PAN Germany

The Myth of Safe Fruit and Vegetables

This briefing paper has the intention to raise awareness within civil society of the fact that the current process of EU harmonization of pesticide levels in food presents a big chance to lower chemical risks. However, if civil society does not get involved in this process as an active watchdog, we may soon be confronted with pesticide levels which only serve free trade and industries' interests - neglecting vulnerable groups.

PAN Germany is part of an international network of more than 600 citizens groups working to oppose the misuse of pesticides and to promote sustainable agriculture and ecologically sound pest management. PAN Germany provides information on pesticide risks and campaigns for alternatives.

BRIEFING

2006

Harmonization of standards is a magic tool for moving towards free trade and prosperity. But: Having innumerable norms in each of the 25 EU Member States does cause some trouble. The NGO community therefore welcomed the approach to harmonize the levels of allowed maximum pesticide residue levels (MRLs) in food. Even more welcomed was the fact that in EU Regulation 396/2005[1] the sensitivity of vulnerable groups such as children and the unborn should present the cut-off value for dangerous pesticide residues.

But – there are some major issues, which have not been solved.

EU Regulation 396/2005

"Maximum Residues Levels (MRLs) should be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn."

Three key questions remain:

1. Whose consumption pattern will be the basis for setting the maximum residues levels?
2. How will the Commission deal with existing international standards, which do not respect the vulnerability of children?
3. What will happen to old harmonised European MRLs created in times where the light of science was not too bright?

[1] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, 16.3.2005, Official Journal of the European Union L 70/1

People eat in different ways

Over the past decades, people in Europe have developed very different consumption patterns, which today - where almost all foodstuff is contaminated with pesticides - leads to different levels of exposure. We have analysed the consequences illustrated by apple consumption.

Small kids, big appetite and large apples

When talking about pesticide exposure through food one needs to look at three figures:

1. the amount of food eaten,
2. the pesticide load in certain food, and
3. the individual unit size in case of large portions, such as for pears and apples.

While it is rather easy to determine pesticide residues in individual foodstuffs, it is rather complicated to get figures about the representative consumption of a population in all its diversity.

Gender, age, culture, religious education, income, etc influence what type of food is consumed and then, in addition to that, there are vegetarians, vegans, macrobiotic diets, etc.

In three European countries so-called dietary studies have recently been published: for Germany, the Netherlands and the United Kingdom. They all differ a lot: the German study only focuses on children aged 2-5 years and neglects minorities, the British study considers various differences in age and living conditions, and also looks at consumption patterns of vegetarians.

EU Regulation 396/2005:

'Acute reference dose' (ARfD) means the estimate of the amount of substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one day, without appreciable risk to the consumer on the basis of the data produced by appropriate studies and taking into account sensitive groups within the population (e.g. children and the unborn).

It is easy to see that even in these fairly Northern European countries consumption patterns differ considerably. British children, for example, like apples the most: a 1.5 to 4 year old British kid with an average body weight of 14.5 kg eats up to 373 gram apples on some days, while a Dutch child aged 1 to 6 years with an average body weight of 17.1 kg only eats 260 gram a day. Then on top of this, there are big apples and small apples – an average apple in the UK weighs 112 g, while a German apple weighs 181 g.

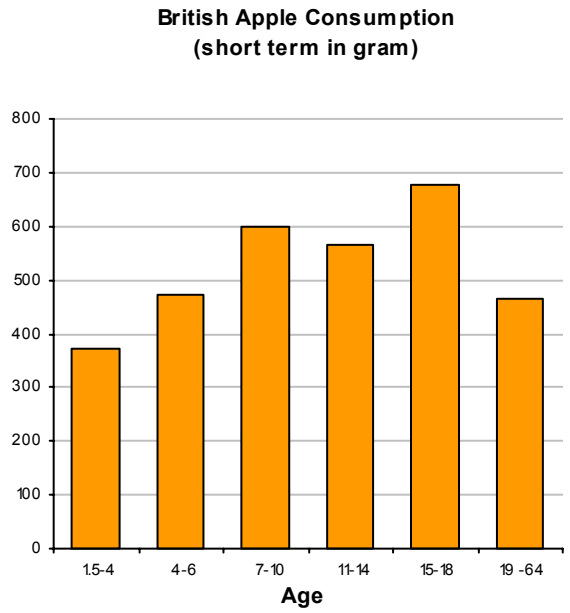
Why is this important?

