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# Human acute exposure assessment of pesticides in fruits and vegetables

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**CONTENTS**

## SUMMARY

The "point estimate" approach is widely used to assess the exposure to acutely toxic pesticides. This method was primarily set up for the authorisation of pesticides, and takes into account the effect of processing on pesticide residue levels and the variability of residue levels between units within one composite sample. It is a method used worldwide because it requires minimal resources and data to calculate, and because it is fairly easy to understand. However, it was recognised during meetings of different organisations and committees (e.g. CODEX) that the method has its drawbacks, of which the most important are the consideration of only one commodity at a time and the use of one high level for both consumption and residue level. Another problem of using this method is the availability of information on processing effects and variability. Information on processing is very limited. Some information can be derived from the literature or from reports of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). However, due to the large amount of pesticide-commodity combinations possible and the different types of processing applicable to one product, this information will inevitably be limited. The availability of information on variability is however even more limited. Hardly any data is available on variability, resulting often in the application of conservative default variability factors. It is unclear how to deal with these uncertainties in the "point estimate" approach. In this report we chose two options that defined the boundaries between which the "point estimate" outcome could fluctuate. One the most 'optimistic' situation in which processing is included and variability is ignored and secondly the most "worst case" situation in which processing effects are ignored and variability is incorporated using the default value. To calculate the exposure using these options we selected five pesticides that were known to be acutely toxic. The results showed clearly that ignoring processing and applying a default value for variability resulted in exposures exceeding the acute reference dose (ARfD). The 'optimistic' approach led to no exposures higher than the ARfD. It was clear from these results that the "point estimate" outcome was influenced by assumptions related to processing and variability. In authorisation of pesticides this may not be a problem, because it may stimulate manufacturers to produce data to eliminate these uncertainties. However, in exposure assessment using monitoring data these uncertainties may lead to wrong risk decisions.

A second completely different method to estimate the acute exposure to pesticides is the probabilistic approach, introduced in exposure assessment in recognition of the drawbacks of the "point estimate". This method considers the whole diet and can thus address the intake of one pesticide through the consumption of more than one product. Furthermore it is able to address uncertainties in processing effects and variability in a more realistic way, and accounts for the whole range of consumption (including non-consumers) and residue levels (including samples below reporting level). The probabilistic approach was also used to calculate the exposure to the five pesticides mentioned earlier. The results showed that of the pesticide exposures exceeding the ARfD according to the "point estimate" only chlorpropham also exceeded the ARfD when using the probabilistic approach. We showed however that this was due to the presence of one elevated residue level in the monitoring database, suggesting use of the pesticide during potato treatment not in accordance with Good Agricultural Practice (GAP).

It can be concluded that the probabilistic approach allows a more realistic evaluation of exposures compared to the "point estimate" approach. It is a method that better simulates what happens in real life by including the whole range of consumption levels (including non-consumers) and residue

To overcome the described limitations of the "point estimate" approach, the probabilistic approach has been introduced in dietary exposure to pesticides.

### *1.1.2 Probabilistic approach*

The probabilistic approach (or Monte Carlo method) has been recognised by different organisations and committees as a useful technique in performing acute dietary intake estimates of pesticide residues (SCP 1998, SSC 2000, The Pesticides Safety Directorate 1998a, WHO 1997). The advantage of this approach above the "point estimate" method is that it takes into account the variation in pesticide residue levels (including levels below reporting level), in food consumption (including non-consumers) and in body mass. Using this information it produces a dietary intake distribution that shows the probability, magnitude and range of dietary exposure levels. It can also assess the exposure to a pesticide residue through the consumption of more than one food item. Furthermore, it has the possibility of incorporating other relevant and available information important in exposure assessment into the analyses and the uncertainties / variation therein. It was recognised that the development of this method relies on well-defined consumption and residue databases, which may not be available in many countries (FAO/WHO 1997, The Pesticides Safety Directorate 1998a).

In the USA the use of the probabilistic approach to estimate the short-term exposure to acute toxic compounds is accepted, but not yet in Europe. Currently however there are several developments within the EU that may stimulate the use of the probabilistic approach on this continent in the near future. One is the EU-project MonteCarlo in which a probabilistic model is developed to calculate the acute exposure to pesticides, additives and nutrients. Within this project RIKILT is responsible for the modelling of pesticide exposure through the diet. Another project is the FOSIE (Food Safety in Europe) project which deals with the procedures required for the correct use of probabilistic models in exposure assessment and focuses on principles and guidelines for the use of these models. Furthermore, at the RIKILT the programme 'Monte Carlo Risk Analysis' (MCRA) has been developed to assess the acute dietary exposure to pesticides using the probabilistic approach. This programme has been used, among others, in the authorisation of pesticides by the Dutch Board for the Authorisation of Pesticides (e.g. CTB 2000). All these initiatives are very helpful and may, in the near future, lead to the acceptance of the use of the probabilistic approach for exposure assessment purposes within Europe.

## 1.2 Parameters needed to estimate the dietary exposure to pesticides

To estimate the short-term exposure to acute toxic pesticides, different parameters need to be addressed. The main issues recognised are processing, variability in residue levels between units of a composite sample and the level assigned to samples with concentrations below the reporting level (LOR; (Crossley 2000, Petersen 2000, U.S. Environmental Protection Agency 2000b). We will discuss these three issues below. Other parameters that are of course important for an accurate exposure assessment are the availability of representative food consumption data and residue levels in fruits and vegetables. These parameters are outside the scope of this project and will therefore not be addressed.

### *1.2.1 Processing*

Pesticide analyses are mainly performed in raw agricultural commodities (RAC), including peel and (other) non-edible parts. Processed or prepared foods are either not monitored or the number of samples is very small. The reason for this is that in legislation limits of residues are mainly set for RACs. RACs are however not eaten as such, but undergo some form of food processing before actual consumption. For example, most vegetables are washed and cooked and non-edible parts are removed, and fruits are often washed, peeled and/or processed into juices or sauces. Processing affects pesticide levels (mainly reduction) as is evident from numerous studies (Celik *et al.* 1995, Holland *et al.* 1994, Petersen *et al.* 1996, Ritchey 1981, Zabik *et al.* 2000), and from the pesticide evaluations reported yearly by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR: e.g. (FAO/WHO 2000, FAO/WHO 2001b). The eventual effect of processing depends on many factors. These include the initial concentration of the residue, the inherent properties of the pesticide itself (e.g. water solubility, systemic versus non systemic), as well as the product to which it has been applied (Burchat *et al.* 1998). Neglecting the effect of processing may often lead to highly exaggerated estimates of exposure but may at times also underestimate chemical levels found in foods as consumed (e.g. dried products as raisins).

To apply processing factors into the exposure assessment, information should be available on the effect of processing on pesticide levels. Some information can be obtained from the literature and from JMPR evaluation reports. However, due to the large amount of pesticides authorised for use in agriculture and the different forms of processing applicable to one product, the amount of detailed information available on the influence of food processing on specific pesticide-commodity combinations is limited. Another source of information may be the manufacturer of the pesticide. This manufacturer, requesting authorisation of a certain pesticide, is obliged to produce information on food processing if relevant. However, this information is mainly confidential and even if available many gaps will certainly remain. Furthermore, conditions under which the effects of processing on a chemical level are evaluated may not always reflect accurately the practice in real life.

