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ASSESSMENT OF RISK OF UNFAVOURABLE EFFECT OF PESTICIDES ON OPERATORS (TO THE PROBLEM OF HARMONIZATION OF HYGIENIC STANDARDS IN UKRAINE)

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Introduction. The assessment of unfavorable effect of pesticides on operators is one of obligatory condition in making a decision on their state registration. A calculation of the exposure dose and definition of the permissible level, as main constituents in risk assessment, are made in ECC according to the unified algorithms. In order to introduce hygienic standards in Ukraine in accordance with European legislation, it is advisable to use the mentioned algorithms with due account of traditional national approaches to the conception on safety of pesticides and on work with them.

Materials and methods. EEC Directives on sanitary legislation and methodical guidance on determination of exposed doses and permissible levels of pesticides for operators. Analysis of materials.

Results. A deterministic predictive operative exposure model *POEM (EUROPOEM)*, using the database, covering worst-case scenario of the work with pesticides and the algorithm of operator exposure level (*AOEL*), the whole set of toxicological data, critical directions of nonoperative exposure levels (*NOAEL*) with the safety coefficient, providing the extrapolation of experimental data on man (operator), can be used as algorithms, presenting uniqueness and transparency of conclusions on risk assessment of pesticide exposure on operators' health. These algorithms can be recommended for risk assessment in pesticide application by operators in Ukraine.

Conclusion. 1. When making a decision by the results of the quantitative level of exposure from the point of view of the predictive value of a model, a preference should be given to the algorithm, based on the most full «historical» databases, including cases not foreseen by worst cases. *UK POEM* and its modified variant *EUROPOEM II*, which are proposed for adoption in Ukraine, as an official algorithm for calculation of the exposure doses of pesticides in their application, seems to be the most acceptable. 2. It seems appropriate to substantiate allowable levels of pesticides in their effects on operators in Ukraine by the algorithm EFSA, with due account of individual judgments on the degree of safety, based on the analysis of all set of available toxicological data and approve them in due order as a state hygienic standard.

Key words: risk assessment, POEM (EUROPOEM), establishing allowable doses of pesticides in Ukraine, hygienic standards

Introduction

The assessment of adverse effects of pesticides on workers (operators) is one of obligatory conditions in decision-making for national registration of pesticides. The quantitative expression of risk, as a degree of the probable assessment of a pesticide hazard, is a relation of the quantity of exposure (exposure dose) to *Acceptable Operator Exposure Level* (*AOEL*), which does not cause any harm to operators' health in their practical application.

The risk assessment is of great significance in adopting standard-legal decisions, directed at health protection of workers, through elimination or decrease of the probability of occurrence of the event of the subject at risk: decrease of duration of a work shift, use of individual equipment for protection of eyes, skin, respiratory system.

The exposure doses are calculated on the basis of maximum values of the content of pesticides in subjects of the environment by the «historical» experience of their application under some standard conditions (area of application, working time, mode of spraying, size of containers, etc.). Also, they can be calculated on the basis of the real content of a pesticide under specific conditions of the working shift («situation» conditions). The calculations are made according to definite rules (algorithms), aiming to receiving the objective information on the content of pesticides in the subjects of the environment (mainly in the working zone air and in the atmospheric air in the area of the supposed drift of an aerosol cloud, on the surface of the working clothing and on the skin surface in operators, soil surface of the treated area), in order to determine a degree of pollution of the environment by a pesticide and the size of the exposed dose, able to exert an adverse effect on operators and other persons, being active or passive participators of the process.

Materials and methods

The exposure models, using different data bases for different categories of workers, have been created in developed countries of Europe, in the USA, Japan and Australia (Table 1).

Also, an exposure model has been developed in Ukraine, where there is used an original method of exposure calculation for determination of the level of situation inhalation and skin absorption under «null» values of pesticides' content in the working zone air and on the skin surface. The method is based on the value of the threshold of quantitative definition [2], as well as on the modification of the German model, used for practical purposes in SI «Institute for Occupational Health of the NAMS of Ukraine » [3].

Basing on Directives 91/414/EEC [4] and European Parliament № 1107/2009 [5], declaring the rules for placing plant protection products (PPP) on the European market for assessment of potential effect of pesticides on operators, it is recommended to use exposure models, developed in Great Britain - *POEN (EUROPOEM)* [6] and Germany – BBA [7].

Results of studies and discussion

Taking into account a positive assessment of the proposed models, specified by coverage of all conditions of pesticide application and the calculated exposure levels, one and the same scenario of their application can present different results.

