

RISK ASSESSMENT FOR PESTICIDES' MRL NON-COMPLIANCES IN POLAND IN THE YEARS 2011-2015

Paweł Struciński, Jan K. Ludwicki, Katarzyna Góralczyk, Katarzyna Czaja,
Agnieszka Hernik, Monika Liszewska*

National Institute of Public Health – National Institute of Hygiene, Department of Toxicology and Risk Assessment,
Chocimska street 24, 00-791 Warsaw, Poland

ABSTRACT

Background. Human exposure to trace levels of pesticide residues present in food of plant origin is inevitable as long as pesticides continue to be applied in agriculture. Since Maximum Residue Levels (MRL) are not toxicological endpoint values, their violation is not by default equivalent to health risk for consumers. However, it is essential to provide a health-based risk assessment for each case of MRL non-compliance reported during monitoring and official control of foodstuffs.

Objective. To assess the potential short-term risk associated with consumption of food products of plant origin containing pesticide residues above MRL values based on notifications forwarded by the National Contact Point for RASFF in Poland during 2011-2015.

Material and Methods. 115 notifications including 127 analytical results non-compliant with respective MRL values were forwarded to provide risk assessment. An internationally accepted deterministic approach based on conservative model assumptions for short-term exposure assessment was applied. The risk was characterized by comparing an estimated dietary intake with respective acute reference dose (ARfD).

Results. Black currant, tea, lettuce, Chinese cabbage and carrot were among the most frequently notified products in years 2011-2015. Among pesticides exceeding respective MRL values, over 90% belonged to fungicides and insecticides/acaricides such as acetamiprid, chlorpyrifos, dimethoate, imidacloprid, dithiocarbamates and procymidone. For 15 and 6 results non-compliant with respective MRL value, a predicted short-term intake exceeded ARfD for children and adults, respectively.

Conclusions. Residue levels that could potentially pose a health threat are found incidentally. The science-based and transparent risk assessment process with regard to the data, methods and assumptions that are applied is essential to risk management authorities.

Key words: *risk assessment, pesticide residues, MRL, dietary intake, RASFF, food safety*

STRESZCZENIE

Wprowadzenie. Narażenie człowieka na śladowe poziomy pozostałości pestycydów obecnych w żywności pochodzenia roślinnego jest nieuniknione tak długo jak środki ochrony roślin są stosowane w rolnictwie. Ponieważ wartości najwyższych dopuszczalnych poziomów pozostałości pestycydów w żywności (NDP) nie są toksykologicznymi wartościami odniesienia, ich przekroczenie nie jest równoznaczne z zagrożeniem dla zdrowia konsumentów. Jednakże dla każdego przypadku niezgodności z NDP stwierdzonej w monitoringu i urzędowej kontroli żywności należy dokonać naukowej oceny ryzyka zdrowotnego.

Cel badań. Ocena potencjalnego ryzyka związanego z krótkoterminowym narażeniem na pozostałości pestycydu na poziomie powyżej wartości NDP na podstawie powiadomień przekazywanych przez Krajowy Punkt Kontaktowy system RASFF w Polsce w latach 2011-2015.

Materiał i metody. Do oceny ryzyka przekazano 115 powiadomień zawierających 127 wyników powyżej wartości NDP. W celu oszacowania wielkości narażenia krótkoterminowego zastosowano model deterministyczny wykorzystujący konserwatywne scenariusze najgorszego przypadku. Ryzyko charakteryzowano porównując oszacowaną dawkę pozostałości pestycydu z odpowiednią wartością ostrej dawki referencyjnej (ARfD).

Wyniki. W latach 2011-2015 najczęściej zgłaszanymi produktami z powodu przekroczenia wartości NDP były czarna porzeczka, herbata, sałata, kapusta pekińska i marchew. Ponad 90% przypadków przekroczenia NDP dotyczyło fungicydów

* **Corresponding author:** Paweł Struciński, National Institute of Public Health – National Institute of Hygiene, Department of Toxicology and Risk Assessment, Chocimska street 24, 00-791 Warsaw, Poland; phone +48 22 5421356, fax: +48 22 8497441, e-mail: pstrucinski@pzh.gov.pl

oraz insektycydów/akarycydów takich jak np. acetamipryd, chlorpiryfos, dimetoat, imidaklopryd, ditiokarbaminiany czy procymidon. W przypadku 15 przekroczeń NDP, oszacowane krótkoterminowe pobranie pozostałości przekraczało wartość ARfD dla dzieci. Dla dorosłych odnotowano 6 takich przypadków.

Wnioski. Poziomy pozostałości pestycydów, które mogą teoretycznie zagrażać zdrowiu konsumentów stwierdza się bardzo rzadko. Transparentny i oparty na wynikach badań naukowych proces oceny ryzyka dostarcza niepodważalne argumenty urzędowi odpowiedzialnym za zarządzanie ryzykiem.

