concentration in the treated soil, together with soil dermal adherence data. As a default, the hand soil loading for a worker should be taken as 0.44 mg/cm^2. A default value for inhalation exposure should be estimated assuming a total inhalation dust exposure of 98.6 mg/m^3.

For handling compost after admixture treatment, the concentration in compost should be derived from the label-recommended application rate for the admixture of product with compost. For other situations, soil concentration values should be sought from the fate and behaviour evaluation: for acute assessment use the highest initial PEC Soil value; if chronic exposure is a concern, an appropriate time weighted average (TWA) value may be used. Where values are not available from the fate and behaviour evaluation, soil concentrations for field applications can be estimated assuming: the distribution is limited to the top 5 cm layer; or 20 cm when cultivation follows the application; soil density is 1.5 g/cm^3; and 100% of the applied dose reaches the soil surface (where ground cover is present, a minimum of 50% of the applied dose reaches the soil surface). In the case of home garden exposures, the more protective assumption that the material is distributed through the uppermost 1 cm should be used.

Potential dermal exposure (µg/day) = hand area (820 cm^2) x hand soil loading (mg soil/cm^2) x concentration in soil (µg substance/mg soil).

Potential inhalation exposure (µg substance/day) = breathing rate (m^3/hr/kg bw) x airborne soil dust concentration (mg/m^3) x soil concentration (µg substance/mg soil) x duration hours

where concentration in soil (µg substance/mg soil) is application rate kg/ha x 10 / depth (1, 5 or 20 cm) x density (1500 mg/cm^3)

4.3. Resident exposure

For exposure through treatment of nearby crops, four pathways of exposure should be considered, and the potential exposures from each relevant pathway summed:

1) Spray drift

The exposures from spray drift should be taken as:

Dermal exposure x Dermal absorption percentage + Inhalation exposure

where the dermal absorption percentage is that for the in-use dilution taken from the toxicological evaluation, and dermal and inhalation exposures are as shown in Table 9.

Table 9: Dermal and inhalation exposures for residents

Method of application	Dermal exposure		Inhalation exposure	
	Adults	**Children**	**Adults**	**Children**
Arable/ground boom applications	1.16 ml spray dilution /person	1.16 ml spray dilution /person	0.00715 ml spray dilution /person	0.00715 ml spray dilution /person
Orchard/broadcast air assisted applications	5.20 ml spray dilution /person	5.20 ml spray dilution /person	0.00207 ml spray dilution /person	0.00207 ml spray dilution /person

2) Vapour

For moderately volatile compounds (vapour pressure ≥ 0.005 Pa and < 0.01 Pa), exposures should be calculated assuming a default concentration in air of 15 µg/m^3 and daily average breathing rates resulting in exposures of 3.5, 4.1, 6.6, 10.5, 16.1 and 17.1 µg/kg bw/day for adults, 11 to <16 year olds, 6 to <11 year olds, 3 to <6 year olds, 1 to <3 year olds, and <1 year olds, respectively.

For compounds with low volatility (vapour pressure <0.005 Pa), exposures should be calculated assuming a default concentration in air of 1 µg/m^3 and daily average breathing rates resulting in exposures of 0.23, 0.27, 0.44, 0.70, 1.07 and 1.14 µg for adults 11 to <16 year olds, 6 to <11 year olds, 3 to <6 year olds, 1 to <3 year olds, and <1 year olds, respectively.

3) Surface deposits

Exposure from surface deposits for children aged less than 1 year should be calculated as:

Dermal exposure + Hand to mouth transfer + Object to mouth transfer

Where for products applied in liquid sprays,

Dermal exposure = 1.8 x Application rate (kg/ha) x Drift percentage x Dermal absorption percentage

Hand to mouth transfer = 0.095 x Application rate (kg/ha) x Drift percentage x Oral absorption percentage

and

Object to mouth transfer = 0.05 x Application rate (kg/ha) x Drift percentage x Oral absorption percentage.

Dermal and oral absorption percentages should be taken from the toxicological evaluation. For the dermal absorption percentage, use the higher of the values for the undiluted product and the in-use dilution.

Values for drift percentage should be taken from Tables 10 or 11, as appropriate.

Table 10: Drift percentages for commercial crops

Crop (distance 10m)	Drift percentage (90th centile)
Field crops	2.9
Fruit tree crops, early (without leaves)	11.8
Fruit tree crops, late (with leaves)	3.6
Grapes	1.2
Hops	5.8
Vegetables, ornamentals and small fruit < 50 cm	2.9
Vegetables, ornamentals and small fruit > 50 cm	1.2

Table 11: Drift percentages for non-professional use in gardens and allotments

Crop, distance	Drift percentage (90th centile)
Low crops (<50 cm), 1m	0.42
Trees, late (with leaves), 3m	3.5
Trees, early (without leaves) (≤ 2 m in height), 3m	13.5
Trees, early (without leaves) (> 2 m in height), 3m	38.1
Vegetables, berry fruits, ornamentals (> 50 in height), 3m	0.72

For children aged 1 to <3 years, dermal exposure should be calculated by replacing the coefficient of 1.8 in the above equation with 2.3. Hand to mouth and object to mouth exposure is the same as for less than 1 year olds.