Because of the (mainly reducing) effect of processing on pesticide levels, it is relevant to have information on processing practices from food consumption surveys. Unfortunately, it is not common practice in this type of survey to inform about food processing practices. For example, if an apple has been washed or peeled before consumption. In the absence of this type of information it may be possible to make general assumptions about processing, like 50% of the population peels the apple before consumption. This type of assumption can be addressed in the probabilistic approach, as well as assumptions about different types of processing for one commodity within one population. For example, 50% of the population consumes apple after peeling, 25% only washes apple before consumption and 25% eats apple in the form of juice. In the "point estimate" approach these assumptions can not be made. In this approach all persons either consume a product after one type of processing or nobody does. For example, apple is always consumed without peel or not.

It is evident that processing is an important factor that needs to be addressed in acute exposure assessment. However, the use of this variable is seriously hampered by lack of information on specific processing factors and on processing practices as they occur in real life.

*1.2.2 Unit variability*

Monitoring measurements are typically performed in composite samples of RACs (e.g. peppers are analysed in samples consisting of 20 individual commodities each). It was demonstrated that pesticides may be unequally distributed within such a sample (Hamey and Harris 1999, Harris 2000, The Pesticides Safety Directorate 1998a). Studies showed that individual units within a composite sample may contain higher residue levels than the level analysed in the composite sample would have indicated (Ambrus 2000, Andersson 2000, Earl *et al.* 2000, The Pesticides Safety Directorate 1998b). To account for this phenomenon, the term variability was introduced in acute exposure assessment of pesticides.

In the "point estimate" approach, variability is defined as the ratio of the maximum or the 97.5$^{th}$ percentile of residue level of an individual commodity to the mean or median composite sample residue level (Harris *et al.* 2000, The Pesticides Safety Directorate 1998b). Variability was only defined for products with a unit weight larger than 0.025 kg (Crossley 2000). For unit weights lower than 0.025 kg is was assumed that the composite residue data reflect the residue levels in the food commodity as consumed. Due to insufficient data from measurements on individual units, the use of default variability factors was recommended (Appendix 1; (FAO/WHO 2001b)). These default values are based on the (conservative) assumption that all residues in a composite sample may be present in one unit. When sufficient data are available on residue levels in each unit to calculate a more realistic variability factor for a commodity, the calculated value should replace the default value (FAO/WHO 2001b). Guidelines on how to apply variability in a probabilistic approach are not available.

Studies in which the variability within a composite sample is studied are not standardised as yet. Studies are performed on batches of individual commodities sampled from different locations, such as wholesalers and retailers, local and central markets, points of entry (for imported products) and processing industries, all as part of monitoring programmes. Variability studies may also be performed as part of field trials. All these studies result in variability factors that may be more or less representative of variability factors applicable to ready-to-eat products. The within-batch variability obtained from field trials may be smaller than that found in batches available for sale. Field trials are normally carried out under controlled circumstances, resulting in residue levels within a batch that are likely to be more uniform than that following commercial application of pesticides. When studied at the level of retailer or (local and central) market the individual units of a composite sample may have been sorted according to size (e.g. fruit) or colour (e.g. red, yellow and green peppers) which will increase the residue level variability within a batch. Variability studies performed at the end of the distribution process will typically be most representative of variability factors applicable to products as consumed. However, these studies are not common. To acknowledge the difference between variability factors derived from field trials and those resulting from studies closer to consumption (typically monitoring programmes), the European Union introduced the term 'homogeneity factor' (European Commission 2001). The homogeneity factor indicates the variation in residue levels between individual units of a composite 'monitoring' sample.

In authorisation of pesticides, default factors for variability are used when no variability study is available. These default factors are set rather high to stimulate manufacturers applying for authorisation of pesticides to perform variability studies. It is therefore very questionable if these

'conservative' factors should also be applied when using monitoring results for exposure assessment. Application of a default factor in the probabilistic approach gives the additional problem that it can not be used as such in single simulations of a probabilistic exposure analysis.

As with processing effects, also on variability factors very limited information is available, often less than on processing. Some studies have been performed as mentioned above, but information remains scarce. Nowadays, Authorisation Committees ask for variability studies when a compound is acute toxic. However, in the past this was not requested so limited data will be available from this source.

It is obvious that variability is an important factor in acute exposure assessment. However, it is clear that the application of variability, mainly when using monitoring data, is questionably due to a large dependency on conservative default variability factors. In the probabilistic approach an additional problem is the lack of guidelines on the incorporation of variability into this type of analysis.

*1.2.3 Samples with levels below the reporting limit*

Another important issue in acute exposure assessment to pesticides is the treatment of samples that are reported to contain no residues (Loftus *et al.* 1992, U.S. Environmental Protection Agency 2000b). These 'non-detects' (NDs) do not necessarily contain no residue, but may have levels below the level (level of reporting, LOR) at which laboratories or monitoring authorities are obliged to report. The status of the LOR used by the laboratory is often not clear. In pesticide exposure assessment the limit is commonly indicated as LOD (limit of detection) or LOQ (limit of quantification). Unfortunately, only residue levels higher than LOD or LOQ are reported, in spite of official IUPAC (International Union for Pure and Applied Chemistry) recommendations to always report the numerical values below LOD or LOQ limits if available (Cressie 1994, Currie 1999, IUPAC 1995).

The effect of the level assigned to the NDs on the estimated chemical intake of a population depends on several factors. These include the percentage of residue levels that are NDs, the level of the LOR relative to the levels monitored above this limit, and the percentage of the crop that has been treated with the pesticides (determines the percentage of NDs that can be considered to be real zeros). This issue is important in acute exposure assessment to pesticides because in pesticide monitoring the majority of samples has residue levels below LOR.

In the USA, the Environmental Protection Agency (EPA) developed a method in which the percentage of NDs that are real zeros depends on the percentage of the crop that has been treated with the pesticide (U.S. Environmental Protection Agency 2000b). For the other NDs, that are estimated to contain residue and are therefore no real zeros, different approaches were recommended, such as assigning them either the LOR or 0.5 × LOR, or using statistical methods to estimate the values or distribution of values associated with the ND values (U.S. Environmental Protection Agency 2000b). In general, these statistical methods should be used only in situations where the NDs compromise less than half the data set and the rest of the data are normally or log normally distributed. In pesticide exposure assessment, however, the number of NDs will often exceed 50% of the data set, making this approach less applicable when addressing dietary exposure to these chemicals. An additional factor that makes this approach difficult to apply is the

lack of data on percentage crop treated. In the absence of information it may be possible to make general assumptions about percentage crop treated, like 50%.

The issue of levels assigned to samples reported to contain no residues can not be addressed in the "point estimate" approach, as is evident from the formula (appendix 1). For this the probabilistic approach is essential. However, there is discussion on whether and how to incorporate this information in a probabilistic approach. Should this information be included at all if the concern is acute exposure to a pesticide (worst-case scenario)? Another problem could be that all the pesticide has been applied during a particular month due to certain environmental conditions, and none during the remainder of the year. Calculation of the percentage of crop treated over the year will therefore be very low, while in that particular month it could be 100%.