Słowa kluczowe: ocena ryzyka, pozostałości pestycydów, NDP, pobranie z diety, RASFF, bezpieczeństwo żywności

INTRODUCTION

Hundreds of plant protection products (PPPs), commonly called as pesticides, are widely used in agriculture. They safeguard crops from pests and diseases in the field and during storage and transportation. There are numerous, unquestionable benefits of pesticide application such as assuring high crop yields during cultivation and prolonging their post-harvest storage. On the other hand they are increasingly feared for their potential health risks for general population related to exposure to pesticide residues in food as well as their effects on ecosystems [3, 22, 23, 33]. Due to the strict authorization and Maximum Residue Levels (MRLs) setting procedures in the European Union (EU), pesticide residues in food of plant origin resulting from correct application of PPPs according to Good Agriculture Practice (GAP) rules may be regarded as acceptable from the human health point of view. To achieve this, the pre-registration risk assessment procedures apply a set of unfavorable scenarios to adopt high safety margins [2, 29, 31]. However, there are numerous reasons that may cause pesticide residues levels above the legally binding MRLs which potentially lead to unnecessary consumers' exposure over health-based limits. These include i.a. failure of post-harvest interval (PHI) established in the authorization procedure, inappropriate or illegal use of PPPs, or finally import of food from the third countries where pesticide legislation differs from that in the EU.

Over a dozen years, pesticide residues are the subject of particular interest of the food safety inspection services in the EU Member States. The EU-coordinated programme (EUCP) and the national surveillance programmes are continuously extended for new products and further pesticides [1, 8, 10, 12, 15, 16, 19, 26, 33]. Food products which do not comply with the MRL cannot be marketed in the EU area. They should be rejected during control at the border or withdrawn when non-compliance is found during inspection of the retail market.

In Poland, the State Sanitary Inspection (SSI) subordinated to the Minister of Health (MH) is responsible for the official control and monitoring of pesticide residues in food present on the market. The supervision

of the proper regulatory compliance in the use of plant protection products is under auspices of State Plant Health and Seeds Inspection Service (SPHSIS) subordinated to Minister of Agriculture and Rural Development (MARD) [35]. The former refers to domestic and imported foodstuffs available on retail market, while the latter covers raw agricultural commodities (RACs) grown in Poland.

In the EU, a Rapid Alert System for Food and Feed (RASFF) has been established to protect consumers and to respond quickly to any potential concerns regarding food and feed safety. In Poland, all threats regarding safety of foodstuffs available on retail market, including violations of MRLs, are reported to the Chief Sanitary Inspectorate (CSI) under the MH which was assigned the role of National Contact Point (NCP) for RASFF. In cases where the MRL non-compliance is found in RACs which have entered the market and could be traced there, the NCP is notified by the sub-point located in the General Veterinary Inspectorate subordinated to the MARD. NCP forwards those notifications with all necessary documents, including laboratory and sampling reports, to the Risk Assessment Team established in 2004 by the Chief Sanitary Inspector in the National Institute of Public Health – National Institute of Hygiene (NIPH-NIH). To evaluate whether a MRL violation can lead to an unacceptable risk to the consumer, an estimated dietary intake calculated according to the worst-case scenario is compared to the appropriate toxicological reference value (TRV), that is acute reference dose (ARfD) for the short-term exposure [11, 12, 17, 24, 31, 34]. The scientific risk assessment output is transparent with regard to the data, methods and assumptions that are applied in the process [13]. Depending on the risk assessment outcome, CSI – the risk managing authority – undertakes follow-up actions aiming to withdraw product from the market provided that it was not sold out before the laboratory issued the final analytical report. In justified cases the CSI transmits a relevant notification to the European RASFF system. The inspection may also provide information to SPHSIS to implement procedures aiming to investigate the possible reasons of non-compliance.

The aim of the study was to assess the potential risk associated with consumption of food products conta-

ining pesticide residues above MRL values based on notifications forwarded by the National Contact Point for RASFF in Poland during 2011-2015.

MATERIAL AND METHODS

Notifications from the National Contact Point for RASFF

A total of 124 notifications regarding MRL non-compliance have been forwarded between January 2011 and August 2015 to the NIPH-NIH by the NCP for RASFF for providing science-based risk assessment. In 9 cases a quantitative risk characterization could not be performed due to such reasons like inappropriate residue definition used by the laboratory, applying own uncertainty (instead of default 50%) to the result above MRL value for non-compliance checking or lack of respective TRVs. Thus, a quantitative risk assessment outcome has been provided for 115 food samples, including fruit (n=47), vegetables (n=49) and other products (n=19). Since in some cases MRL non-compliances concerned two, and even more pesticides, a risk was characterized for total of 127 analytical results exceeding respective MRL values. The number of notifications sent to the Risk Assessment Team in the particular years is presented in Table 1.

Table 1. Number of notifications concerning MRL non-compliances for which risk assessments were performed on request of the National Contact Point for RASFF during the period of 2011-2015

Year	Total number of notifications	Number of notifications for which risk assessment was performed
2011	22	17
2012	30	30
2013	27	23
2014	22	22
2015*	23	23
Total	124	115

* until 31.08.2015

Short-term dietary exposure and acute risk characterization

In this study we applied an internationally accepted deterministic approach based on conservative model assumptions which is commonly used for post-regulation risk assessment purposes to evaluate whether the MRL violation for given pesticide/product combination may pose a risk for consumer. In case of MRL violations an acute exposure assessment is performed which aims to estimate the worst realistic scenario based on high-level and short-term intakes that can happen within a period of 24 hours. It is assumed that one would eat a large portion (LP) of that product that is defined as the

97.5th percentile consumption of the food product among eaters only. It is also assumed that the residues are not evenly distributed in the individual units analysed in the composite sample. Such an approach should better represent an acute situation in which a consumer is eating a large portion of the commodity within a short period of time (one day or meal) [11, 12, 17, 34]. An estimated intake is then compared to the most recent ARfD value established or recommended by the European Food Safety Authority (EFSA).