The British kid frequently eats about 3 apples a day, each 112 g, and one or two of these apples may contain much higher pesticide residues than another. This has to be taken into account when estimating exposure in the diet. The consequences of these regional differences are clear: exposure varies regionally and so does the health risk.

Assessment of pesticide risks looks at exposure and toxicity. Globally, there are about 800 pesticides (active ingredients) in use. These, plus a number of break down-products, may occur in our food. All of these substances are different in their toxicity. For assessing the risk of pesticide residues in food scientists use two toxicological limits: one for the long term (chronic) risk, and another for the short term (acute) risk.

For a long time official risk managers only cared about the long-term effect which a pesticide's residues may cause. They calculated and applied, within risk management, the *Acceptable Daily Intake* (ADI) – the pesticide dose a person can consume each day over a lifetime without being harmed, based on the state-of the-art science at that time. More recently, since the mid-nineties scientists have started to look at the acute (direct) toxicity of pesticide residues, because there are some substances which are so toxic that even their residues may harm people. They introduced the Acute Reference Dose (ARfD) – the pesticide dose a person could consume within a short time (a day) without being harmed.

Now the matter becomes tricky: both values are expressed on the basis of body weight. But it makes a huge difference whether a 20 kg heavy child eats 400 g of apples contaminated with pesticide or an adult of 76 kg eats 400g of these apples.



British 4-6 year old children (20.5 kg) frequently eat more amounts apple than the average adult (76 kg).

According to the new EU regulation ADI and ARfD must take into account the sensitive groups such as children. We highly welcomed the approach! But for what kind of child? The apple-loving British kid or the sweets- and pepper-loving German kid[2], the Hungarian kid or the African child living in Paris?

In contrast to the ADI- and ARfD value, the MRLs are not a safety limit but related to the residues expected to occur when growers apply pesticides following Good Agricultural Practice (see box, page 5). The opinion of officials is, that occasionally exceeding MRLs does not pose an appreciable health risk unless health-based limits (the ADI or ARfD) are exceeded.

The following table shows a worst-case calculation of percentage of the ARfD resulting from pesticide residues in apples at a concentration identical to the currently allowed MRL. The calculation compares a consumer exposure model for three young children from the UK, the Netherlands and Germany. In theory, the MRLs respectively the analyzed residues should not exceed 100% of the ARfD.

[2] German children eat about 3 times more sweet pepper than British children.

Table 1 Exposure calculation for acute risks from pesticides in apples. The calculation compares a Consumer Exposure Model for toddlers from three EU member states [I - VII]

			Intake in % of the Acute Reference Dose (ARfD)		
Pesticide	**EU-MRL for apples**	**ARfD (mg/kg body weight)***	**German child 2 ≤ 5 years 16.15 kg**	**British child 1.5 - 4 years 14.5 kg**	**Dutch child 1 - 6 years 17.1 kg**
Imazalil	5	0,05	820	720	636
Carbendazim	2	0,02	820	720	636
Chlorothalonil	1	0,015	547	480	424
Ethephon	3	0,05	492	432	382
Pyrazophos	0,05	0,001	410	360	318
Parathion	0,2	0,005	328	288	255
Bifenthrin	0,3	0,01	246	216	191
Captan	3	0,1	246	216	191
Triazophos	0,02	0,001	164	144	127
Vinclozolin	1	0,06	137	120	106
Carbaryl	3	0,2	123	108	95

Worst case scenario: the highest residue found is equivalent to the MRL

German Large Portion: 238 g German Apple Weight: 181 g Variability factor: 7
British Large Portion: 373 g British Apple Weight: 112 g
Dutch Large Portion: 260 g Dutch Apple Weight: 138 g

The method for this calculation is used internationally: further information is available in Annex I of the Briefing and at the web-site of the World Health Organization (WHO), http://www.who.int/foodsafety/chem/acute_data/en/ .

* ARfD values used, are those assessed by the Germany Bundesinstitut für Risikobewertung (BfR) and not by the WHO, because BfR values are up to date (January 2006).

The German average size of apples was determined by weighing 10 different apple brands (Braeburn, Elstar, Boskop, … and Jonagold) with a market share of 83,7%. This seems to be quite accurate. The Dutch risk assessors used American apples as a baseline, which seems to be less accurate.