Thus, when applying fungicide Shirlan 500 SC (a.i. – Fluazinam, 500 г/л) of Ishihara Sangyo Kaisha Ltd. (Japan) on potatoes (application rate 0,4 l/ha, four times, using boom spraying) in Scotland the calculated meanings of values of the exposed doses without using personal protective equipment (PPE) by the German model made 0,062131458 мg/кg/day; by the British model (with account of different packing capacity of the pesticide) – 0,0930975 мg/кg/day (1 liter); 0,06809375 мg/кg/day (5 liters) and 0,062131448 мg/кg/day (10 liters). The obtained values are over the permissible level for Fluazinam exposure by 15–23 times, making the exposure level a priori unacceptable. The use of the British model (protective gloves) or the full set by the German model (protection of respiratory tract, eyes and skin surface) do not fully correct the risk assessment, keeping the excess of the permissible level by 1,5–3,0 times for German and English models [8].

In 2010 the Commission on PPP and on their residues of the European Food Safety Authority (EFSA) developed a conclusion for «Guidance on the assessment of exposure of operators, residents and bystanders in risk assessment for plant protection products», where there were indications on some

Table 1

Models for assessment of exposure levels and available data bases (cited by Guidance of EFSA [1])

Category of the exposed contingent	Name of the data base (model)
Operators in field conditions	German model
Operators in field conditions	UK POEM
Operators in field conditions	Agricultural model for operators (AOEM)
Operators in field conditions, workers	EUROPOEM II
Operators in field conditions	PHED
Operators in field conditions	TNsG Biocides
Amateurs, residents and bystanders	ConsExpo
Amateurs	French data
Operators (greenhouse)	South Europe
Operators (greenhouse)	Denmark
Operators (greenhouse),workerse (mechanical forks, planters)	Seed Tropex
Residents and bystanders	BREAM
Residents and bystanders	CRD 2008
Residents and bystanders	California EPA

uncoordinated approaches, adopted by legislative acts in exposure assessment [9]. With this in view the Commission has proposed a number of changes and amendments for their practical usage. There have been developed recommendations on the use of the deterministic model for exposure assessment; a proposal has been given on the need in risk assessment for operators and participants in single exposure to a pesticide in such cases, when this pesticide is really dangerous by its toxic effect.

In the opinion of the working group it is necessary to take such scenarios into consideration, where the calculation of exposure is made with account of non threshold effect of a pesticide through decrease of the level of uncertainty (increase of the coefficient of safety) from the point of view of the modern knowledge.

The basic principle of the new edition of the Guidance was the principle of the data accuracy and transparency, the possibility to control and reproduce the results. A decision has been adopted to take into account only the databases and expert's conclusions, which could be assessed by the EC Working Group and, if necessary, by a third party, in accordance with the Arhus Convention [10].

When making a decision by the results of the quantitative exposure level from the point of view of the predictive value of a model, a preference should be given to algorithms, based on the most full «historical» databases, covering cases, not foreseen by an optimum situation (*«worst case»*). In our opinion the model *UK POEM* and its modified variant *EUROPOEM II* satisfy the mentioned conditions most fully.

The other constituent of risk assessment is a permissible level of the effect on workers – operators and those persons, who, by these or other reasons, are involved in the process of pesticide spraying. This is the most complicated part of the task, which requires the analysis of the full set of toxicological data, concerning different ways of entering the body (inhalation and percutaneous), types of exposure (sub-acute, sub-chronic, chronic) and directions of the potential toxic effect (reproductive function, teratogenic and cancer effects, mutagenesis, neurotoxic effect, organotropism). The choice, on the basis of the analysis of the experimental model of the toxic effect, mostly corresponding to real conditions of pesticides' application and their potential hazards for workers, and, at last, grounding the *AOEL*, basing on the set of toxicological data, is very important at this stage of risk assessment. *AOEL* – is a hypothetic maximum inner dose of a pesticide, based on a value (values) of experimentally established noneffective levels (*NOE(A)L*)of pesticide exposure, satisfying these conditions.

Till recent time a determinative method of definition, recommended by the German model, assumes the use of *NO(A)EL*) for these purposes on rats in subchronic experiment with the «safety coefficient» 25. It is pointed that this approach is recommended to be used in such cases, when a pesticide causes a general toxic effect on the body, without manifestations of delayed effects (carcinogenicity, teratogenicity, neurotoxicity, reproduction). This fact, from the point of view of the modern conception about *AOEL*, predetermines weak sides of the model not only in the aspect of directions of the toxic effect of a pesticide, but, also, concerning completeness of the conception of the model on the nature and consequences of the toxic effect.