### 1.3 Acute reference dose

For the assessment of acute exposure to pesticides, the concept of acute reference dose (ARfD) has been developed (FAO/WHO 1999, Herrman 2000). The ARfD was introduced to evaluate the possible acute health effects after a single or a short-term oral exposure to certain specific (groups of) pesticides. Although the ARfD has already been used for several years within the field of acute exposure assessment to pesticides, the concept of the ARfD is still subject to debate. Issues still being discussed include (1) the exposure duration that should be covered when addressing acute exposure (single meal, one day, several subsequent days), (2) the appropriate studies to be conducted when establishing an ARfD, (2) endpoints used for allocating an ARfD, (3) the compounds that should have an ARfD, and (4) the safety factors to be used (Dewhurst 2000, Herrman 2000, Moretto 2000, Raaij 2001, Renwick 2000). Because of this there is (at least for certain aspects) at present no definitive consensus on the ARfD. In a Dutch guidance document for setting an ARfD these different issues are addressed and possible guidelines are proposed (Raaij 2001). One guideline is to restrict the definition of the ARfD to the exposure during one single day. In this report we follow this guideline.

When an ARfD is lacking for a compound of which it is clear that it is acutely toxic, e.g. due to its classification as e.g. organophosphates or carbamates, the ADI is occasionally used for the calculation of the acute exposure. The ADI was defined by the JECFA as 'the amount of a substance, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk'. From this it can be concluded that the ARfD cannot be set at a lower level than the ADI. Equating the ARfD with the ADI may thus be seen as a 'worst case' approach, and will generally lead to an overestimation. It may therefore be recommendable to understand better the possible acute toxicological properties of a certain pesticide, before, as a precaution, setting the reference dose at a low, strict level. It is outside the scope of this paper to address the points raised above in more detail. For more information we refer to the Dutch guidance document mentioned above.

In the following paragraphs we will illustrate the use of the "point estimate" and the probabilistic approach in assessing the acute exposure to pesticides. In these calculations we included information on processing when available and applied default variability factors depending on the unit weight of the specific RAC (appendix 1). We first selected the top 20 of pesticides in 2000 that exceeded most the maximum residue level (MRL; table 1) in the Netherlands. Of those

**Table 1.** Top 20 of pesticides that exceeded most the maximum residue level (MRL; $mg \cdot kg^{-1}$) in 2000 in the Netherlands, including the acute reference dose as defined by the JMPR[1] (ARfD; $mg \cdot kg^{-1} \cdot d^{-1}$).

| compound | number of samples exceeding MRL | ARfD ($mg \cdot kg^{-1} \cdot d^{-1}$) | year of evaluation by JMPR |
|---|---|---|---|
| **top 20 of pesticides exceeding MRL** | | | |
| fludioxonil | 22 | - | |
| pyrimethanil | 21 | - | |
| thiabendazole | 21 | - | |
| methamidophos[2] | 19 | - | |
| triadimenol | 15 | - | |
| tebuconazole | 9 | - | |
| chlormequat | 9 | .05 | 1999 |
| triadimefon | 8 | - | |
| fenthion[2] | 8 | .01 | 1997 |
| penconazole | 7 | - | |
| acrinathrin | 6 | - | |
| carbendazim | 6 | - | |
| iprodion | 6 | - | |
| chlorthalonil | 5 | - | |
| deltamethrin | 5 | .05 | 2000 |
| kresoxim-methyl | 5 | - | |
| bitertanol | 4 | - | |
| dicloran | 4 | - | |
| methomyl[3] | 4 | - | |
| pirimicarb[3] | 4 | - | |
| **'initial' "point estimate" exceeded ARfD** | | | |
| chlorpropham | - | .03 | 2000 |
| mevinphos[2] | - | .003 | 1996 |

[1] Joint FAO/WHO Meeting on Pesticide Residues
[2] organophosphate compound
[3] carbamate compound

pesticides known to be acutely toxic due to the definition of an ARfD a "point estimate" and Monte Carlo analysis were performed. Two additional pesticides were addressed of which the outcome of an initial "point estimate" calculation (without including variability and processing) indicated that the residue intake exceeded the ARfD (table 1). Due to the limited availability of information on processing, and due the complete lack of it on variability and on how to deal with that in the "point estimate" we chose two different scenarios. These scenarios defined the lower- and upper boundary between which the "point estimate" outcome could fluctuate. One the most 'optimistic' situation in which processing is included and variability is ignored (scenario A) and the other the most "worst case" situation in which processing effects are ignored and variability is incorporated using the default value (scenario B). The effect of assigning levels to the samples below LOR as a function of the percentage crop treated was not addressed for reason of comparison: only the Monte Carlo analysis can address this issue.

## 2 METHODS

### 2.1 Pesticide residue data

The pesticides used for the intake calculations are listed in table 1. Residue data originated from the monitoring programmes of the Dutch Health Inspectorate, the Dutch Produce Association and The Greenery, UK. Data are based on the analysis of composite samples and are stored in the Quality Agricultural Products Database (KAP; (Klaveren 1999)). Residue data of 2000 were used in the analyses.

### 2.2 Food consumption data

Food consumption data of the Dutch National Food Consumption Survey (DNFCS) of 1997/1998 were used to calculate the dietary exposure to pesticides (Kistemaker *et al.* 1998). In this survey 6,250 respondents aged 1 to 97 years (of which 530 young children, aged 1 to 6 years) recorded their food intake over two consecutive days. The amount eaten was weighed accurately. The unit of intake for the calculations is 24 h in order to obtain random daily consumption patterns. In this way 12,500 eating 'moments' were available for the total Dutch population and 1,060 moments for young children. With the use of the conversion model Primary Agricultural Products (CPAP), developed at the State Institute for Quality Control of Agricultural Products (RIKILT), the consumption of food products, as recorded in the DNFCS, was translated to the consumption of raw agricultural commodities (Dooren *et al.* 1995). In this way the residue concentrations analysed in raw agricultural commodities could be linked directly to consumption.

### 2.3 Processing factors

Concentrations of pesticides found on raw agricultural commodities (RAC) were corrected for processing effects, such as washing, peeling and heating, when available. The processing factors applied were derived from the literature (Burchat *et al.* 1998, Cabras *et al.* 1998a, Cabras *et al.* 1998b, Celik *et al.* 1995, Hasegawa *et al.* 1991, Holland *et al.* 1994, Newsome *et al.* 2000) or from the reports of the 1997 and 2000 JMPR (FAO/WHO 1998, FAO/WHO 2001a). For the organophosphate pesticides we used the processing factors as applied in a report of the Dutch consumer's organisation and the Dutch environmental group (Luijk *et al.* 2000). When no information was available on processing effects we assumed that there was no effect of processing present (e.g. for chlormequat and deltamethrin; see appendix 2A). In the "point estimate", the most likely and / or conservative processing type was assumed. For example, apple was always consumed after washing, including peel. In the Monte Carlo analysis on the other hand, we used information about different types of processing applicable to one RAC from the Dutch food consumption database. In this database foods are coded in such a way that information can more or less be obtained about different processing practices, such as cooking and canning. However, no information is available on washing practices and for peeling only information is available for apples. We therefore assumed washing or peeling of fruits and vegetables when likely, e.g. peeling when an orange or banana was consumed and washing when pear or lettuce was consumed raw. We were not able to find processing factors for all pesticide - commodity combinations addressed in this report, as well as for all possible forms of processing applicable to a certain product. Because of this, we applied processing factors for a certain type

of processing irrespective of the product. For example, the effect of peeling on fenthion levels in grapefruit was applied to all other citrus fruits containing fenthion and could have been eaten after peeling (e.g. orange, mandarin).