In fact, for the EU co-ordinated monitoring by the European Commission the UK Consumer Exposure Model is used to evaluate the acute risk. Every year this evaluation shows specific pesticide/ commodity combinations were the highest residue found in a composite sample exceed the ARfD for a (British!) child and also for adults. In the year 2002 the Commission stated, that „on basis of the results of the acute exposure assessment a heath risk cannot be excluded, especially for vulnerable groups“[3].However, regulation 396/2005 says the Commission will take care of vulnerable groups. They should take into account all kinds of regional differences.

How EU MRLs were set

In the EU, MRLs are only set for individual active ingredients. Multiple residues are not considered in a SUM MRL as in drinking water. The procedure to establish a MRL for one pesticide (active ingredient) consists of four steps:

1. Establishment of the residue level in or on an agricultural crop treated with the pesticide under conditions of the Good Agricultural Practice (GAP) in a supervised trial.
2. Estimation of the total daily intake of the specific pesticide using appropriate consumer intake models and the established residue level.
3. Adjustment of an '*acceptable daily intake*' (ADI) using data from toxicological tests. This involves finding the highest dose that would produce no adverse effects over a lifetime (chronic) exposure period and then applying appropriate safety factors.
4. Establishment of the residue level from step (1.) as the maximum residue level (MRL) under the condition that the estimated daily consumer intake for all foodstuffs calculated in step (2.) is lower than the ADI calculated in (3.). In cases where the calculated intake is higher, the use conditions need to be modified to reduce the residue level in the commodity. If this is not possible the use of that pesticide on that crop cannot be tolerated and the MRL is set at the limit of determination (effectively zero).

[3] European Commission (2004): Monitoring of Pesticide Residues in Products of Plantorigin in the European Union, Norway, Iceland and Lichtenstein—2002 Report. SANCO/17/04 final

Free trade versus health protection?

According to the new EU regulation sensitivity of vulnerable groups and the acute reference dose of each individual pesticide for these groups must be considered. Besides the problems of variable European data on children's consumption and apple's sizes – this seems to be revolutionary!

But other problems are a cloud on the horizon.

Maximum residue levels published by the international Codex Alimentarius Commission have to be taken into consideration[4]. The World Trade Organization (WTO) only respects these Codex MRLs as 'true' values.

Theoretically, governments are "allowed" by the WTO to set own standards as long as risk assessment and risk management are consistent (see box). However, other countries might challenge new standards as soon as they hinder the global trade.

If Europe comes up with MRLs that are much lower than the Codex MRLs trouble starts. Low MRLs might be seen as a trade barrier discriminating countries outside the EU. Since Codex MRLs are based on the weight and diet of a 60 kg adult person conflicts are very likely.

World Trade Organization (WTO):

"Governments are free to set their own standards provided they are consistent in the way they try to avoid risks over the full range of products, are not arbitrary, and do not discriminate."

There is no information available how the European Union will handle this problem. Will the European Union avoid potential trade conflicts in the WTO and lower the standards? Or will the EU influence the Codex Commission to set higher standards?

Happily harmonized?

Harmonization of maximum residue levels within the EU is nothing new – it started already in1976[5] with the EU MRLs for 43 pesticides, and until 1990[6] three more Directives were added. Alltogether, for over 150 pesticides and 30,000 pesticide/commodity combinations common EU MRLs (i.e. Community-wide MRLs) already exist (website see box page 8).

The new regulation 396/2005 strives towards harmonization of the remaining national MRLs. In 2005, all Member States were required to submit data on their national MRLs to the 'Authority' - the European Food Safety Authority (EFSA).

Neither the new regulation nor the website of EFSA give information on MRLs, which were *already* harmonized between 1976 and 2005. These old EU MRLs do not consider the vulnerability of certain groups - and in fact are not safe (see Annex II and Table 1).

[4] Preamble of 396/2005: "Through the World Trade Organisation, the Community's trading partners should be consulted about the MRLs proposed, and their observations should be taken into account before the MRLs are adopted. MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being set, taking into account the corresponding good agricultural practices."

See also Article 4 of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food.

[5] Council Directive of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables, (76/895/EEC), (OJ L 340, 9.12.1976, p. 26)

[6] Council Directive of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (90/642/EEC), (OJ L 350, 14.12.1990, p. 71)

Are they going to be re-evaluated? Now?

Annex II (see page 11) shows 48 examples of pesticide/commodity combinations, which are not safe for German children. The method for this calculation is the same as above in Table 1 (see Annex I). Residues were set at the EU MRL and consumption was assumed for raw fruit and vegetables.