According to the latest European Commission requirements [5], a revised version of the model for calculating the acute and chronic consumer exposure developed by EFSA [9], so-called PRIMo model rev.2, was used. For the short-term exposure assessment it uses the most critical, large portion consumption data among 19 national diets collected (including children and adults) provided to EFSA by the Member States. Calculation of so-called Predicted Short-Term Intake (PSTI) is based on the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) International Estimated Short-Term Intake (IESTI) equations [14, 34]. Depending on the commodity unit weight (U) and large portion (LP) consumed, three cases are distinguished in the model:

- case 1: unit weight < 25 g; no variability of residue levels among units is expected; PSTI is calculated according to the formula:

$$PSTI = \frac{LP \times OR}{bw}$$

where: LP – large portion, OR – observed residue level, *bw* – body weight

- case 2: unit weight >25 g, variability of residue levels among units is expected;

- 2a: unit weight < large portion; PSTI is calculated according to the formula:

$$PSTI = \frac{(U \times OR \times v) + (LP - U) \times OR}{bw}$$

where: U – unit weight, OR – observed residue level, *v* – variability factor, LP – large portion, *bw* – body weight

- 2b: unit weight ≥ large portion; PSTI is calculated according to the formula:

$$PSTI = \frac{LP \times OR \times v}{bw}$$

where: LP – large portion, OR – observed residue level, *v* – variability factor, *bw* – body weight

- case 3: processed/bulked/blended commodities; no variability of residue levels is expected; PSTI is calculated according to the formula for case 1.

For sub-cases 2a and 2b variability factors (v) defined as the ratio between the 97.5 percentile and the average of pesticide residues in individual units are used to account for the unit-to-unit variability in composite samples. Depending on unit weight of a product and its relation to the amount consumed, default variability factors of 3, 5, 7 and 10 are currently used [14, 20]; PRIMo model rev.2 applies factors of 5 and 7 [9]. For cases 1 and 3 a factor of 1 is applied.

Calculated PSTI values are then compared to the most recent ARfD values established or recommended by the EFSA. Intakes that exceed the TRV applied are considered as potentially associated with possible health implications. In case where ARfD is not defined, the predicted short-term intake is checked against the acceptable daily intake (ADI) knowing that this approach generally leads to an overestimation of the risk.

The following model assumptions are additionally applied in the calculations in a transparent and open way:

- a result is regarded as non-compliant if the result of confirmatory analysis exceeds the MRL by more than the default expanded uncertainty of 50% [4, 6];
- the current residue definition for risk assessment purposes, as set by EFSA, is used. If it was not set or when it differs from residue definition established for monitoring purposes and the conversion factor between two definitions was not set, the result reported by the laboratory compliant with residue definition for monitoring is used. In some cases laboratory was asked for providing additional analysis allowing to perform risk assessment;
- no processing factors reflecting theoretical reduction of residue due to washing, cooking or peeling are taken into account;
- for dithiocarbamates, the worst-case scenario is applied assuming that the quantified carbon disulfide

(CS₂) originated from the dithiocarbamate with the lowest ARfD among these fungicides listed in the EU MRL legislation was a potential origin of residue [8]. When ARfD values are the same, then the active substance with the highest conversion factor from CS₂ is chosen;

- in case of MRL non-compliances in rapeseed, consumption of rapeseed oil and rapeseed oil-based margarines was taken into account in exposure estimation.

RESULTS AND DISCUSSION

In contrast to previous years [25], the recent notifications received through the national RASFF system were practically not dominated by any products. The only exception was black currant – notifications concerning this product accounted for almost half of all notifications on fruit with acaricide fenazaquin being the most frequent reason of MRL non-compliances. Other frequently notified products in years 2011-2015 included: tea, lettuce, Chinese cabbage and carrots. It is worth mentioning that tea samples, in addition to the pesticide residues above the MRL, contained up to dozen pesticides below the respective MRL values. Products of plant origin, for which a risk assessment due to MRLs violation was performed on request of NCP for RASFF are shown in Figure 1.