## 2.4 Variability within composite samples

Because hardly any data are available on variability within composite samples, we applied default variability factors, as defined by the JMPR (Appendix 1; (FAO/WHO 2001b)), in both the "point estimate" and the probabilistic approach. In the "point estimate" one single value for variability was applied, as defined (appendix 1). In the probabilistic approach however, one single value for variability can not be used as such in single simulations of a probabilistic exposure analysis. Due to lack of guidelines on how and which distribution of variability to apply in a probabilistic approach, we incorporated variability in the analyses following the following procedure. First the programme calculated for a selected respondent the amount of units consumed by dividing the amount consumed during one day by the unit weight of the product. The number of units consumed determined the number of residue levels to be selected from the residue database (e.g. consumption of two apple units resulted in the selection of two levels). For each 'unit' residue level a lognormal distribution was assumed characterised by $\mu$ and $\sigma$, the mean and standard deviation of the log-transformed concentrations. The variability factor $v$ was converted into the standard deviation according to $\sigma = 1/2\ln(v)$, the sampled residue level $c$ was converted to the mean according to $\mu = \ln(c) - 1/2\sigma^2$. For each consumed unit a residue level was drawn from the lognormal and back transformed to normality.

For example, a respondent with a body weight of 80 kg consumed 0.48 kg of pear. The amount of units consumed equals 3.2, based on a unit weight of 0.15 kg. The default variability factor for pear is 7 ((FAO/WHO 2001b); appendix 1) which is converted to a standard deviation of 0.973. From the residue database four levels (3 × 1 unit and 1 × 0.2 unit) of chlormequat are drawn, e.g. 1.60, 11.9, 7.2 and 238.2 $mg \cdot kg^{-1}$. The means of the lognormal are 0.0, 2.0, 1.5 and 5.0 $mg \cdot kg^{-1}$, respectively. For each unit consumed a residue level is drawn from each lognormal and back transformed to normality, e.g. 1.1, 12.5, 10.3 and 210.2 $mg \cdot kg^{-1}$. The exposure, disregarding processing effects, will then equal

$$\frac{0.15\times 1.1 + 0.15\times 12.5 + 0.15\times 10.3 + 0.03\times 210.2}{80} = 0.12\ mg \cdot kg^{-1} \cdot d^{-1}$$

Variability was not applied to foods that were consumed after the RAC had undergone some kind of industrial bulking or blending, e.g. fruit juices or applesauce. This is in accordance with the guidelines for the "point estimate" (FAO/WHO 2001b).

## 2.5 "Point estimate" approach

In this report we use the "point estimate" approach as defined in the report of the 2000 JMPR (Appendix 1; (FAO/WHO 2001b). We calculated the "point estimate" for all products with at least one positive residue level for one of the 22 selected compounds and for which an ARfD was defined (table 1). "Point estimates" were calculated following two scenarios: 1) the most favourable situation in which processing is included and variability is ignored (scenario A) and 2) the most "worst case"

situation in which processing effects are ignored and variability is incorporated using the default value (scenario B). The results of the two scenarios define the possible outer limits of likely "point estimate" outcomes. "Point estimates" were calculated for both the total Dutch population (body weight = 65.8 kg) and young children aged between 1 and 6 years (body weight = 17.1 kg).

## 2.6 Monte Carlo technique

The Monte Carlo analysis was developed to simulate real life dietary exposure to pesticides and other possible compounds in the best way possible. At the RIKILT, the programme 'Monte Carlo Risk Analysis' (MCRA) has been developed to assess the acute exposure to pesticides through the diet using the probabilistic approach. This programme is written in the statistical package GenStat (GenStat 2000) and was applied in this project for the calculation of the acute dietary exposure to those pesticides for which an ARfD was defined (table 1). The programme operates as follows. First it selects randomly a consumer out of the consumption database. The consumption of every single RAC (that could contain the pesticide of interest) for this person on one day is multiplied with a randomly selected residue concentration out of the residue database for that particular RAC. After each RAC consumed by the selected person is multiplied with a selected residue concentration, the residue intake of this consumer is added and stored in the output programme. By repeating this procedure many times a probability distribution for pesticide intake is produced. To estimate the median and the upper percentiles of the distribution of dietary exposure, the Monte Carlo analysis was repeated two times (A and B, see appendix 3) with 50,000 iterations for the total Dutch population. All estimates of possible intakes are adjusted for the individual's self-reported body weight, and all respondents are included (both consumers and non-consumers).

To calculate the exposure to the different pesticides using the Monte Carlo technique we incorporated the consumption of all RACs that could contain a certain pesticide in the analysis as based on the Dutch monitoring results of 2000 (see above). For example, fenthion was present on four products, namely grapefruit, mandarin/tangerines, orange and peach (appendix 2A and 2B). For chlorpropham, we excluded the consumption of the raw agricultural commodity potato due to potato starch consumption. For the production of potato starch industrial potatoes are used, which are processed quickly and therefore not treated with chlorpropham.

## 2.7 Acute reference dose

To assess if a consumer risk was present, the outcome of both the "point estimate" and the probabilistic approach were compared with the ARfD for each pesticide. In the probabilistic approach we used for this the 99.9$^{th}$ percentile (P99.9) level of the exposure distribution. The ARfDs were derived from the JMPR as published by the International Programme on Chemical Safety in their inventory up to 2000 (IPCS 2001). Table 1 lists the ARfDs used in this report. Of only five of the 22 compounds ARfDs were established.

## 3 RESULTS

### 3.1 "Point estimate" approach

Table 2 lists, for a selection of 15 compound - product combinations, the outcome of the "point estimate" for the two scenarios and for both the total population and young children. For a total overview of the results, see appendix 2A and 2B. When considering scenario A, of the 13 selected combinations none resulted in an exposure exceeding the ARfD (%ARfD > 100) in both populations. In the 'worst case' scenario (scenario B) the number of exposures exceeding the ARfD increased. Of all the possible combinations examined (22; appendix 2B), 18% exceeded the ARfD in the total population and 23% in young children.