For older children and adults, exposure via hand to mouth and object to mouth transfer can be ignored. For products applied as sprays, dermal exposure for children aged 3 to <6, 6 to <11, and 11 to <16 years and for adults should be calculated by replacing the coefficient 1.8 in the above equation with 3.1, 4.3, 6.4, and 7.3, respectively.

For products applied as granules the dermal exposure, hand to mouth and object to mouth transfers are calculated with coefficients with values 1/5th of the values given above. Drift from applications of granules should be assumed to be 3%.

4) Entry into treated crops

For entry into crops, only dermal exposure need be considered. Use the same method and values for DFR and transfer coefficient as for workers, with an assumption of 15 minutes exposure per day.

For entry onto treated lawns, exposures should be calculated as for surface deposits (see above) but taking the drift percentage as 100%.

4.4. Bystander exposure

For exposure through treatment of crops, four pathways of exposure should be considered, and the potential exposures from each relevant pathway summed:

1) Spray drift

The exposures from spray drift should be taken as:

Dermal exposure x Dermal absorption percentage + Inhalation exposure

where the dermal absorption percentage is that for the in-use dilution taken from the toxicological evaluation, and dermal and inhalation exposures are as shown in Table 12.

Table 12: Dermal and inhalation exposures for bystanders

Method of application	Dermal exposure		Inhalation exposure	
	Adults	Children	Adults	Children
Arable/ground boom applications	5.33 ml spray dilution/person	5.33 ml spray dilution/person	0.022 ml spray dilution/person	0.022 ml spray dilution/person
Orchard/broadcast air assisted applications	285 ml spray dilution/person	285 ml spray dilution/person	0.00435 ml spray dilution /person	0.00435 ml spray dilution /person

2) Vapour

For moderately volatile compounds (vapour pressure ≥ 0.005 Pa and < 0.01 Pa), exposures should be calculated assuming a default concentration in air of 15 µg/m^3 and hourly average breathing rates resulting in exposures of 3.5, 4.1, 6.6, 10.5, 16.1 and 17.1 µg/kg bw/day for adults, 11 to <16 year olds, 6 to <11 year olds, 3 to <6 year olds, 1 to <3 year olds, and <1 year olds, respectively.

For compounds with low volatility (vapour pressure <0.005 Pa), exposures should be calculated assuming a default concentration in air of 1 µg/m^3 and daily average breathing rates resulting in exposures of 0.23, 0.27, 0.44, 0.70, 1.07 and 1.14 µg for adults 11 to <16 year olds, 6 to 11 year olds, 3 to <6 year olds, 1 to <3 year olds, and <1 year olds, respectively.

3) Surface deposits

Exposure from surface deposits for children aged less than 1 year should be calculated as:

Dermal exposure + Hand to mouth transfer + Object to mouth transfer
where
Dermal exposure = 3.6 x Application rate (kg/ha) x Drift percentage x Dermal absorption percentage

Hand to mouth transfer = 0.095 x Application rate (kg/ha) x Drift percentage x Oral absorption percentage
and
Object to mouth transfer = 0.05 x Application rate (kg/ha) x Drift percentage x Oral absorption percentage.

Dermal and oral percentages should be taken from the toxicological evaluation. For the dermal absorption percentage, use the higher of the values for the undiluted product and the in-use dilution.

Values for drift percentage should be taken from Tables 10 or 11, as appropriate.

For children aged 1 to <3 years, dermal exposure should be calculated by replacing the coefficient of 3.6 in the above equation with 4.6. Hand to mouth and object to mouth is the same as for less than 1 year olds.

For older children and adults, exposure via hand to mouth and object to mouth transfer can be ignored. Dermal exposure for products applied as sprays for children aged 3 to <6, 6 to <11, and 11 to <16 years and for adults should be calculated by replacing the coefficient of 3.6 in the above equation with 6.1, 8.6, 12.6, and 14.5, respectively,

with drift percentages derived from Tables 10 or 11, as appropriate.

For products applied as granules the dermal exposure, hand to mouth and object to mouth transfers are calculated with coefficients with values 1/5th of the values given above. Drift from agricultural applications of granules should be assumed to be 3%.

4) Entry into treated crops

For entry into crops, only dermal exposure needs be considered. Use the same method and values for DFR and transfer coefficient as for workers, with an assumption of 15 minutes exposure per day.

For entry onto treated lawns, exposures should be calculated as for surface deposits (see above) but taking the drift percentage as 100%.

When estimating the maximum exposure that a bystander might reasonably be expected to incur in a single day by higher tier methods, account must be taken of the possibility that a bystander could be a resident.

GLOSSARY

Acceptable Operator Exposure Level (AOEL): The reference value against which non-dietary exposures to pesticides are currently assessed. It is intended to define a level of daily exposure throughout a spraying season, year on year, below which no adverse systemic health effects would be expected. The AOEL is normally derived by applying an assessment factor (most often 100) to a No Observed Adverse Effect Level (NOAEL) (corrected if appropriate for incomplete absorption) from a toxicological study in which animals were dosed daily for 90 days or longer. Less often, the critical NOAEL comes from a study with a shorter dosing period (e.g. a developmental study).