Among products where number of MRL non-compliances has been substantially reduced as compared to the previous study [25] one should mention apples (28 vs 5) and spinach (12 vs 3). Illegal use of carbendazim in the cultivation of fungi (champignons) has been permanently eliminated, hence during the last few years, no sample of this mushroom has been questioned because

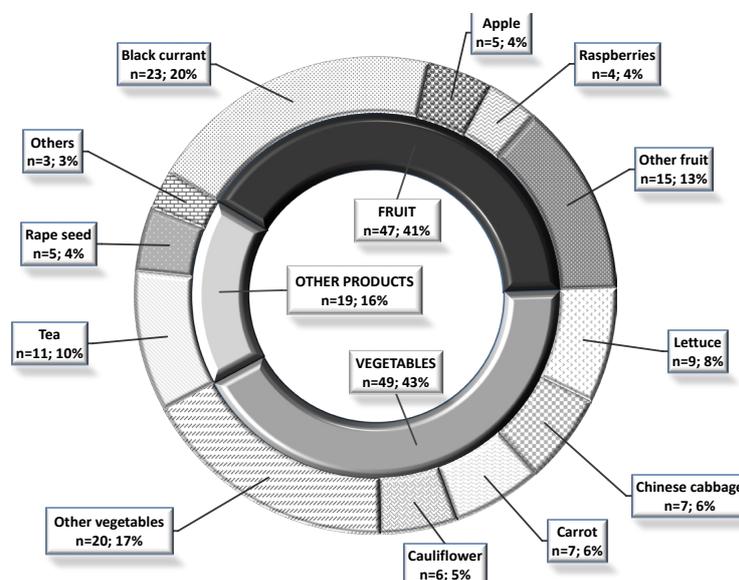


Figure 1. Products for which risk assessment was performed on request of NCP for RASFF due to MRL non-compliances

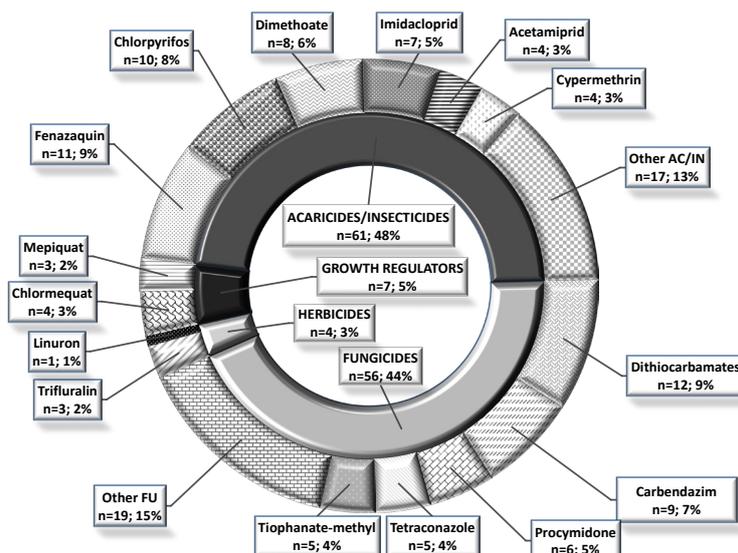


Figure 2. Active substances the most frequently notified in Poland due to MRL non-compliances divided into their mode of biocidal action (AC/IN – acaricides/insecticides, FU – fungicides)

Table 2. A list of food products/pesticide combinations with MRL non-compliances notified through the NCP for RASFF

Commodity	Pesticide residues exceeding particular MRL values
Apple	Carbendazim (NA) ^a , diazinon (NA) ^a , dimethoate, flusilazole (NA) ^a , mepiquat
Aubergine	Procymidone (NA) ^a
Black currant	Cypermethrin, difenoconazole, fenvalerate/esfenvalerate, fenazaquin, flusilazole (NA) ^a , carbendazim (NA) ^a , propargite (NA) ^a , thiophanate-methyl
Broccoli	Dithiocarbamates
Carrot	Chlorpyrifos, diazinon (NA) ^a , tetraconazole, trifluralin (NA) ^a ,
Cauliflower	Chlorpyrifos, dimethoate, dithiocarbamates
Celery (leaves)	Linuron
Chinese cabbage	Acetamiprid, chlorothalonil, chlorpyrifos, dimethoate, pyrimethanil, propamocarb
Cucumber	Chlorfenapyr (NA) ^a , dieldrin (NA) ^a
Oyster mushroom (cultivated fungi)	Mepiquat
Dill	Chlorpyrifos, chlorpyrifos-methyl
French bean	Procymidone (NA) ^a
Gooseberry	Difenoconazole, propiconazole
Grape	Chlormequat, penconazole
Kiwi	Folpet, pyraclostrobin
Lettuce	Chlorothalonil, chlorpyrifos, dimethoate, dithiocarbamates, fenvalerate/esfenvalerate, carbendazim (NA) ^a , thiophanate-methyl
Peach	Carbendazim (NA) ^a
Pear	Chlormequat, mepiquat
Pepper	Thiophanate-methyl
Plum	Dimethoate
Radish	Dimethoate
Rape seed	Pyrimifos-methyl, tetraconazole
Raspberry	Dithiocarbamates, spirodiclofen
Rice	Piperonyl butoxide ^b
Spinach	Chlorpyrifos, cyfluthrin (NA) ^a , iprodione
Strawberry	Procymidone (NA) ^a
Tea	Acephate (NA) ^a , acetamiprid, dithiocarbamates, imidacloprid, tolfenpyrad (NA) ^a , triazophos (NA) ^a

^a Currently not approved under Regulation (EC) No 1107/2009

^b Not listed as active substance of plant protection products

of any MRL violation. On the other hand a number of tea samples with residues above MRL increased from 1 to 11 [25]. According to data from RASFF Portal [30] over half cases of border rejections because of MRL

violations in food reported by Poland between 1.01.2011 and 31.08.2015 were batches of tea.