### 3.2 Monte Carlo approach

The Monte Carlo analysis was performed for each of the five compounds for which an ARfD was defined (as in the "point estimate"). Calculations were performed for the total Dutch population, including all RACs that were analysed for a certain compound. For an overview of the results, see appendix 3. Table 3 gives a summary of this appendix by listing only the mean P99.9 of exposure of two simulations (A and B) for all the compounds studied. It is evident from this table that, except for chlorpropham, the P99.9 of the exposure distribution did not exceed the ARfD for any of the compounds studied. For chlorpropham the calculated intake exceeded the ARfD by 67%. This was almost completely due to potato consumption. The variability factor applied was 7 and the processing factor was 0.11 (Newsome *et al.* 2000). When studying the chlorpropham levels in potato as used in the analysis it became evident that one level exceeded both the last but one

**Table 2.** "Point estimate" exposure as percentage of the acute reference dose (%ARfD[1]; %) to different pesticides for both the total Dutch population and young children (1 - 6 years). Calculations were performed including processing and no variability (scenario A) or including variability but no processing (scenario B).

| | | %ARfD[1] | | | |
|---|---|---|---|---|---|
| | | scenario A | | scenario B | |
| compound | product | total | children | total | children |
| chlormequat | carrot | 9.6 | 19 | 25 | 78 |
| | pear | 7.0 | 14 | 23 | 74 |
| chlorpropham | potato | 41 | 85 | 1539 | 5248 |
| | turnip tops/greens | 0.7 | 1.7 | 6.4 | 16 |
| deltamethrin | endive | 1.4 | 3.9 | 14 | 38 |
| | grape | 1.3 | 2.6 | 6.7 | 13 |
| | sweet pepper | 0.1 | 0.1 | 1.0 | 1.0 |
| fenthion | grapefruit | 0.1 | 1.5 | 7.7 | 21 |
| | orange | 1.5 | 3.3 | 110 | 380 |
| | peach | 6.6 | 17 | 34 | 119 |
| mevinphos | broccoli | 1.3 | 1.7 | 12 | 32 |
| | cabbage lettuce | 5.4 | 12 | 201 | 429 |
| | endive | 36 | 96 | 1316 | 3555 |
| | orange | 2.6 | 5.8 | 13 | 45 |
| | spinach | 3.9 | 8.8 | 14 | 32 |

[1] %ARfD was calculated as the "point estimate" divided by the ARfD and multiplied by 100.

**Table 3.** The 99.9th percentile (P99.9) of the distribution of dietary exposure ($mg \cdot kg^{-1} \cdot d^{-1}$) to different pesticides in the total Dutch population, including the acute reference dose (ARfD; $mg \cdot kg^{-1} \cdot d^{-1}$) and percentage of the ARfD (%ARfD; %). Simulations were performed including variability (default values) and processing (when available). Values are means of two different Monte Carlo simulations with 50,000 iterations each.

| compound | P99.9 ($mg \cdot kg^{-1} \cdot d^{-1}$; C) | ARfD ($mg \cdot kg^{-1} \cdot d^{-1}$; D) | %ARfD ((C÷D) × 100) |
|---|---|---|---|
| chlormequat | .0074 | .05 | 15 |
| chlorpropham[1] | .0502 | .03 | 167 |
| chlorpropham[2] | .0276 | .03 | 92 |
| deltamethrin | .0002 | .05 | 0.4 |
| fenthion | .0002 | .01 | 2 |
| mevinphos | .0002 | .003 | 6 |

[1] calculation including all chlorpropham levels derived from monitoring programmes in 2000
[2] calculation as in ([1]) but excluding the one value above the maximum residue level for chlorpropham (17.7 $mg \cdot kg^{-1}$)

residue level in the database (4.7 $mg \cdot kg^{-1}$) and the maximum residue level (5 $mg \cdot kg^{-1}$). This level equalled 17,7 $mg \cdot kg^{-1}$ and suggested use of the pesticide during potato treatment that was not in accordance with Good Agricultural Practice (GAP). We therefore repeated the analysis without this higher level, which resulted in a P99.9 exposure below the ARfD (table 3).

# 4 DISCUSSION

We demonstrated in this document the use of the "point estimate" and the probabilistic approach to calculate the acute exposure to acutely toxic pesticides. Of the pesticide exposures exceeding the acute reference dose (ARfD) with the "point estimate" (irrespective of scenario) only chlorpropham also exceeded the ARfD when using the Monte Carlo approach. We showed however that this was mainly due to the presence of a high residue level in the monitoring residue database. When this level was removed from the analysis none of the pesticide exposures resulted in an exposure higher than the ARfD.

## 4.1 "Point estimate" approach versus the probabilistic approach

The "point estimate" approach can be used as a first step in evaluating if an observed level higher than the maximum residue level (MRL) can lead to a risk to any consumer (a 'screening' tool). When the "point estimate" outcome exceeds the ARfD there may be a possible health risk. However, the formula to calculate the "point estimate" includes a number of definitions causing the "point estimate" exposure outcomes often to overestimate real exposure. The most important are the use of "high-end" residue levels (maximum level analysed in a monitoring programme) and "high-end" consumption levels (P97.5 level of consumption for consumers only). Furthermore, in many cases no data on both variability and processing are available. In those cases "worst case" assumptions are made, as ignoring possible processing effects and applying a default factor for variability (scenario B in this report). When these "worst case" assumptions are necessary the use of the "point estimate" to calculate the exposure seems less useful: a good quantitative judgement of the outcome is not possible due to the large dependency on "worst-case" assumptions. When information is not available it is desirable to perform sensitivity analyses. For this the use of the probabilistic approach is essential.

On the other hand however, "point estimates" may also be biased to underestimates of exposure. In the "point estimate" residues are considered to be present only in the specific commodity of interest and all remaining foods consumed during the day are assumed to be residue-free. This is an oversimplification of reality, where pesticides are often present on more than one commodity. Ignoring other food sources of the same residue would tend the "point estimate" to produce exposure estimates that are biased low. Because of this it is desirable to have an approach that estimates the total dietary intake of a pesticide, and not just the possible intake from a single "high-end" residue food source. In other words, an approach that takes a holistic (or "whole truth") approach to risk. A method recognised to meet these needs is the probabilistic approach in which the whole diet is considered. It is evident from our results (table 2 and 3) that the probable tendency of the "point estimate" to both under- and overestimate the exposure to pesticides by the procedures described above will predominantly result in an overestimate of dietary exposure. It is however conceivable that there may be situations where the opposite is true.

We calculated the "point estimate" following two scenarios, due to the large uncertainties in processing and variability. The outcomes of these scenarios define the possible outer boundaries between which the outcome of the "point estimate" could be situated when representative data on both processing and variability are available. The processing factors used to calculate scenario A are however not always accurate. Due to lack of information general assumptions were frequently

made as described in § 2.3. Furthermore for some pesticides (e.g. chlormequat and deltamethrin) no information on processing was available. Due to this the lower limit of the range may not be the 'true' lower limit, and could have been either lower (e.g. in case of chlormequat and deltamethrin) or higher. The upper boundary of the range (scenario B) will on the other hand be fairly correct. We applied variability using a conservative default factor, which in practice will most certainly overestimate the true 'unknown' variability factor. The number of times that the "point estimate" exposure exceeded the ARfD illustrates the difference between the scenarios. In scenario A, none of the "point estimate" exposures exceeded the ARfD in both the total population and young children. In scenario B the number of exposures higher than the ARfD was 4 and 5, respectively (appendix 2). Differences were especially large when there was a strong reducing effect of processing and when a large variability factor was applied (e.g. fenthion on citrus fruits; appendix 2, table 2). Compared with the results of the probabilistic approach, scenario B can be considered as 'worst case' and may therefore not be an appropriate tool for the evaluation of exposure. However, scenario A may be considered as too 'optimistic'. None of the "point estimate" exposures following scenario A exceeded the ARfD, while the Monte Carlo analysis indicated that chlorpropham could be a problem. Although it was demonstrated that this was most likely due to use of the pesticide during potato treatment that was not in accordance with Good Agricultural Practice (GAP). A possible conclusion could therefore be that if scenario A does not exceed the ARfD and scenario B does, it may be advisable to study further what happens in between these two 'boundaries'. For this the possible assumptions made when calculating the "point estimate' should be studied further. An option could be to perform a Monte Carlo analysis to obtain a better understanding of the important variables that attribute to the exposure.