Theoretically, a farmer applying pesticides according to Good Agricultural Practice should stay well below these limits – but look at the insecticide Phosphamidon and the fungicide Imazalil in pears. Residues exactly as high as the allowed MRL exceed the Acute Reference Dose 27 times and 9 times, respectively. Even residues of 0,006 mg/kg of Phosphamidon and 0,6 mg/kg of Imazalil – almost a tenth of the MRL - exceeds the ARfD for German children. Phosphamidon has not been registered for use in Germany since 2002 and in July 2003 it lost authorization in the EU. Nonetheless, residues were detected in French apricots and a number of German vegetables in 2004 [VIII].

Who guarantees that all farmers producing food inside and outside the EU adhere to Good Agricultural Practice? Nobody can guarantee that all pear growers using Imazalil cause residues that are below 0,6 mg/kg. Imazalil and some other pesticides listed in Annex II already entered the EU list of authorized pesticides (Annex I of Directive 91/414).

What about those EU MRLs for pesticides which authorization has expired and when are the old EU MRLs going to be re-evaluated?

Get Involved!

At a first glance the new regulation on pesticide residues in food looks like a great progress towards more protection of children and consumers in general. A second look reveals that there are a number of open questions. We do not know whose diet will be considered as THE European diet and what unit sizes for fruit and vegetables are taken into account in the harmonization process. And we do not know what role the MRLs proposed by the Codex Alimentarius Commission and older harmonized EU MRLs play. Therefore… Civil society must actively watch the development in the next months and years.

According to the general food law (Regulation 178/2002) risk assessment shall be undertaken in an independent, objective and transparent manner. Currently there is no transparency at all about the MRL harmonization process. EFSA – the responsible “Authority” - does not inform the public. Searching the EFSA website gives no results at all. Maybe you want to ask “when are they going to publish something?”

But it is not only interesting how EFSA will address the above mentioned harmonization problems, equally interesting is the approach of the individual Member States. Do you know, e.g. whether or not your government has submitted MRLs that were evaluated for the risk they pose to children? Or which diet studies were used?

However, the European Commission, the Member States and EFSA must take consumer protection and human health serious.

Our demands are:

- Maximum Residue Levels must be set at the lowest achievable level based on Best Agricultural Practice, because pesticides present a risk for human health and the environment.
- Maximum Residues Levels must consider diets of different consumption patterns as well as minorities, e.g. those of consumer groups with high vegetable intakes, such as vegetarians.
- Transparency from EFSA and the Member States regarding the harmonization process, especially regarding what type of diets are considered and unit weights.
- Transparency from EFSA regarding the position towards MRLs set by the Codex Alimentarius Commission.
- Priority of public health over international standards mostly serving free trade.
- Rapid and consequent re-evaluation of all existing EU MRLs – taking into consideration the vulnerability of certain groups, especially children and the unborn, and applying the "Acute Reference Dose" as toxicological threshold.

Websites:

Website of the European Commission: "Health and Consumer Protection"
[http://europa.eu.int/comm/food/plant/protection/index_en.htm]

- List of harmonized MRLs:
  http://europa.eu.int/comm/food/plant/protection/pesticides/index_en.htm
- Authorization status of new and existing pesticides:
  http://europa.eu.int/comm/food/plant/protection/evaluation/index_en.htm
- Food monitoring reports:
  http://europa.eu.int/comm/food/fvo/specialreports/pesticides_index_en.htm

Website of the European Food Safety Authority (EFSA) the 'Authority' in the MRL harmonization process

- Information regarding the MRL harmonisation process is limited:
  http://www.efsa.eu.int

PAN Websites

- Pesticide residues in food:
  http://www.pesticide-residues.org (PAN Germany)
- Database on pesticides:
  http://www.pesticideinfo.org (PAN North America)
- Pesticide Use Reduction in Europe:
  http://www.pan-europe.info (PAN Europe)

Sources

I. EC (2004) MRL Table available at http://europa.eu.int/comm/food/plant/protection/index_en.htm

II. BfR (2004): Grenzwerte für die gesundheitliche Bewertung von Pflanzenschutzmittelrückständen, Information 002/2006 des BfR vom 6. Januar 2006, Bundesinstitut für Risikobewertung, Berlin

III. BfR (2005): BfR entwickelt neues Verzehrsmodell für Kinder, Information Nr. 016/2005 des BfR vom 2. Mai 2005, Bundesinstitut für Risikobewertung, Berlin