In the acting Guidance on hygienic assessment of new pesticides in Ukraine threshold limit values of pesticides in the working zone air are used as a criterion for assessment of the safety of the work environment ($MAC_{w.z.}$) [11]. Nowadays, taking into account high increasing quantity of pesticides and the lack of $MAC_{w.z.}$, established for the majority of them in due order, these recommendations are available for the limited use. The use of a temporary standard - a tentative safety exposure level ($MAC_{w.z.}$) of a pesticide for the working zone air cannot be considered as an alternative of $MAC_{w.z.}$, because of the calculated character of the normative and its temporary status. The main shortcoming of this approach is that, one of main destinations of the safety criterion, i.e. its cumulative part in two main and inseparable routes of entry of pesticides into the body – skin penetration and inhalation, is not executed.

According to practice available in *EFSA*, the recommended *AOELs* are accepted by the group of experts on commission principles. These values (as well as *ADI*) are periodically re-examined because of occurrence of new, not known before toxicological data. The information about them are published in periodical reviews [12]. When establishing *AOEL* by the overall adopted algorithm, a question is unavoidably appears on the choice of the experimental model of the toxic effect, which, to most extent, is responsible for the prognosticated value of *AOEL* for a human, i.e. on the priority direction of the toxic effect of a pesticide in the experiment.

Since August 2002 the *EFSA* issues reviews on active ingredients of pesticides, allowed for application in EC countries. One of the results of such reviews, in particular, is the substantiation of the recommended *AOEL* value.

The list of some meanings of *AOEL* for active ingredients of pesticides, allowed for application in Ukraine, is presented in Table 2.

As it is seen from the presented data, the priority criteria of the toxic effect, when substantiating the *AOEL*, refers to different trends of effects, depending on toxicological properties, inherent to each specific substance. A probabilistic approach to the choice of the priority direction of the toxic effect creates certain difficulties in *AOEL* substantiation. This, to some extent, is a subjective decision, in spite of its commission character. It is proved by a historical experience of *AOEL* substantiation: from a subjective operator's perception in the process of work and after it, to the deterministic approach (*AOEL = NOEL* for rats in subchronic experiment with the safety coefficient 25), and, at last, – to a probabilistic assessment of the toxic effect, on the basis of the general collection of toxicological data, including the data obtained on volunteers. The substantiation of *AOEL* is a work of a group of experts, whose commission assessment is based on the individual perception of materials of the toxicological dossier and interpretation of such theoretical regulations as selective toxicity, adaptation, comparative toxicokinetics and metabolism, allometric regularities, chronotoxicological effects, and others.

It is seen that in modern conditions the substantiation of *AOEL* is practically going on according to the same principle as the substantiation of *ADI*. So, when addressing the problem of the hygienic regulation in

Table 2

***EFSA* recommended permissible doses of some pesticides for operators (*AOEL*) in Ukraine**

Name	*AOEL*	Type of study /animals
Carbendazim	0,02	Developmental toxicity / Rabbit
Carboxin	0,055	Subchronic toxicity / Rat
Chlorsulfuron	0,43	Chronic toxicity / Dog
Clethodim	0,2	Subchronic, chronic toxicity / Dog
Clomazone	0,133	Chronic toxicity / Dog
Clopyralid	1,0	Chronic toxicity / Dog
Cymoxanil	0,01	Chronic toxicity / Dog
Cypermethrin	0,02	Chronic toxicity / Dog
Cyprodinil	0,03	Subchronic toxicity / Rat
Desmedipham	0,04	Subchronic toxicity / Dog
Difenoconazole	0,16	Developmental toxicity / Rat
Dimethomorph	0,15	Subchronic toxicity / Rat, dog
Dithianon	0,0135	Subchronic toxicity / Dog
Epoxiconazole	0,008	Chronic toxicity / Dog
Ethametsulfuron-methyl	0,1	Developmental toxicity / Rabbit
Ethephon	0,03	Chronic toxicity / Dog
Fenamidon	0,3	Subchronic toxicity / Rat
Fenarimol	0,02	Reproductive toxicity / Rat
Fenitrotion	0,013	Subchronic toxicity / Rat
Fenoxaprop-p-ethyl	0,014	Reproductive toxicity / Rat
Fenoxycarb	0,1	Subchronic toxicity / Rat
Fenpropidin	0,02	Chronic toxicity / Dog
Florasulam	0,05	Subchronic toxicity / Dog
Fluazifop-p-butyl	0,02	Subchronic toxicity / Rat
Fluazinam	0,004	Chronic /Dog; Developmental toxicity/ Rabbit
Flucarba Zone	0,3	Developmental toxicity / Rabbit
Fludioxonil	0,59	Subchronic toxicity / Dog
Flumioxazin	0,022	Subchronic toxicity / Rat
Fluopyram	0,05	Subchronic toxicity / Mouse
Flurochloridone	0,04	Developmental toxicity / Rat
Fluroxypyr	0,8	Subchronic toxicity / Rat, mouse
Flutriafol	0,05	Subchronic, chronic toxicity / Dog
Fipronil	0,0035	Subchronic, chronic toxicity / Rat, dog