Actual dermal exposure: Exposure to the skin that would occur in the presence of clothing and/or personal protective equipment.

Acute Acceptable Operator Exposure Level (AAOEL): A term used in this report to describe a reference value against which acute non-dietary exposures (i.e. those that might be incurred in a single day) could be assessed. This would be relevant only to those plant protection products for which such exposures might produce significant toxicity.

Ad hoc exposure assessment: An assessment of exposures incorporating data specific to a one or more uses of a particular plant protection product, which is considered to provide a more reliable estimate of potential exposure than the normal first-tier approach using more generic data.

.**Aggregate risk assessment**: Risk assessment that takes into account all pathways and routes of exposure to a single chemical

Bystanders: Persons who are located within or directly adjacent to the area where PPP application or treatment is in process or has recently been completed; whose presence is quite incidental and unrelated to work involving PPPs, but whose position might lead them to be exposed; and who take no action to avoid or control exposure.

Centile: A value that partitions a distribution of measurements at a specific point when they are ranked in ascending order of magnitude. For example, the 75th centile from a sample of measurements is a value that is $\geq$ 75% of the measurements and $\leq$ 25% of the measurements.

Cumulative risk assessment: Risk assessment for combined exposure to two or more chemicals by all relevant pathways and routes.

Dislodgeable foliar residue: The residue of a pesticide following deposition on foliage or fruit, which can be transferred to a worker or bystander through contact with the foliage or fruit.

Drift (expressed as % areic mass): The deposition of a substance per unit receiving (non target) surface, expressed as a percentage of the amount applied per unit area target surface. For example, at 1% drift, the deposition per square metre surface water is 1 mg when the dosage is 1 kg per ha (100 mg per square metre)

Engineering controls: Methods of reducing exposure to pesticides (or other hazardous agents) through appropriately designed equipment (e.g. a closed tractor cab with air filtration).

Filtration unit (on a tractor cab): A device that removes pesticide residues from the air that enters a closed tractor cab.

Formulation: The composition of a pesticide product as supplied.

Hand to mouth transfer: Transfer of pesticide residues from contaminated surfaces to the mouth via the hand – potentially a significant pathway of exposure, especially in infants.

In-use preparation: The form in which a pesticide is applied after any dissolution, dilution or mixing of the product as supplied.

Log-normality: The nature of a statistical distribution in which the logarithms of individual measurements have a Gaussian or "normal" distribution. For a given scenario, measurements of individual exposures often have a log-normal distribution.

Non-professional operators: People who apply plant protection products non-occupationally – for example, in their gardens.

Normalisation (of exposure): Adjustment of exposure estimates to take account of the amount of a product handled or applied.

Object to mouth transfer: Transfer of pesticide residues to the mouth from contaminated objects through placement of the object in the mouth – a pathway of exposure of greatest importance in infants.

Operators: Persons who are involved in activities relating to the application of a plant protection product (PPP); such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the plant protection product, and emptying/cleaning the machinery/containers after use. Operators may be either professional (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users).

Parametric: Relating to a summary characteristic of the (theoretically infinite) population from which a sample is derived. Population parameters can be estimated from corresponding sample statistics. For example, a sample mean may provide an estimate of the mean of the population from which the sample was derived.

'Para-occupational exposure': Exposure of other members of a professional operator's household that occurs as a consequence of transfer of residues from his clothing or person, in the home.

Personal protective equipment: Certified equipment worn by an operator or worker that is designed to reduce hazardous exposures (e.g. gloves, coveralls, face masks).

Potential dermal exposure: Exposure to the skin that would occur in the absence of clothing or personal protective equipment.

Product: A pesticide preparation as supplied. It includes not only the active substance(s), but also co-formulants such as emulsifiers, solvents and safeners.

Residents: Persons who live, work or attend school or any another institution adjacent to an area that is or has been treated with a PPP; whose presence is quite incidental and unrelated to work involving PPPs but whose position might lead them to be exposed; who take no action to avoid or control exposure; and who might be in the location for 24 hours per day.

Saliva extraction percentage: The fraction (expressed as a percentage) of pesticide extracted from a contaminated hand or object via saliva.

Systemic exposure: Exposure of organs and tissues that occurs following absorption and distribution of a chemical in the body.

Task-specific factor (worker re-entry): A factor (with units ha/hr x 10^{-3}) relating to a specified task carried out by a re-entry worker (e.g. cutting ornamentals). It is multiplied by the rate at which a pesticide was applied to derive an estimate of potential exposures through inhalation.

Transfer coefficient: The rate at which dislodgeable foliar residues can be transferred to a worker during a specified activity (expressed in terms of the area of contaminated foliage or fruit from which residues are transferred per hour).

Turf transferable residue: Equivalent to a dislodgeable foliar residue for residues of plant protection products deposited on lawns.

Workers: In the context of this opinion, the term worker refers to persons who, as part of their employment, enter an area that has been treated previously with a plant protection product, or who handle a crop that has been treated with a plant protection product.