The differences between products (and pesticide residues) notified by the NCP for RASFF may be, ho-

wever, explained by numerous reasons, like differences in the annual sampling plans, development of analytical capabilities of laboratories, better compliance with GAP among farmers or improved border control which prevents getting imported products which do not meet health quality requirements to the market.

Among pesticides notified by the NCP for RASFF due to MRL violation, over 90% belonged to fungicides and insecticides/acaricides. Acetamiprid, chlorpyrifos, dimethoate, imidacloprid, dithiocarbamates and procymidone were the most frequently reported residues, similarly to the data from recent RASFF report [7]. The profile of the most frequently notified active substances in Poland (2011-2015) divided into their mode of biocidal action is presented in Figure 2. The pesticide/product combinations for which risk assessments were provided are presented in Table 2. It is worthy to note that substantial number of notifications concerned pesticides not approved in the EU.

MRLs are the upper legal levels of a concentration for pesticide residues in or on food or feed based on GAPs and to ensure the lowest possible consumer exposure [8, 18]. Results over the MRL values do not by default pose a risk for health, however for each MRL violation risk assessment must be provided. For 15 out of 127 analytical results non-compliant with respective MRL value, an estimated short-term exposure exceeded ARfD for children who are the most vulnerable subpopulation of consumers (range from 102% to 2258%). This represents 11.8% of MRL non-compliances, and this value is almost the same like in the previous study (11.5%) of Ludwicki and Kostka [25]. In adults, the exposure expressed per kg bw is lower than in children, thus the estimated exposure exceeded ARfD value in 6 cases only (range from 100,2% to 2171%). The highest intake was reported for combination chlorpyrifos/Chinese cabbage. Among above cases, none of the pesticide/product combinations had a dominant share. A distribution of potential short-term dietary exposure calculated for all MRL violations

for children and adults is presented in Figure 3. A list of MRL non-compliances which potentially pose a health risk with detailed description of input data and output of risk characterization expressed as percentage of ARfD is presented in Table 3.

A total of about 2800 samples, including over 500 EUCP samples and almost 2300 national control samples per year are currently analyzed by the SSI [10, 12]. Number of RACs samples analyzed annually in the frame of supervision of the proper regulatory compliance in the use of plant protection products is about 2000-3000 [21, 27, 28]. Both monitoring systems cover up to over 260 pesticide residues, depending on the particular laboratory capabilities. All analyses are carried out in the accredited laboratories of two afore mentioned inspection services. Undoubtedly, 115 notifications on MRL exceedances forwarded by the NCP for RASFF during almost five years represent a very small percentage of all samples analyzed for presence of pesticide residues in food of plant origin in Poland. Additionally, only every tenth was associated with potential health threat. It should be stressed, however, that MRL non-compliances found in RACs were notified only for those cases where the product could be traced on the market, therefore the total number of MRL non-compliances in RACs was undoubtedly somewhat higher.

Considering that a worst case scenario approach was applied in the assessment, a potential risk is likely to overestimate the actual exposure situation that occurred in practice. On the other hand, prevention of being exposed to pesticide residues exceeding concentrations that may lead to adverse health effects is one of the fundamental rules of public health protection.

CONCLUSIONS

Residue concentrations in food of plant origin, even those above respective MRL values, are generally safe

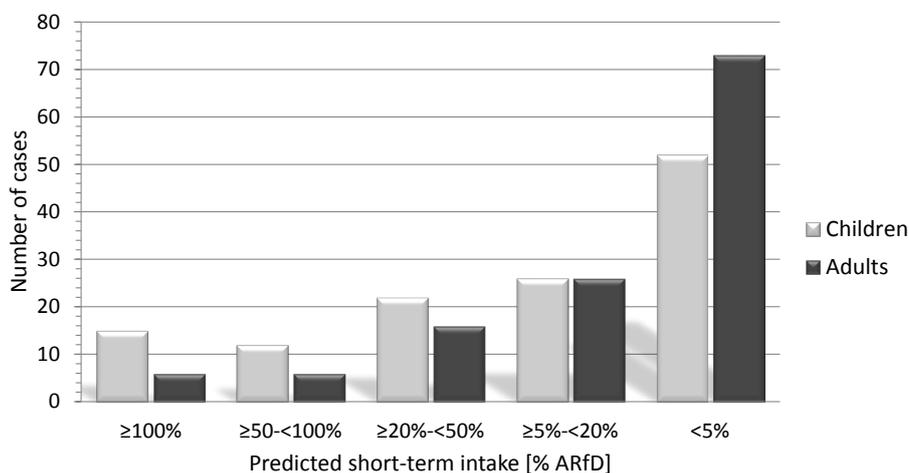


Figure 3. A distribution of potential short-term dietary exposure for children and adults calculated for all MRL violations

Table 3. A list of MRL non-compliances resulting in Predicted Short-Term Intake (PSTI) values exceeding relevant ARfD, therefore evaluated as posing potential risk for consumers' health (MRLs, residue definitions and ARfD values were applicable at the time of sampling)