IV. U. Banasiak, H. Heseker, C. Sieke, C. Sommerfeld, C. Vohmann (2005): Abschätzung der Aufnahme von Pflanzenschutzmittel-Rückständen in der Nahrung mit neuen Verzehrsmengen für Kinder, Bundesgesund heitsblatt – Gesundheitsforschung - Gesundheitsschutz 2005, 48:84–98, Springer Medizin Verlag

V. L. Hüther, U. Prüße, K. Hohgardt (2004): Mittlere Gewichte von Obst- und Gemüseerzeugnissen – deutsche Daten zur Abschätzung des von Pflanzenschutzmittelrückständen in Lebensmitteln ausgehenden möglichen akuten Risikos. Gesunde Pflanzen 56:55–60

VI. Pesticide Safety Directorate, PSD (2006): Website, New intake calculation models for consumer intake as sessments: http://www.pesticides.gov.uk > Home » Pesticide Approvals » Pesticides Registration » UK Consumer Intake Models, accessed 11.01.2006

VII. RIKILT (2004): Estimation of the acute dietary exposure to pesticides using the probabilistic approach and the point estimate methodology, Report 2004.008, RIKILT - Institute of Food Safety, Wageningen, The Netherlands

VIII. LSGV (2005): Jahresbericht 2004, Landesamt für Soziales, Gesundheit und Verbraucherschutz, LSGV, Saarbrücken

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Annex I: Calculating Pesticide Intake

Depending on the data on consumption, the pesticide intake for each commodity is calculated from the equation defined for different cases, as described below.

Case 1

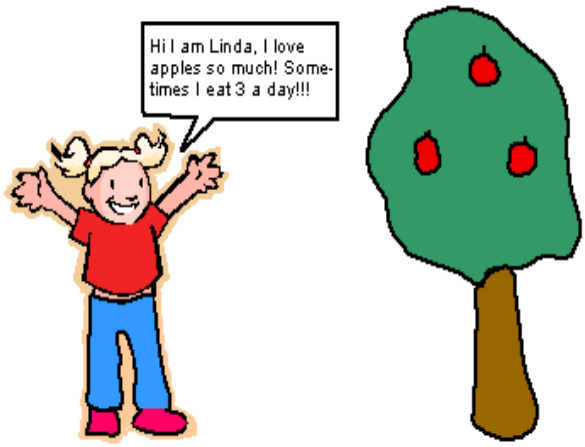
The concentration of residues in a composite sample (raw or processed) reflects that in a large-sized portion of the commodity. This is assumed to be the case when the unit weight is below 25 g (e.g. for strawberries, raspberries, cherries and other small fruits).

Intake = (LP * (HR or HR-P)) /bw

LP is the large portion, HR the residue and P a processing factor for processed food, bw stands for body weight.

Case 2

The typical unit, such as a single piece of fruit or vegetable, might have a higher residue than the composite sample, e.g. when a unit weight of a commodity is above 25 g. The variability factors (v) shown below are applied in the equations.



Linda lives in London, her weight is 14.5 kg and some days she eats 0.373 kg a day.	The average apple marketed in the UK weights 0.112 kg - thus Linda eats over 3 apples some days.
bw = Body weight: 14.5 kg, **LP** = Large Portion: 0,373 kg	**U** = Unit weight: 0,112 kg
The individual apples Linda eats may each contain a different pesticide concentration. That's the reason for the Variability factor **(v)**, which ranges from 1 to 10 depending on the crop, for apples its 7.	
The equation for calculating Linda's short term pesticide intake of this particular residue per kg body weight via raw apples: $\frac{U * (HR) * v + (LP-U) * (HR)}{\text{Body weight}}$	
The calculated intake per kg bw is than compared to the Acute Reference Dose (ARfD), which is given in mg/kg body weight.	
Please note: For each crop other unit weights - and other variability factors - may apply: More information http://www.who.int/foodsafety/chem/acute_data/en/ Annex 2 of this Briefing lists the German parameters for the listed crops.	

Commodity characteristic	Variability (v)
Unit weight is > 250 g, with the exception of head cabbage	5
Unit weight is ≤ 250 g	7
Unit weight is ≤ 250 g, from granular soil treatment	10
Leafy vegetables with unit weight is ≤ 250 g with the exception of head lettuce	10
Head lettuce and head cabbage	3

Case 2a The unit weight of the whole portion is lower than that of the large portion, LP.
Intake = (U * (HR or HR-P) * v+ (LP-U) * (HR or HR-P)) / bw

Case 2b The unit weight of the whole portion is higher than that of the large portion, LP.
Intake = (LP * (HR or HR-P) * v) / bw

Source: The text was taken from http://www.who.int/foodsafety/chem/acute_data/en/ and slightly modified by the author. Graphics and explanation by the author.