## 4.2 Reference point of the distribution

The outcome of the Monte Carlo analysis is a distribution of possible exposures that describes the probability with which certain exposures may occur in a certain population. The cut-off point used of such a distribution above which health effects may occur could be the P99.9. This percentile indicates that 1 out of 1,000 persons has an exposure higher than the P99.9 level of exposure and 999 persons have a lower exposure. This demarcation point can be compared with the ARfD to evaluate the existence of a possible health risk. In the USA the Environmental Protection Agency (EPA) applies the P99.9 level as cut-off point (U.S. Environmental Protection Agency 2000a). When the P99.9 exceeds the ARfD it may be advisable to perform a qualitative judgement of the certainties and uncertainties that determine the high exposures. These exposures may be due to extreme high values in the food consumption and / or residue database, or by selecting a very high residue level due to the application of variability (§ 2.4). Another factor that should be considered in this respect is over reporting of food consumption, which may occur with 'healthy' foods, such as fruits and vegetables, leading to unrealistic consumption levels.

## 4.3 Conclusions

We can conclude that the probabilistic approach is a more quantitative and complete method to estimate the dietary exposure to pesticides compared to the "point estimate" approach. The "point estimate" approach may indicate what is possible, while the Monte Carlo technique also indicates how probable that possibility is. In modern exposure assessment, it is important to not only focus on a specific high level of exposure, but also to consider the likelihood that such an exposure will

occur in real life. For this it is essential to incorporate data about the whole range of consumption levels (including non-consumers) and residue levels (including the levels below LOR) in the exposure assessment. By quantifying the risk of a high exposure level, well-balanced risk decisions can be made. The Monte Carlo method is therefore a promising approach in dietary exposure assessment of pesticides and will certainly become an important tool in both the authorisation of pesticides as in evaluating exposure using monitoring data.

At present for only a few compounds addressed an ARfD has been established by the JMPR. We were therefore able to calculate the acute exposure for only five of the 22 compounds identified. Very likely more compounds than these five may have been acutely toxic but have not been identified as such by the JMPR so far. In the future of more compounds it will become clear if they are acutely toxic or not, and thus if acute dietary exposure assessments are warranted.

## 4.4 Recommendations

When addressing the acute exposure to acutely toxic pesticides we recommend the use of a tiered approach. The "point estimate", due to its simplicity and its worldwide use and acceptance, may be used as a first screening tool to identify possible pesticides that may pose a health problem. When no information on variability is available we advise not to include only the default factor in the calculations. This will lead to many unrealistic exposures exceeding the ARfD, which may result in waste of available resources and time. A possible option is to calculate the "point estimate" incorporating processing (when available) and to apply variability, but at more possible levels than just the maximum (default) level. The probabilistic approach can be applied to study if the "point estimate" outcome really gives reason for concern. The level of percentage of the ARfD at which a "point estimate" may necessitate the performance of a probabilistic approach is a decision for risk managers. Independent of the refinement of exposure assessment using a tiered approach, there is a need to perform probabilistic approaches. These approaches take a holistic (or "whole truth") approach to risk, allowing for a more realistic evaluation of exposures.

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**APPENDIX 1.** "POINT ESTIMATE"

The equation used by the Joint FAO/WHO Meeting on Pesticide Residues, 2000 (FAO/WHO 2001b):

$$\text{International Short-Term Intake (IESTI)} = \frac{\{U * HRL(-P) * v\} + \{(LP - U) * HR(-P)\}}{bw}$$

where:

U = unit weight of edible portion (kg) or if the large portion consumption is less than one commodity unit than U is equal to the large portion consumption and the second term of the equation drops out.

HRL(-P) = highest residue level in composite sample of edible portion (HR; $mg \cdot kg^{-1}$), or corrected for processing (HR-P) calculated by multiplying the HR in the raw commodity by the processing factor.

$v$ = variability factor.

LP = largest portion reported (eaters at P97.5 of consumption), kg per day. Where LP is less than or equal to U, the second term of the equation drops out.

bw = mean body weight of the target population subgroup, kg.

**Default variability factors as defined for use in the "point estimate"** (FAO/WHO 2001b):

| | |
|---|---|
| unit weight of whole portion > 250 g: | $v = 5$ |
| 25 ≤ unit weight of whole portion ≤ 250 g: | $v = 7$ |
| unit weight of whole portion ≤ 250 g after granular soil treatment: | $v = 10$ |
| Leafy vegetables, unit weight of whole portion ≤ 250 g: | $v = 10$ |

When sufficient data are available on residues in each unit to calculate a more realistic variability factor for a commodity, the calculated value should replace the default value.

