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Agrochemical Consulting and Registration Office

Registration of pesticides in Ukraine: Basic overview, recent changes and challenges, industry feedback

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FAQ

1. There are 3 declared actors in a registration: 1) holder 2) producer of a formulation 3) producer of AI
2. Registration validity is 10 years
3. It is possible to sell a registration or to shift from one company to another
4. Foreign company can be a registration holder
5. It is not possible to register a second brand name
6. There is no “me too” registration
7. Its is possible to change a producer in a registration, but within last years the exact producer and requirements became not very clear

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FAQ: UA and EU

Ukraine:

1) Unclear situation with “Annex I”: registration of AIs exists, but no one is doing it
2) Not possible to register and place on the market only AI
3) Data on AI is submitted for registration of final product
4) Repetition of studies (even for equivalent AIs), no data sharing
5) No such thing as data protection expiration
6) More precise timing and clear requirements
7) Possibility to estimate dossier and registration costs (+/- 10%) at the very beginning
8) Data can be generated during registration process (Application – studies – registration)
9) Very few commercial certified CROs, testing is done mainly by state organizations
10) Studies are cheaper but would not qualify in EU (yet)

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Authorities and institutes

Authorities

- Ministry of Environment and Natural resources (MoE)
- Ministry of Health (MoH)

Expert Institutions

- Efficiency trials: Crop protection Institute, Institute of Agroecology, Beetroot Institute, Potato Farming Institute, etc
- Toxicology, residue, hygiene of labor: Institute of Hygiene and Ecotoxicology n.a. Medved, Institute of Labor Medicine, National Medical University
- Eco Toxicology: Institutes belonging to the National Academy of Sciences, National Academy of Agricultural Sciences, Medical Institutes, etc

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Overview: Timing

1) Full dossier available, local studies done, requirements met:

Takes 1 – 1,5 years

Registration for 10 years

2) Tox. dossier is not complete (some studies on active ingredient are missing, but 6 pack acute tox is available)

- Applicant shows that studies were started (for example, in Ukraine) and claims to complete them and provide the results within a year
- Registration is granted for 1-2 seasons with an obligation to comply with requirements in full. Further, its is not possible to prolong it if requirements are not met

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Requirements

Checklist for registration of a pesticide in Ukraine		
Document	**Prepared by**	**Language**
Application with short data on pesticide	Made according to stundard form using data provided by producer	Ukr
Biological efficacy trials	Must be made in Ukraine	Ukr
Acute tox studies on product formulation (acute oral, acute dermal, inhalation, skin and eye irritation, sensibilisation)	May be made in another country according to GLP and OECD	Urk, En, RU
Hygienic reglamentation of pesticide	Must be made in Ukraine	Urk, En, RU
Method of residue determination in water, soil, air and harvest	New to be developed in nothing is avaliable in the country. If previously developed and published, open sources may be used	Ukr or RU
Methods of qualitative determenation	SIPAC or producer's methods used	Urk, En, RU
Tox studies on active ingridient vary for each AI. Usual list is: subchronic (for all), mutagenicity (for all), cancerogenicity, terratogenicity, embriotox, reproduction tox - for some, upon request.	May be made in another country according to GLP and OECD	Urk, En, RU
Studies for product's impact on: soil worms and microorganisms, aquatic organisms (fish, algae, daphnia), bees, birds (for some, upon request)	May be made in another country according to GLP and OECD, but Ukrainian always qualify and raise no questions and comments	Urk, En, RU