Commodity, year (country of origin)	Pesticide (residue definition for enforcement)	Residue level (MRL value) [mg kg ⁻¹]	Residue definition for risk assessment	ARfD [mg kg ⁻¹ bw day ⁻¹] (source, year)	v (case)	PSTI [mg kg ⁻¹ bw day ⁻¹] (% ARfD)	
						Children	Adults
Chinese cabbage, 2015 (Poland)	Chlorpyrifos (chlorpyrifos)	3.04 (0.5)	As for enforcement ^a	0.005 (EFSA 2014)	5 (2b)	0.1129 (2257.8%)	0.1086 (2171.4%)
Cauliflower, 2015 (Poland)	Chlorpyrifos (chlorpyrifos)	0.71 (0.05)	As for enforcement ^a	0.005 (EFSA 2014)	5 (2b)	0.0470 (939.7%)	0.0226 (451.4%)
Peach, 2012 (Spain)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim)	2.83 (0.2)	As for enforcement	0.02 (EC 2006)	7 (2a)	0.1679 (839.5%)	0.0495 (247.3%)
Pears, 2014 (Poland)	Chlormequat (chlormequat)	4.6 (0.1)	Sum of chlormequat and its salts expressed as chlormequat chloride ^b	0.09 (EFSA 2008)	7 (2a)	0.4189 (465.5%)	0.0987 (109.7%)
Pears, 2012 (Poland)	Chlormequat (chlormequat)	4.2 (0.1)	Sum of chlormequat and its salts expressed as chlormequat chloride ^b	0.09 (EFSA 2008)	7 (2a)	0.3825 (425.0%)	0.0902 (100.2%)
Lettuce, 2012 (Poland)	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)	1.28 (0.01)	As for enforcement	0.01 (EFSA 2006)	5 (2b)	0.0336 (336.3%)	0.0137 (137.4%)
Apple, 2014 (Poland)	Dimethoate (sum of dimethoate and omethoate expressed as dimethoate)	0.084 (0.02)	Toxicologically adjusted sum of dimethoate and omethoate, expressed as dimethoate ^c	0.01 (EFSA 2013)	7 (2a)	0.0288 (288.0%)	0.0066 (66.0%)
Apple, 2015 (Poland)	Flusilazole (flusilazole)	0.12 (0.02)	As for enforcement	0.005 (EC 2006)	7 (2a)	0.0118 (235.1%)	0.0027 (53.9%)
Orange, 2015 (Turkey)	Fenvalerate (fenvalerate (any ratio of constituent isomers (RR, SS, RS & SR) including esfenvalerate))	0.26 (0.02)	Esfenvalerate	0.0175 (EFSA 2014)	7 (2a)	0.0359 (205.4%)	0.0069 (39.6%)
Apple, 2011 (Poland)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim)	0.41 (0.2)	As for enforcement	0.02 (EC 2006)	7 (2a)	0.0402 (200.8%)	0.0092 (46.0%)
Lettuce, 2014 (Poland)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)	28.8 (5)	Mancozeb ^{d,e}	0.6 (EC 2005)	5 (2b)	1.0829 (180.5%)	0.4423 (73.7%)
Cucumber, 2012 (Poland)	Aldrin and dieldrin (aldrin and dieldrin combined expressed as dieldrin)	0.08 (0.02)	As for enforcement	0.003 (EFSA 2007)	5 (2b)	0.0045 (150.1%)	0.0015 (50.0%)
Tomato, 2012 (Poland)	Vinclozolin (vinclozolin, sum of vinclozolin and all metabolites containing the 3,5-dichloraniline moiety, expressed as vinclozolin)	1.24 (0.05)	As for enforcement	0.06 (SCoFCAH 2006)	7 (2a)	0.0721 (120.2%)	0.0189 (31.5%)
Lettuce, 2011 (Poland)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim)	0.84 (0.1)	As for enforcement	0.02 (EC 2006)	7 (2a)	0.0227 (113.5%)	0.0093 (46.4%)
Lettuce, 2013 (Poland)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)	13.0 (5)	Mancozeb ^{d,e}	0.6 (EC 2005)	5 (2b)	0.6121 (102.0%)	0.2500 (41.7%)

^a Two separate plant residue definitions for risk assessment were set: 1) chlorpyrifos and 2) TCP (3,5,6-trichloropyridinol) and its conjugates expressed as TCP. For PSTI calculation, the first one was applied.

^b No conversion factor (from monitoring to risk assessment) established; quantified level of chlormequat applied for PSTI calculation.

^c Toxicologically adjusted sum of dimethoate and omethoate, expressed as dimethoate (0.294 mg kg⁻¹) for the acute exposure was calculated as: $C_{\text{dimethoate}} + 6 \times C_{\text{omethoate}}$; potency factor of 6 on a short-term basis is derived taking into account that omethoate has a 6 times higher acute toxicity than dimethoate

^d Origin of the residue according to Regulation 396/2005 (and amending Regulations): mancozeb.