Annex II: Percentage of the Acute Reference Dose (ARfD) for 48 pesticides/crop combinations at maximum residue limits (MRLs) for German Children

For the calculations in the table below a new German national dietary study and newly published unit weights were used. All calculations were done according to the international standards as described above. For each fruit the large portion, the unit weight and the variability factor is given in the table. The ARfD of the German authorities is also given. Only commodities which are consumed raw and mostly unpeeled (except pineapple) were considered – therefore processing factors did not apply.

Pesticide (active ingredient)	Residue at EU MRL (mg/kg)	ARfD (mg/kg bw)	% ARfD German child 2 - 5 years, 16.15 kg
Pineapple, Portion: 150 g, Unit weight: 876 g, Variability factor: 5			
Prochloraz	5	0,1	232
Apricot, Portion: 200 g, Unit weight: 50 g, Variability factor: 7			
Chlorothalonil	1	0,015	206
Procymidone	2	0,035	177
Parathion	0,2	0,005	124
Pears, Portion: 232 g, Unit weight: 206 g, Variability factor: 7			
Phosphamidon	0,15	0,0005	2732
Imazalil	5	0,05	911
Ethephon	3	0,05	546
Parathion	0,2	0,005	364
Bifenthrin	0,3	0,01	273
Captan	3	0,1	273
Methidathion	0,3	0,01	273
Strawberries, Portion: 252 g, Unit weight: n.n. Variability factor: 1			
Phosphamidon	0,15	0,0005	468
Chlorothalonil	3	0,015	312
Cyhalothrin lambda	0,5	0,0075	104
Raspberries, Portion: 90 g, Unit weight: n.n. Variability factor: 1			
Chlorothalonil	10	0,015	374
Kiwi, Portion: 200 g, Unit weight: 75 g, Variability factor: 7			
Phosphamidon	0,15	0,0005	1207
Procymidone	10	0,035	1150
Vinclozolin	10	0,06	671
Turnip, Portion: 162 g, Unit weight: 265 g, Variability factor: 5			
Oxydemeton-methyl	0,05	0,0015	167
Carbofuran	0,2	0,009	111
Head lettuce, Portion: 87 g, Unit weight: 348 g, Variability factor: 3			
Carbendazim	5	0,02	404
Bifenthrin	2	0,01	323
Mevinphos	0,5	0,003	269
Cyhalothrin lambda	1	0,0075	215
Methomyl	2	0,02	161
Vinclozolin	5	0,06	135

Pesticide (active ingredient)	Residue at EU MRL (mg/kg)	ARfD (mg/kg bw)	% ARfD German child 2 - 5 years, 16.15 kg
Sweet pepper, Portion: 145 g, Unit weight: 155 g, Variability factor: 7			
Chlorothalonil	2	0,015	840
Endosulfan	1	0,015	420
Ethephon	3	0,05	378
Chlorpyrifos-methyl	0,5	0,01	315
Fenamiphos	0,1	0,003	210
Deltamethrin	0,2	0,01	126
Peaches, Portion: 193 g, Unit weight: 128 g, Variability factor: 7			
Chlorpyrifos-methyl	0,5	0,01	297
Fenarimol	0,5	0,02	148
Bifenthrin	0,2	0,01	119
Plums Portion: 151 g, Unit weight: 52 g, Variability factor: 1			
Mevinphos	0,5	0,003	474
Methamidophos	0,3	0,003	285
Tomatoes, Portion: 150 g, Unit weight: 99 g, Variability factor: 7			
Methamidophos	0,5	0,003	765
Ethephon	3	0,05	276
Endosulfan	0,5	0,015	153
Captan	3	0,1	138
Fenarimol	0,5	0,02	115
Table grapes, Portion: 212 g, Unit weight: 324 g, Variability factor: 5			
Procymidone	5	0,035	935
Carbendazim	2	0,02	655
Vinclozolin	5	0,06	546
Methidathion	0,5	0,01	327
Captan	3	0,1	196
Bifenthrin	0,2	0,01	131

The ARfD values for Phosphamidon in this table were requested from the German Bundesinstitut für Risikobewertung [http://www.bfr.bund.de].