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NECESSITY OF HARMONIZATION OF PESTICIDE HYGIENIC STANDARDS IN FOOD PRODUCTS DURING UKRAINE'S EUROPEAN INTEGRATION (ON FUNGICIDES EXAMPLE)

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Summary. *In this article the results of a comparative assessment of the regulatory framework of Ukraine in safe content of fungicides in food products with the regulatory bases of other countries: the USA, Japan, Canada, Europe are presented; divisions were established, their causes were dedicated and possible solutions of the problem of regulatory harmonization of Ukrainian regulatory framework to international standards were suggested.*
Key words: maximum residue limits, harmonization, fungicides, international standards.

At present time in Ukraine adaptation and harmonization of the regulatory framework in the field of agriculture to the international standards are quite actively developing [1, 2]. Such policy provides euro integration of Ukraine and simplifies the conditions of export of agricultural products. To integrate into the internal market of the European Union (EU), Ukraine should focus on European requirements, since the main barriers to trade with the EU lies in the requirements for safety and quality of products, its characteristics, conformity assessment procedures with the technical requirements [3, 4].

Today in Ukraine 400 values of acceptable daily doses (ADD) and ten times more of maximum allowable levels (MAL) values of pesticides are approved. With a quarter of them (more than 100 values of ADD) are fungicides. Therefore, it is necessary to analyze compliance with hygienic standards and regulations of fungicides in food that occupy a leading position according to their assortment and volume of application in Ukraine and other countries among all preparations for crops protection.

In addition, this class of pesticides used mainly two-, three times during the crops' growing season. Such conditions of application can lead to fungicides accumulation in agricultural raw materials [5].

The aim of work was a comparative assessment of the Ukrainian regulatory framework of safe pesticides contents in food stuffs with the regulatory bases of other countries: the US, Japan, Canada, European countries for establishing of fundamental differences, their causes and possible ways of solving the problem.

Materials and methods. We have conducted a comparative estimation of value of ADD and ADI (acceptable daily intakes), MAL and MRL in the agricultural production of the most common and widely used pesticides in the world: triazoles (difenoconazole, tebuconazole, flutriafol); methoxyacrylates (pyraclostrobin, trifloxystrobin, azoxystrobin); cyanopyrrole (boscalid, metalaxyl-M); anilinopyrimidines (cyprodinil, pyrimethanil); pyrazolecarboxamides (fluxapyroxad, penthiopyrad, isopyrazam, sedaxan) [6-11].

Also the most common (both for domestic use and for export) cultures were selected [12, 13]: cereals (wheat and corn/maize), vegetables (potatoes, tomatoes), garden fruits (apples, grapes), pulses (soybeans, peas). In addition, corn and soybeans are related to oilseeds.

The values of ADD and MAL in food products, approved in Ukraine are given from DSanPiN 8.8.1.2.3.4.- 000-2001 [14-16]. Also data bases of Europe [6], Japan [7], Canada [8] and Codex Alimentarius [9] were used.

Results and discussion. The results of comparative analysis showed that 47 % of the test substances, ADD values that are approved in Ukraine, coincide with the values of acceptable daily intakes (ADI), substantiated by experts of FAO/WHO, USA, Japan (table 1). In all other cases the value of ADD, which was approved in Ukraine, much lower than values, established in other countries.

The analysis of national health legislation in the field of regulation of the safe use of pesticides and legislation of advanced countries showed that the national regulatory framework is characterized by more stringent requirements. Reasons for inconsistencies between the values of ADI (FAO/WHO) and ADD (DSanPiN 8.8.1.2.3.4-000-2001) are [17]:

1) Using for ADD calculation underthreshold doses, established in toxicological experiment, as opposed to the threshold dose, used for ADI substantiation;

2) Usage in substantiation of ADD value of more "hard" safety coefficients (taking into account possible species sensitivity, long-term effects, high persistence in the environment, etc.).

3) Using of the comprehensive hygienic standardization principle provides for the distribution of the ADD value between food products, drinking water and atmosphere air.