Name	*AOEL*	Type of study /animals
Folpet	0,1	Developmental toxicity / Rabbit
Foramsulfuron	0,1	Developmental toxicity / Rabbit
Fosetyl aluminium	5	Subchronic toxicity / Rat
Imazamox	14,0	Subchronic toxicity / Rat
Isoproturon	0,015	Subchronic toxicity / Dog
Isoxaflutole	0,02	Subchronic toxicity / Rat
Krezoxim-methyl	0,9	Subchronic / Rat; Chronic / Dog
Lufenuron	0,01	Chronic toxicity / Dog
Malathion	0,03	Subchronic toxicity / Rat
Mancozeb	0,035	Subchronic toxicity / Rat, dog
Mesotrione	0,015	Reproductive toxicity / Mouse
Metalaxyl	0,08	Subchronic toxicity / Dog
Metamitron	0,036	Subchronic toxicity / Dog
Metconazole	0,01	Developmental toxicity / Rabbit
Metiram	0,016	Chronic toxicity / Dog
Metolachlor	0,15	Subchronic toxicity / Dog
Metsulfuron-methyl	0,7	Subchronic toxicity / Rat
Metazachlor	0,2	Subchronic toxicity / Rat
Myclobutanil	0,03	Subchronic, chronic toxicity / Dog
Nicosulfuron	0,8	Subchronic toxicity / Dog
Penconazole	0,03	Subchronic, chronic toxicity / Dog
Pencycuron	0,15	Reproductive toxicity / Rat
Penoxsulam	0,18	Subchronic toxicity / Dog
Phenmedipham	0,13	Subchronic toxicity / Rat
Phozalone	0,01	Chronic toxicity / Dog
Picloram	0,3	Chronic / Dog; Developmental toxicity / Rabbit
Picoxystrobin	0,043	Subchronic, chronic toxicity / Dog
Pinoxaden	0,1	Developmental toxicity / Rabbit

Name	*AOEL*	Type of study /animals
Pirimifos-methyl	0,02	Subchronic, neurotoxicity / Rat, dog
Prochloraz	0,02	Subchronic toxicity / Dog
Propisochlor	0,025	Chronic toxicity / Dog
Prosulfuron	0,06	Subchronic toxicity / Dog
Prothioconazole	0,2	Developmental toxicity / Rat
Pyraclostrobin	0,015	Developmental toxicity / Rabbit
Pyridaben	0,005	Subchronic, chronic toxicity / Dog
Qizalofop-p-ethyl	0,01	Subchronic toxicity / Rat, mouse
Rimsulfuron	0,07	Subchronic, chronic toxicity / Dog
Spirodiclofen	0,009	Chronic toxicity / Dog
Spiroxamine	0,015	Chronic toxicity / Dog
Sulfosulfuron	0,4	Subchronic, chronic toxicity / Dog
Tebuconazole	0,03	Chronic toxicity / Dog
Tepraloxydim	0,06	Subchronic, chronic toxicity / Dog
Teflutrin	0,0015	Subchronic, chronic toxicity / Dog
Terbutilazine	0,0032	Chronic toxicity / Dog
Tetraconazole	0,03	Chronic toxicity / Dog
Thiabendazole	0,070	Chronic toxicity / Rat
Thiametoxam	0,08	Subchronic toxicity / Dog
Thifensulfuron-methyl	0,07	Subchronic toxicity / Rat
Tolylfluanid	0,3	Subchronic toxicity / Dog
Tribenuron	0,07	Subchronic toxicity / Rat
Trifloxystrobin	0,06	Chronic toxicity / Rat
Trifluralin	0,026	Subchronic toxicity / Rat
Triflusulfuron-methyl	0,04	Subchronic toxicity / Rat
Triticonazole	0,025	Chronic toxicity / Dog
Tritosulfuron	0,15	Subchronic toxicity / Dog