## **APPENDIX 2A.** RESULTS "POINT ESTIMATE" APPROACH: INCLUDING PROCESSING AND NO VARIABILITY

S = Source ARfD: J = JMPR
Country = -- = imported
= NL = The Netherlands

| Compound | Product | U kg | Pr.factor | Country | MRL mg/kg | ARfD mg/kgbw/d | S | P975_total kg/d | p975_chld kg/d | maximum mg/kg | Intake_total mg/kg bw/d | Intake_chld mg/kg bw/d | %ARfD_total | %ARfD_chld |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CHLORPROPHAM | FENNEL | .3080 | .11 | NL | .050 | .03000 | J | .308 | .0000 | .040 | .000021 | .000000 | .07 | .00 |
| | POTATOES | .2160 | .11 | NL | 5.000 | .03000 | J | .420 | .2250 | 17.700 | .012428 | .025618 | 41.43 | 85.39 |
| | | .2160 | .11 | -- | 5.000 | .03000 | J | .420 | .2250 | .900 | .000632 | .001303 | 2.11 | 4.34 |
| | TURNIP TOPS/GREENS | .3140 | .11 | -- | .050 | .03000 | J | .314 | .2018 | .400 | .000210 | .000520 | .70 | 1.73 |
| | WHEAT | .2520 | 1.00 | NL | .050 | .03000 | J | .252 | .1437 | .030 | .000115 | .000253 | .38 | .84 |
| CHLORMEQUAT | CARROT | .0800 | 1.00 | NL | .050 | .05000 | J | .300 | .1550 | 1.050 | .004791 | .009516 | 9.58 | 19.03 |
| | PEAR | .1500 | 1.00 | NL | 3.000 | .05000 | J | .402 | .2130 | .570 | .003482 | .007100 | 6.96 | 14.20 |
| | WHEAT | .2520 | 1.00 | -- | 2.000 | .05000 | J | .252 | .1437 | .350 | .001340 | .002947 | 2.68 | 5.89 |
| | | .2520 | 1.00 | NL | 2.000 | .05000 | J | .252 | .1437 | .340 | .001302 | .002863 | 2.60 | 5.73 |
| DELTAMETHRIN | CABBAGE LETTUCE, COS LETT | .1280 | 1.00 | NL | .500 | .05000 | J | .128 | .0710 | .220 | .000428 | .000913 | .86 | 1.83 |
| | ENDIVE | .4260 | 1.00 | -- | .500 | .05000 | J | .426 | .2990 | .110 | .000712 | .001923 | 1.42 | 3.85 |
| | GRAPE | .4000 | 1.00 | -- | .100 | .05000 | J | .400 | .2000 | .110 | .000669 | .001287 | 1.34 | 2.57 |
| | STRAWBERRY | .3330 | 1.00 | NL | .050 | .05000 | J | .333 | .2080 | .070 | .000354 | .000851 | .71 | 1.70 |
| | | .3330 | 1.00 | -- | .050 | .05000 | J | .333 | .2080 | .060 | .000304 | .000730 | .61 | 1.46 |
| | SWEET PEPPER | .1150 | 1.00 | -- | .200 | .05000 | J | .115 | .0299 | .040 | .000070 | .000070 | .14 | .14 |
| FENTHION | GRAPEFRUIT | .1600 | .05 | -- | .050 | .01000 | J | .301 | .1303 | .040 | .000009 | .000152 | .09 | 1.52 |
| | MANDARIN, TANGERINES | .1000 | .05 | -- | .050 | .01000 | J | .210 | .1650 | .140 | .000022 | .000068 | .22 | .68 |
| | ORANGE | .1600 | .05 | -- | .050 | .01000 | J | .340 | .2000 | .560 | .000145 | .000327 | 1.45 | 3.27 |
| | PEACH | .1100 | .75 | -- | .050 | .01000 | J | .230 | .1560 | .250 | .000655 | .001711 | 6.55 | 17.11 |
| MEVINPHOS | BLACKBERRY | .1250 | .75 | NL | .100 | .00300 | J | .125 | .0000 | .040 | .000057 | .000000 | 1.90 | .00 |
| | BROCCOLI | .0740 | .27 | NL | .100 | .00300 | J | .319 | .1062 | .030 | .000039 | .000050 | 1.30 | 1.67 |
| | CABBAGE LETTUCE, COS LETT | .1280 | .27 | NL | .500 | .00300 | J | .128 | .0710 | .310 | .000163 | .000348 | 5.43 | 11.60 |
| | ENDIVE | .4260 | .27 | NL | .500 | .00300 | J | .426 | .2990 | .610 | .001066 | .002880 | 35.53 | 96.00 |
| | ORANGE | .1600 | .75 | -- | .200 | .00300 | J | .340 | .2000 | .020 | .000078 | .000175 | 2.60 | 5.83 |
| | SPINACH | .5630 | .27 | NL | .500 | .00300 | J | .563 | .3330 | .050 | .000116 | .000263 | 3.87 | 8.77 |

## **APPENDIX 2B.** RESULTS "POINT ESTIMATE" APPROACH: INCLUDING VARIABILITY AND NO PROCESSING

S=Source ARfD: J = JMPR
Country = -- = imported
= NL = The Netherlands

| Compound | Product | U kg | Variab. | Country | MRL mg/kg | ARfD mg/kgbw/d | S | P975_total kg/d | p975_chld kg/d | maximum mg/kg | Intake_total mg/kg bw/d | Intake_chld mg/kg bw/d | %ARfD_total | %ARfD_chld |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CHLORPROPHAM | FENNEL | .3080 | 1 | NL | .050 | .03000 | J | .308 | .0000 | .040 | .000187 | .000000 | .62 | .00 |
| | POTATOES | .2160 | 7 | NL | 5.000 | .03000 | J | .420 | .2250 | 17.700 | .461599 | 1.574368 | 1538.66 | 5247.89 |
| | | .2160 | 7 | -- | 5.000 | .03000 | J | .420 | .2250 | .900 | .023471 | .080053 | 78.24 | 266.84 |
| | TURNIP TOPS/GREENS | .3140 | 1 | -- | .050 | .03000 | J | .314 | .2018 | .400 | .001909 | .004725 | 6.36 | 15.75 |
| | WHEAT | .2520 | 1 | NL | .050 | .03000 | J | .252 | .1437 | .030 | .000115 | .000253 | .38 | .84 |
| CHLORMEQUAT | CARROT | .0800 | 7 | NL | .050 | .05000 | J | .300 | .1550 | 1.050 | .012451 | .038990 | 24.90 | 77.98 |
| | PEAR | .1500 | 7 | NL | 3.000 | .05000 | J | .402 | .2130 | .570 | .011279 | .037100 | 22.56 | 74.20 |
| | WHEAT | .2520 | 1 | -- | 2.000 | .05000 | J | .252 | .1437 | .350 | .001340 | .002947 | 2.68 | 5.89 |
| | | .2520 | 1 | NL | 2.000 | .05000 | J | .252 | .1437 | .340 | .001302 | .002863 | 2.60 | 5.73 |
| DELTAMETHRIN | CABBAGE LETTUCE, COS LETT | .1280 | 10 | NL | .500 | .05000 | J | .128 | .0710 | .220 | .004280 | .009135 | 8.56 | 18.27 |
| | ENDIVE | .4260 | 10 | -- | .500 | .05000 | J | .426 | .2990 | .110 | .007122 | .019234 | 14.24 | 38.47 |
| | GRAPE | .4000 | 5 | -- | .100 | .05000 | J | .400 | .2000 | .110 | .003343 | .006433 | 6.69 | 12.87 |
| | STRAWBERRY | .3330 | 1 | NL | .050 | .05000 | J | .333 | .2080 | .070 | .000354 | .000851 | .71 | 1.70 |
| | | .3330 | 1 | -- | .050 | .05000 | J | .333 | .2080 | .060 | .000304 | .000730 | .61 | 1.46 |
| | SWEET PEPPER | .1150 | 7 | -- | .200 | .05000 | J | .115 | .0299 | .040 | .000489 | .000491 | .98 | .98 |
| FENTHION | GRAPEFRUIT | .1600 | 7 | -- | .050 | .01000 | J | .301 | .1303 | .040 | .000766 | .002129 | 7.66 | 21.29 |
| | MANDARIN, TANGERINES | .1000 | 7 | -- | .050 | .01000 | J | .210 | .1650 | .140 | .001723 | .006263 | 17.23 | 62.63 |
| | ORANGE | .1600 | 7 | -- | .050 | .01000 | J | .340 | .2000 | .560 | .011064 | .037988 | 110.64 | 379.88 |
| | PEACH | .1100 | 7 | -- | .050 | .01000 | J | .230 | .1560 | .250 | .003381 | .011930 | 33.81 | 119.30 |
| MEVINPHOS | BLACKBERRY | .1250 | 1 | NL | .100 | .00300 | J | .125 | .0000 | .040 | .000076 | .000000 | 2.53 | .00 |
| | BROCCOLI | .0740 | 7 | NL | .100 | .00300 | J | .319 | .1062 | .030 | .000348 | .000965 | 11.60 | 32.17 |
| | CABBAGE LETTUCE, COS LETT | .1280 | 10 | NL | .500 | .00300 | J | .128 | .0710 | .310 | .006030 | .012871 | 201.00 | 429.03 |
| | ENDIVE | .4260 | 10 | NL | .500 | .00300 | J | .426 | .2990 | .610 | .039492 | .106661 | 1316.40 | 3555.37 |
| | ORANGE | .1600 | 7 | -- | .200 | .00300 | J | .340 | .2000 | .020 | .000395 | .001357 | 13.17 | 45.23 |
| | SPINACH | .5630 | 1 | NL | .500 | .00300 | J | .563 | .3330 | .050 | .000428 | .000974 | 14.27 | 32.47 |