Table 1

Acceptable daily doses and maximum residue levels of different classes of fungicides in agricultural plants

Chemical class	Active ingredient	Crop		Data bases								
				Ukrainian [14-16]		Codex [9]		EU [6]		Japan [7]		Canada [8]
				MRL, mg/kg	ADI, mg /kg	MRL, mg/kg	ADI, mg /kg	MRL, mg/kg	ADI, mg /kg	MRL, mg/kg	ADI, mg /kg	MRL, mg/kg
triazoles	difenoconazole	c	w	0,05	0,002	0,02	0,01	0,1	0,01	0,1	0,0096	0,1
			m	—		—		0,05		0,1		—
		v	pt	0,1		4,0		0,1		0,1		4,0
			t	0,1		—		2,0		0,6		0,6
		f	a	0,1/0,05**		—		0,8		0,1		5,0
			g	0,05/0,05**		3,0		3,0		4,0		4,0
		p	s	—		0,02		0,05		0,05		0,15
			ps	—		0,7		0,1		—		0,03
	tebuconazole	c	w	0,2	0,03	0,15	0,03	0,1	0,03	2,0	0,029	0,15
			m	0,025/0,1*		—		0,02		0,05		0,05
		v	pt	0,05		—		0,02		0,1		—
			t	0,04/0,05**#		0,7		0,9		1,0		—
		f	a	0,05/0,03**		1,0		0,3		1,0		—
			g	0,1/0,01**		6,0		0,5		5,0		5,0
		p	s	0,01/0,05*		0,15		0,15		0,3		0,08
			ps	—		—		0,2		0,5		—
	flutriafol	c	w	0,1	0,01	0,15	0,01	0,5	0,01	0,5	0,33	—
			m	—		—		0,5		—		0,01/0,02*
		v	pt	—		—		0,2		—		—
			t	—		—		0,3		0,3		—
		f	a	0,05/0,05**		—		0,4		0,3		0,4
			g	0,05/0,01**		0,8		0,8		1,0		1,5
		p	s	0,2		0,4		0,5		0,4		0,4
			ps	0,4		—		0,05		—		—
methoxyacrylates	pyraclostrobin	c	w	0,2	0,03	0,2	0,03	0,2	0,03	0,2	0,034	0,2
			m	0,2		0,02		0,02		0,02		—
		v	pt	0,1		0,02		0,02		0,02		—
			t	0,2/0,1**#		0,3		0,3		0,5		1,0
		f	a	0,2/0,05**#		0,5		0,5		1,0		1,5
			g	0,1		2,0		1,0		3,0		2,0
		p	s	0,05		0,05		0,05		0,2		0,04
			ps	—		0,3		0,3		0,3		0,05

Continuation of table 1

Chemical class	Active ingredient	Crop		Data bases: Ukrainian [14-16] MRL, mg/kg	Ukrainian [14-16] ADI, mg /kg	Codex [9] MRL, mg/kg	Codex [9] ADI, mg /kg	EU [6] MRL, mg/kg	EU [6] ADI, mg /kg	Japan [7] MRL, mg/kg	Japan [7] ADI, mg /kg	Canada [8] MRL, mg/kg
methoxyacrylates	trifloxystrobin	c	w	0,05	0,02	0,2	0,04	0,3	0,1	0,2	0,05	0,05
			m	0,05		0,02		0,02		0,05		0,05/0,1*
		v	pt	0,02		0,02		0,02		0,04		0,04
			t	0,07/0,05**#		0,7		0,7		0,7		0,5
		f	a	0,04/0,05**#		—		0,7		3,0		2,0
			g	0,06/0,05**#		3,0		3,0		5,0		0,08
		p	s	0,05		—		0,01		0,08		0,02
			ps	—		—		0,01		—		0,03
	azoxystrobin	c	w	0,2	0,03	0,2	0,2	0,5	0,2	0,3		0,03
			m	0,2		0,02		0,02		0,05		—
		v	pt	0,2		7,0		7,0		1,0		8,0
			t	0,01/0,01**		—		3,0		3,0		0,2
		f	a	—		—		0,01		2,0		2,0
			g	0,1/0,1		2,0		2,0		10,0		4,0
		p	s	0,2		0,5		0,5		0,5		0,5
			ps	0,2		—		0,15		0,5		0,2
cyanopyrroles	fludioxonil	c	w	0,02	0,015	—	0,4	0,01	0,37	0,05	0,33	0,02
			m	0,01		—		0,01		0,05		0,02
		v	pt	0,02		5,0		5,0		0,02		6,0
			t	0,04/0,05**#		3,0		3,0		5,0		5,0
		f	a	0,05#/0,1**#		—		5,0		5,0		5,0
			g	0,04#/0,05**#		2,0		5,0		5,0		2,0
		p	s	0,4		—		0,01		0,07		—
			ps	0,2		0,07		0,4		0,3		0,4
	boscalid	c	w	—	0,04	0,5	0,04	0,5	0,04	0,7	0,044	0,2
			m	—		—		0,5		0,1		1,0
		v	pt	0,2		—		2,0		2,0		0,05
			t	—		—		3,0		5,0		1,4
		f	a	0,5/0,05**#		2,0		2,0		2,0		2,0
			g	0,3/0,15**#		5,0		5,0		10,0		3,5
		p	s	—		—		3,0		3,0		0,1
			ps	—		—		3,0		3,0		2,5