Ukraine and following principles of full harmonization of standards, normative and rates, it seems absolutely logical to substantiate *AOEL* in Ukraine by the European algorithm. It is possible to simply use values *AOEL*, recommended by *EFSA*, however the experience of *ADI* substantiation in Ukraine shows that, their values very often do not coincide with those adopted in Europe (as well as «intercontinental» differences in *ADI* values in the North America, Japan and Russia). The procedure of establishing *AOEL* as a hygienic standard can be just the same, as for *ADI*.

Conclusions

1. When adopting a decision by the results of the quantitative exposure level from the point of view of the prognosticated value of the model, the preference should be given to the algorithm, based on the most full «historical» databases, including cases, which are not foreseen by «worst cases»). The British model *UK POE* and its modified variant *EUROPOEM II*, which satisfy the necessary conditions at most, are proposed for adoption in Ukraine as an official algorithm for calculating exposed doses for pesticides in their application.
2. It seems appropriate to substantiate permissible levels of pesticides in their effects on operators in Ukraine by the algorithm *EFSA*, with due account of individual judgments on the degree of safety, based on the analysis of all set of available toxicological data and approve them in due order as a state hygienic standard.

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ОЦІНКА РИЗИКУ НЕБЕЗПЕЧНОГО ВПЛИВУ ПЕСТИЦИДІВ НА ОПЕРАТОРІВ (ДО ПИТАННЯ ГІГІЄНІЧНИХ НОРМАТИВІВ В УКРАЇНІ)

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Вступ. Оцінка ризику несприятливого впливу пестицидів на операторів – одна з обов'язкових умов для прийняття рішення щодо державної реєстрації. Розрахунок експозиційної дози та визначення допустимого рівня впливу як основних складових оцінки ризику проводяться в ЕЕС за єдиними алгоритмами. Для інтеграції гігієнічних

нормативів в Україні з європейським законодавством представляється доцільним використовувати ці алгоритми при збереженні традиційних вітчизняних підходів до розуміння безпеки пестицидів і їхнього застосування.
Матеріали та методи дослідження. Директивні матеріали ЕЕС щодо санітарного законодавства і методичні посібники з визначення експозиційних доз та допустимих рівнів впливу пестицидів на оператора. Аналіз матеріалів.
Результати. Детермінована британська експозиційна модель *POEM (EUROPOEM)*, заснована на базі даних, що охоплює позаштатні сценарій роботи з пестицидами (*«worst cases»*), і алгоритм встановлення гіпотетичного допустимого рівня (*AOEL*) з використанням всієї сукупності токсикологічних даних, критичних напрямів токсичної дії та недіючих доз (*NOAEL*) з коефіцієнтами запасу, що забезпечують екстраполяції експериментальних даних на людину (оператора), представляються алгоритмами, найбільшою мірою створюють однозначність і прозорість висновків при оцінці ризику впливу пестицидів на здоров'я операторів. Ці алгоритми можуть бути рекомендовані для оцінки ризику при застосуванні пестицидів для операторів в Україні.
Висновки. 1. У прийнятті рішення за результатами кількісного рівня впливу з точки зору прогностичної цінності моделі перевага повинна бути віддана алгоритму, заснованому на найповніших «історичних» базах даних, що включають випадки, які не передбачені штатними ситуаціями («worse case»). Найбільшою мірою цим умовам задовольняє британська модель *UK POEM* та її модифікований варіант – *EUROPOEM II*, які пропонуються для прийняття в Україні як офіційний алгоритм розрахунку експозиційних доз пестицидів при їхньому застосуванні. 2. Обгрунтування допустимого рівня впливу пестицидів на операторів представляється доцільним проводити в Україні за алгоритмом *EFSA* з урахуванням власних уявлень щодо ступеня безпеки на підставі аналізу всієї сукупності токсикологічних даних та затверджувати в установленому порядку як державний гігієнічний стандарт.

Ключові слова: оцінка ризику, Британська прогностична експозиційна модель *POEM (EUROPOEM)*, допустима доза пестицидів в Україні, інтеграція, гігієнічні стандарти

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