^e For risk assessment, concentration of CS₂ was recalculated to mancozeb using conversion factor of 1.78.

from the toxicological point of view. However, there are cases, where pesticide residues' levels in food could potentially pose a threat to human's health. Even though substantial overestimation of exposure provides a large margin of safety for consumers, it is justified to continuously perform official controls and monitoring surveys to check the compliance of products with MRLs and look for potential threat for consumers' health. The science-based and transparent risk assessment process with regard to the data, methods and assumptions that are applied is essential to risk management authorities maintaining and building trust and credibility of food regulation and the wider food system.

Acknowledgements

This study was financially supported by the National Institute of Public Health – National Institute of Hygiene, Warsaw, Poland in frame of public health protection activities, project numbers 2014/4/ZŚM and 2015/4/ZŚM and by the Chief Sanitary Inspectorate (contract No 62/14/GIS/NISP/BŻ).

The Authors would like to thank the staff of the National Contact Point for RASFF located in the Chief Sanitary Inspectorate for good past, current and future cooperation.

Conflict of interest

The authors declare no conflict of interest.

REFERENCES

1. Claeys W.L., De Voghel S., Schmit J.-F., Vromman V., Pussemier L.: Exposure assessment of the Belgian population to pesticide residues through fruit and vegetable consumption. *Food Addit Contam Part A* 2008;25(7): 2014;160:851-863
2. Czaja K., Góralczyk K., Struciński P., Hernik A., Korcz W., Snopczyński T., Ludwicki J.K.: Analiza podstaw naukowych ustalania definicji najwyższych dopuszczalnych poziomów pozostałości pestycydów (NDP) [Analysis of scientific background of establishing definitions for Maximum Residue Levels (MRLs)]. *Rocz Panstw Zakł Hig* 2009;60(3):207-212 (in Polish)
3. Damalas C.A., Eleftherohorinos I.G.: Pesticide exposure, safety issues, and risk assessment indicators. *Int J Environ Res Public Health* 2011;8:1402-1419
4. EC (European Commission) 2002. Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC. *Off J Eur Comm L*187:30-43
5. EC (European Commission) 2011. Draft guidance document on notification criteria for pesticide residue findings to the Rapid Alert System for Food and Feed (RASFF). SANCO/3346/2001 rev 12, Brussels, 12 May 2011
6. EC (European Commission). 2013. Guidance document on analytical quality control and validation procedures for pesticide residues analysis in food and feed. SANCO/12571/2013, 19 November 2013 rev. 0
7. EC (European Commission) 2015. RASFF for safer food – The Rapid Alert System for Food and Feed – 2014 annual report. Luxembourg, Publications Office of the European Union, 2015
8. EC (European Commission) 2005. 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. *Off J Eur Comm L*70:1-16, as amended
9. EFSA (European Food Safety Authority) 2013. EFSA calculation model: Pesticide Residue Intake Model “PRIMO” revision 2. Available from: <http://www.efsa.europa.eu/en/mrls/mrlteam.htm> (accessed 30.07.2015).
10. EFSA (European Food Safety Authority) 2015. National summary reports on pesticide residue analysis performed in 2013. EFSA supporting publication 2013:EN-755, 162 pp. Available from: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/755e.pdf (accessed 30.07.2015)
11. EFSA (European Food Safety Authority) 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, 15 March 2007. Available from: <http://www.efsa.europa.eu/en/efsajournal/doc/32r.pdf> (accessed 30.07.2015)
12. EFSA (European Food Safety Authority) 2015. The 2013 European Union report on pesticide residues in food. *EFSA J* 2015;13(3):4038, 169 pp., doi:10.2903/j.efsa.2015.4038
13. EFSA (European Food Safety Authority) 2009. Transparency in risk assessment. Guidance of the Scientific Committee in the Scientific Aspects of Risk Assessment carried out by EFSA. Part 2: General principles. *EFSA J* 2009;1051:1-22.
14. FAO 2009. FAO manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed, Second Edition, Rome, 2009. Available from: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/FAO_manual2nded_Oct07.pdf (accessed 30.07.2015)
15. Góralczyk K., Struciński P., Hernik A., Czaja K., Korcz W., Ludwicki J.K.: Monitoring i urzędowa kontrola pozostałości pestycydów w żywności w Polsce w 2004 roku [Monitoring and official control of pesticide residues in foodstuffs in Poland in 2004]. *Rocz Panstw Zakł Hig* 2005;56(4):307-316 (in Polish)
16. Góralczyk K., Struciński P., Korcz W., Czaja K., Hernik A., Snopczyński T., Ludwicki J.K.: Badania pozostałości pestycydów w żywności pochodzenia roślinnego w Polsce w latach 2004 – 2007 [The survey of pesticide residues in food of plant origin in Poland, 2004-2007]. *Rocz Panstw Zakł Hig* 2009;60(2):113-119 (in Polish)