Continuation of table 1

Chemical class	Active ingredient	Crop		Data bases								
				Ukrainian [14-16]		Codex [9]		EU [6]		Japan [7]		Canada [8]
				MRL, mg/kg	ADI, mg /kg	MRL, mg/kg	ADI, mg /kg	MRL, mg/kg	ADI, mg /kg	MRL, mg/kg	ADI, mg /kg	MRL, mg/kg
cyanopyrroles	metalaxyl-M	c	w	0,2	0,03	—	0,08[1]	0,05[2]	0,08	0,05[2]	0,022	0,2[2]
			m	0,1/0,5*		—		0,05		0,05		0,05
		v	pt	0,04		0,05[1]		0,05		0,3		0,5
			t	0,04/0,04**		0,5[1]		0,2		2,0		1,0
		f	a	—		—		1,0		0,2		0,1
			g	0,04/0,04**		1,0[1]		2,0		1,0		2,0
		p	s	0,4		0,05[1]		0,1		0,05		1,0
			ps	0,2#		0,05[1]		0,05		0,2		0,2
anilinopyrimidines	cyprodinil	c	w	0,1	0,03	0,5	0,03	0,5	0,03	0,5	0,027	—
			m	—		—		0,02		0,5		—
		v	pt	—		—		0,02		—		—
			t	0,1/0,1**#		—		1,5		0,5		1,5
		f	a	0,05/0,05**		—		1,5		5,0		1,7
			g	0,05/0,05**		3,0		3,0		5,0		2,0
		p	s	—		—		0,02		0,1		0,6
			ps	—		—		1,0		0,2		0,6
	pyrimethanil	c	w	—	0,02	—	0,2	0,05	0,17	—	0,17	—
			m	—		—		0,01		—		—
		v	pt	—		0,05		0,05		0,05		0,05
			t	0,05		0,7		1,0		2,0		0,5
		f	a	0,2/0,2**		—		15,0		14,0		14,0
			g	0,2/0,2**		4,0		5,0		10,0		5,0
		p	s	—		—		0,02		—		—
			ps	—		—		0,5		1,0		—
pyrazolecarboxamides	fluxapyroxad	c	w	0,2	0,02	0,3	0,02	0,4	0,02	0,3	0,021	0,3
			m	—		0,01		0,01		0,2		0,01
		v	pt	0,1		0,03		0,03		0,03		—
			t	—		—		0,6		0,7		0,7
		f	a	—		—		0,9		0,9		0,8
			g	—		—		0,01		2,0		2,0
		p	s	—		0,15		0,15		0,3		0,15
			ps	—		0,4		0,4		0,4		0,4

Continuation of table 1

Chemical class	Active ingredient	Crop		Ukrainian [14-16] MRL, mg/kg	Ukrainian [14-16] ADI, mg /kg	Codex [9] MRL, mg/kg	Codex [9] ADI, mg /kg	EU [6] MRL, mg/kg	EU [6] ADI, mg /kg	Japan [7] MRL, mg/kg	Japan [7] ADI, mg /kg	Canada [8] MRL, mg/kg
pyrazolecarboxamides	penthiopyrad	c	w	0,2	0,1	0,1	0,1	0,1	0,1	0,2	0,081	0,15
			m	—		0,01		0,01		0,02		0,01/ 0,05[2]
		v	pt	—		0,05		0,05		0,06		0,06
			t	0,1/0,1**		—		2,0		3,0		3,0
		f	a	0,1/0,1**		—		0,5		2,0		0,5
			g	0,1/0,1**		—		0,01		10,0		—
		p	s	0,1/0,2*		0,3		0,3		0,4		0,4
			ps	—		0,3		0,3		0,4		
	isopyrazam	c	w	0,1	0,01	0,03	0,06	0,2	0,03	0,2	0,055	4
			m	—		—		0,01		0,2		
		v	pt	—		—		0,01		—		
			t	—		—		1,5		—		
		f	a	0,1#/0,1**#		—		0,7		—		
			g	—		—		0,01		—		
		p	s	—		—		0,01		—		
			ps	—		—		0,01		—		
	sedaxan	c	w	0,01	0,1	0,01	0,1	0,01[3]	0,11	0,01	0,11	0,01
			m	—		—				0,01		0,01
		v	pt	—		—				—		0,02
			t	—		—				—		—
		f	a	—		—				—		—
			g	—		—				—		—
		p	s	—		0,01				0,01		0,01
			ps	—		—				—		0,01

Notes:
c — cereals; v — vegetables; f — fruits; p — pulses; w — wheat; m — maize; pt — potato; t — tomato; a — apple; g — grape; s — soybean; ps — peas;
— not allowed, LOQ; * — oil; ** — juice;
1 — for metalaxyl; 2 — for both metalaxyl and metalaxyl-M; 3 — default for all cultures; 4 — only bananas.