**APPENDIX 3.** PERCENTILES OF EXPOSURE ($MG \cdot KG^{-1} \cdot D^{-1}$) OF TWO MONTE CARLO SIMULATIONS (INCLUDING VARIABILITY AND PROCESSING) FOR FIVE PESTICIDES

**chlormequat ARfD=0.05 mg·kg$^{-1}$·d$^{-1}$**

| percentile | A | B | mean | sd |
|---|---|---|---|---|
| 50 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 90 | 0.0001 | 0.0001 | 0.0001 | 0.0000 |
| 91 | 0.0002 | 0.0002 | 0.0002 | 0.0000 |
| 92 | 0.0002 | 0.0002 | 0.0002 | 0.0000 |
| 93 | 0.0003 | 0.0003 | 0.0003 | 0.0000 |
| 94 | 0.0004 | 0.0003 | 0.0004 | 0.0000 |
| 95 | 0.0005 | 0.0005 | 0.0005 | 0.0000 |
| 96 | 0.0007 | 0.0006 | 0.0006 | 0.0000 |
| 97 | 0.0009 | 0.0009 | 0.0009 | 0.0000 |
| 98 | 0.0013 | 0.0013 | 0.0013 | 0.0000 |
| 99 | 0.0021 | 0.0022 | 0.0022 | 0.0001 |
| 99.5 | 0.0032 | 0.0035 | 0.0033 | 0.0002 |
| 99.9 | 0.0068 | 0.0079 | 0.0074 | 0.0008 |
| mean[1] | 0.0001 | 0.0001 | 0.0001 | 0.0000 |
| % pos | 32.3 | 32.4 | 32.4 | 0.1 |

**chlorpropham[2] ARfD=0.03 mg·kg$^{-1}$·d$^{-1}$**

| percentile | A | B | mean | sd |
|---|---|---|---|---|
| 50 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 90 | 0.0009 | 0.0009 | 0.0009 | 0.0000 |
| 91 | 0.0010 | 0.0011 | 0.0011 | 0.0000 |
| 92 | 0.0012 | 0.0013 | 0.0012 | 0.0000 |
| 93 | 0.0014 | 0.0015 | 0.0014 | 0.0000 |
| 94 | 0.0017 | 0.0018 | 0.0017 | 0.0001 |
| 95 | 0.0021 | 0.0022 | 0.0021 | 0.0001 |
| 96 | 0.0027 | 0.0028 | 0.0027 | 0.0001 |
| 97 | 0.0036 | 0.0037 | 0.0036 | 0.0000 |
| 98 | 0.0052 | 0.0053 | 0.0053 | 0.0001 |
| 99 | 0.0096 | 0.0095 | 0.0096 | 0.0000 |
| 99.5 | 0.0169 | 0.0162 | 0.0166 | 0.0005 |
| 99.9 | 0.0528 | 0.0477 | 0.0502 | 0.0035 |
| mean | 0.0006 | 0.0006 | 0.0006 | 0.0000 |
| % pos | 59.4 | 59.4 | 59.4 | 0.0 |

**chlorpropham[3] ARfD=0.03 mg·kg$^{-1}$·d$^{-1}$**

| percentile | A | B | mean | sd |
|---|---|---|---|---|
| 50 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 90 | 0.0008 | 0.0008 | 0.0008 | 0.0000 |
| 91 | 0.0009 | 0.0009 | 0.0009 | 0.0000 |
| 92 | 0.0010 | 0.0010 | 0.0010 | 0.0000 |
| 93 | 0.0012 | 0.0012 | 0.0012 | 0.0000 |
| 94 | 0.0014 | 0.0014 | 0.0014 | 0.0000 |
| 95 | 0.0017 | 0.0017 | 0.0017 | 0.0000 |
| 96 | 0.0021 | 0.0021 | 0.0021 | 0.0000 |
| 97 | 0.0027 | 0.0027 | 0.0027 | 0.0000 |
| 98 | 0.0039 | 0.0040 | 0.0040 | 0.0001 |
| 99 | 0.0066 | 0.0070 | 0.0068 | 0.0003 |
| 99.5 | 0.0109 | 0.0106 | 0.0108 | 0.0002 |
| 99.9 | 0.0266 | 0.0285 | 0.0276 | 0.0014 |
| mean | 0.0004 | 0.0004 | 0.0004 | 0.0000 |
| % pos | 59.1 | 59.2 | 59.2 | 0.1 |

**deltamethrin ARfD=0.05 mg·kg$^{-1}$·d$^{-1}$**

| percentile | A | B | mean | sd |
|---|---|---|---|---|
| 50 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 90 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 91 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 92 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 93 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 94 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 95 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 96 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 97 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 98 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 99 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 99.5 | 0.0001 | 0.0001 | 0.0001 | 0.0000 |
| 99.9 | 0.0002 | 0.0002 | 0.0002 | 0.0000 |
| mean | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| % pos | 5.1 | 5.0 | 5.1 | 0.1 |

**fenthion ARfD=0.01 mg·kg$^{-1}$·d$^{-1}$**

| percentile | A | B | mean | sd |
|---|---|---|---|---|
| 50 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 90 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 91 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 92 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 93 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 94 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 95 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 96 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 97 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 98 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 99 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 99.5 | 0.0001 | 0.0001 | 0.0001 | 0.0000 |
| 99.9 | 0.0002 | 0.0002 | 0.0002 | 0.0000 |
| mean | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| % pos | 8.9 | 9.1 | 9.0 | 0.1 |

**mevinphos ARfD=0.003 mg·kg$^{-1}$·d$^{-1}$**

| percentile | A | B | mean | sd |
|---|---|---|---|---|
| 50 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 90 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 91 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 92 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 93 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 94 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 95 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 96 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 97 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 98 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 99 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 99.5 | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| 99.9 | 0.0002 | 0.0002 | 0.0002 | 0.0000 |
| mean | 0.0000 | 0.0000 | 0.0000 | 0.0000 |
| % pos | 4.0 | 4.1 | 4.1 | 0.1 |

[1] mean: mean of the distribution of dietary exposure to the pesticide

[2] calculated including all chlorpropham levels derived from monitoring programmes in 2000

[3] calculated excluding one value above the maximum residue level for chlorpropham (17.7 $mg \cdot kg^{-1}$)