17. Hamilton D., Ambrus Á., Dieterle R., Felsot A., Harris C., Petersen B., Racke K., Wong S.-S., Gonzalez R., Tanaka K., Earl M., Roberts G., Bhula R.: Pesticide residues in food – acute dietary exposure. *Pest Manag Sci* 2004;60:311-339
18. Hamilton J.H.: MRL calculations based on both intra- and inter-trial residue variability. *Regul Toxicol Pharmacol* 2015;72:1-7
19. Hjorth K., Johansen K., Holen B., Andersson A., Christensen H.B., Siivinen K., Toome M.: Pesticide residues in fruits and vegetables from South America – A Nordic project. *Food Control* 2011;22(11):1701-1706
20. IGHRC (The Interdisciplinary Group on Health Risks from Chemicals). 2010. Current approaches to exposure modeling in UK Government Departments and Agencies (cr15). Institute of Environment and Health, Cranfield University, UK. Available from: [http://ieh.cranfield.ac.uk/ighrc/pdf/cr%20reports/cr15\[1\].pdf](http://ieh.cranfield.ac.uk/ighrc/pdf/cr%20reports/cr15[1].pdf) (accessed 30.07.2015)
21. Instytut Ogrodnictwa. Analiza pozostałości środków ochrony roślin w płodach rolnych. Sprawozdanie za rok 2012 [Analysis of pesticide residues in raw agricultural commodities. Report 2012], Skierniewice, grudzień 2012 (in Polish). Available from: http://www.inhort.pl/files/program_wieloletni/wykaz_publicacji/obszar5/2012_Analiza%20pozostalosci.pdf (accessed 30.07.2015)
22. Karabelas A.J., Plakas K.V., Solomou E.S., Drossou V., Sarigiannis D.A.: Impact of European legislation on marketed pesticides – A view from the standpoint of health impact assessment studies. *Environ Int* 2009;35:1096-1107
23. Kjeldsen L.S., Ghisari M., Bonefeld-Jørgensen E.C.: Currently used pesticides and their mixtures affect the function of sex hormone receptors and aromatase enzyme activity. *Toxicol Appl Pharmacol* 2013;272:453-464
24. Low F., Lin H.-M., Gerrard J.A., Cressey P.J., Shaw I.C.: Ranking the risk for pesticide dietary intake. *Pest Manag Sci* 2004;60:842-848
25. Ludwicki J.K., Kostka G.: Przekroczenia dopuszczalnych poziomów pozostałości pestycydów w żywności zgłaszane do oceny ryzyka zgodnie z procedurami RASFF w Polsce [Violations of MRLs for pesticide residues in food reported for risk assessment according to RASFF procedures in Poland]. *Roczn Panstw Zakl Hig* 2008;59(4):389-396 (in Polish)
26. Matt D., Pehme S., Peetsmann E., Luik A., Meremäe K.: Pesticide residues in Estonian local and imported food in 2008-2011. *Acta Agr Scand, Sect B – Soil Plant Sci* 2013:sup1;78-85
27. Miszczak A., Research Institute of Horticulture, Skierniewice, personal communication, 20.07.2015
28. Nowacka A., Gnusowski B., Walorczyk S., Drożdżyński D., Raczkowski M., Hołodyńska A., Frąckowiak D., Wójcik A., Ziółkowski A., Przewoźniak M., Swoboda W. et al.: Pozostałości środków ochrony roślin w płodach rolnych (rok 2011) [Pesticide residues in Polish crops (2011)]. *Prog Plant Prot* 2012;52(4):1106-1116 (in Polish)
29. Noworyta-Głowacka J., Bańkowski R., Wiadrowska B., Ludwicki J.K.: Ocena toksykologiczna środków ochrony roślin w procesie rejestracyjnym UE [Toxicological evaluation of crop protection chemicals in the EU registration proces]. *Rocz Panstw Zakl Hig* 2010;61(1):1-6 (in Polish)
30. RASFF Portal website 2015. <https://webgate.ec.europa.eu/rasff-window/portal/> (accessed on 30.07.2015)
31. Struciński P., Góralczyk K., Czaja K., Hernik A., Korcz W., Ludwicki J.K.: Ocena ryzyka dla konsumenta przy przekroczeniach najwyższych dopuszczalnych poziomów pozostałości (NDP) w żywności [Consumer risk assessment in case of maximum residue levels (MRLs) violations in food]. *Rocz Panstw Zakl Hig* 2007;58(2):377-388 (in Polish)
32. Struciński P., Góralczyk K., Czaja K., Hernik A., Korcz W., Ludwicki J.K.: Ocena ryzyka związana z narażeniem na pozostałości pestycydów w żywności pochodzenia roślinnego na etapie rejestracji środka ochrony roślin [Dietary risk assessment for pesticide residues in food of plant origin during plant protection product's registration process]. *Rocz Panstw Zakl Hig* 2006;57(4):303-315 (in Polish)
33. Struciński P., Morzycka B., Góralczyk K., Hernik A., Czaja K., Korcz W., Matuszak M., Minorczyk M., Łyczewska M., Pruss B., Ludwicki J.K.: Consumer risk assessment associated with intake of pesticide residues in food of plant origin from the retail market in Poland. *Hum Ecol Risk Assess* 2015; 21(8): 2036-2061
34. Tucker A.J.: Pesticide residues in food – Quantifying risk and protecting the consumer. *Trends Food Sci Technol* 2008;19:S49-S55
35. Wojtyła A., Biliński P., Jaworska-Łuczak B.: Regulatory strategies to ensure food and feed safety in Poland – update review. *Ann Agric Environ Med* 2010;17:215-220.

Received: 31.07.2015

Accepted: 06.10.2015