Analysis of MAL values (table 1), approved in Ukraine and MRL of other countries (USA, Japan, Canada, Europe) showed that the total matches of the standards observed only in 10,7 %, complete mismatch — at 60,7 %. It should be noted that 28,6 % of standards were at the same order of numbers.

It was noted that most matches of MAL and MRL values were in wheat: the same values in 24,0 % of cases, similar — in 44,0 % of cases. While the MAL values in apples and grapes, approved in Ukraine, does not coincide with MRL in any of the studied countries, amount of values of the same order are only 18,2 % and 4,1 %, respectively. As for oil crops (corn and soybeans), were found just 8,0 % of matches of Ukrainian MAL with MRL values of other countries, values at the same level — 48,0 % of cases, different — 44,1 %.

Comparative analysis of MAL and MRL values, approved in other countries, found that 30,0-68,3 % of cases in Europe, USA and Japanese standards are the same; in 20,0-40,2 % of cases — close in meanings; and only 11,5-28,3 % — different. When comparing the MRL values of above mentioned countries and Canada was found that groups of same values, the values of the same order and different values make up about a third of each.

The main differences between the studied parameters in Ukraine and in the world are:

1. MRL of fungicides for corn and soybean oils are established only in Ukraine and partially in Canada, for apple, grape and tomato juice — only in Ukraine.

2. More the same values of fungicide MAL and MRL were established for new active substances, provided into the practice of agriculture in recent years (penthiopyrad, sedaxan).

3. In most of cases the MAL values, approved in Ukraine are by 1-2 orders of magnitude (in the case of apples and grapes by 3 orders of magnitude) lower than the corresponding indices of MRL, approved in other countries.

4. The main difference between the MAL and MRL values of fungicides for oilseed is that the values, approved in Ukraine, higher than values, approved in other studied countries (63,6 % of cases — including standards that differ, 44,0 % — of all MRL of these cultures).

Described differences can be explained by different methodological approaches to the substantiation of MAL values. In Ukraine the maximum allowable level is calculated based on the value of residues in harvests of agricultural crops, acceptable daily dose, risk assessment considering acceptable daily intake and daily real intake from all crops in which the substance is registered [18]. In other countries, the value of residues in harvests of crops and estimated values of the relative risks in the results obtained are taking into account primarily [6-9].

Conclusions

1. Overcoming of the mentioned problems requires not only the elimination of internal contradictions in the regulatory frameworks of various countries and international recommendations based on a systematic approach [19] but differentiated approach to the substantiation and approval of standards.

2. Considering belonging of fruits and juices to baby food, the substantiation of MAL values of fungicides should be guided by the principles of comprehensive hygienic standardization, forced in Ukraine [18].

3. High MAL values for oilseeds, approved in Ukraine, need to be revised, which, in turn, requires the improvement of analytical methods for the control of pesticide residues in these cultures.

This article shows the comparative analysis of hygienic standards in food products of active substances belonging to the group of fungicides, in future articles we plan to continue analysis of mentioned problem on groups of herbicides and insecticides.

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Необхідність гармонізації гігієнічних нормативів пестицидів у харчових продуктах на етапі євроінтеграції України (на прикладі фунгіцидів)

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***Резюме**. У роботі наведено результати порівняльної оцінки нормативної бази України з безпечного вмісту фунгіцидів у харчових продуктах з нормативними базами інших країн світу: США, Японія, Канада, країни Європи, встановлено розбіжності, зазначено їхні причини і запропоновано можливі шляхи вирішення проблеми гармонізації нормативної бази України з міжнародними стандартами.*
Ключові слова: максимально допустимі рівні, гармонізація, фунгіциди, міжнародні стандарти.

Необходимость гармонизации гигиенических нормативов пестицидов в пищевых продуктах на этапе евроинтеграции Украины (на примере фунгицидов)

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***Резюме**. В работе приведены результаты сравнительной оценки нормативной базы Украины по безопасному содержанию фунгицидов в пищевых продуктах с нормативными базами других стран мира: США, Япония, Канада, страны Европы и установлены расхождения, указаны их причины и предложены возможные пути решения проблемы гармонизации нормативной базы Украины с международными стандартами.*
Ключевые слова: максимально допустимые уровни, гармонизация, фунгициды, международные стандарты.

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