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Requirements

Certificates of analysis and certificates of composition for product a.	Must be submitted by producer	Urk, En, RU
Certificates of analysis and certificates of composition for AI (with impurities in 5 batches).	Must be submitted by producer	Urk, En, RU
MSDS and certificate of origin	Must be submitted by producer	Urk, En, RU
Letters from manufactureres of product and AI	Must be submitted by producer	Ukr, RU
Registration certificate for product from the country of manufacturing (ex. ICAMA reg.cert. for Chinese producers)	Must be submitted by producer	Urk, En, RU
Manufacturing license from factories	Must be submitted by producer	Urk, En, RU
Full application dossier (DRr)	Made at the final stage of the registration process using data submitted originaly plus all studies and expert conclusions obtained in Ukraine	Urk
Details use instruction	Made at the final stage of the registration process using data submitted originaly plus all studies and expert conclusions obtained in Ukraine	Urk
Label draft	Made at the final stage of the registration process using data submitted originaly plus all studies and expert conclusions obtained in Ukraine. Must be approved by authorities	Urk
Sanitary and epidemiological conclusion	Issued by the Ministry of Health and Ministry of Ecology after joined evaluation of DRr	Urk

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Overview: Steps

1. Application is submitted to the Ministry of Environment (January)
2. Inclusion into **biological efficiency trials plan of the Ministry of Environment (January-February)**
3. **Communication of trials programme** and calendar plan (March)
4. Submission of toxicological dossier
5. Submission of eco toxicological dossier
6. ADI, Hyg.of labor trials, residue
7. Collection of biological efficiency reports and submission of this reports to toxicologists (November)
8. Collection of toxicological conclusions (November)
9. Preparation of updated Application
10. Submission of all documentation to MoE
11. Expertise of MoH (tox), Expertise of MoE (comprehensive)
12. Scientific Expert Council approval (MoE)
13. Registration issued

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Costs

Cost of registration of copper based product	11/10/2017 (USD=26,6)				
Institute (executing agency)	**Subject**		**2 018**	**Note**	
Ministry of Ecology	Reg. certificate for 2\10 years	400	2 000		
	Expertise	400	400		
	"Support"	800	1 500		
Subtotal		1 600	3 900		
BIOLOGICAL EFFICACY					
Institute of Agroecology	Biological efficacy trials: apple, peach, pear, nectarine, plum, cherry		9 023		
Subtotal	-	-	9 023		
TOXICOLOGY					
Institute of Ecohygiene and Toxicology n.a. Medvedev (GLP)	Dossier expertise		4 491		
	Hygiene of labor		11 309		
	Residues: apple, peach, pear, nectarine, plum, cherry		26 806		
Committee of Hygienic reglamentation	Scientific examination of materials on substantiation of hygienic standards and regulations		1 460		
Institute of Ecohygiene and Toxicology n.a. Medvedev (GLP)	Acute tox studies on Copper oxide (GLP, OECD)		10 000	may be replaced by own data	CD
	Toxicologycal evaluation of the formulation (acute experiments GLP, OECD)		13 750	may be replaced by own data	CD
Subtotal			67 816		
ECOTOXICOLOGY					
Institute of Agroecology	bee's (not important study protocol, the object of research, test duration, etc.)		950	may be replaced by own data	CD
	fish (not important study protocol, the object of research, test duration, etc.)		1 100		CD
	dafnia (not important study protocol, the object of research, test duration, etc.)		1 100		CD
	water-plants (not important study protocol, the object of research, test duration, etc.)		1 100		CD
	birds (not important study protocol, the object of research, test duration, etc.)		1 700		CD
	soil worms (not important study protocol, the object of research, test duration, etc.)		1 100		CD
	soil microorganisms (not important study protocol, the object of research, test duration, etc.)		1 100		CD
Subtotal			8 150		
SAMPLES, DELIVERY, TRANSLATIONS, CUSTOMS CLEARENCE					
Various organisations	Price is approximate		1 000		
	Total cost max for registration for 10 years with CD		89 889		
	Total cost min for registration for 10 years without CD		59 589		

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Studies

Toxicological evaluation

Product:
Acute oral, acute dermal, acute inhalational toxicity, skin and eye irritation, sensibilization

A.I.:
Acute oral, acute contact toxicity, skin and eye irritation, sensibilization
Sub-chronic toxicity (90 days) – oral, inhalation, dermal, etc
Cancerogenicity, mutagenicity, reproductive toxicity, neurotoxicity, metabolite toxicity

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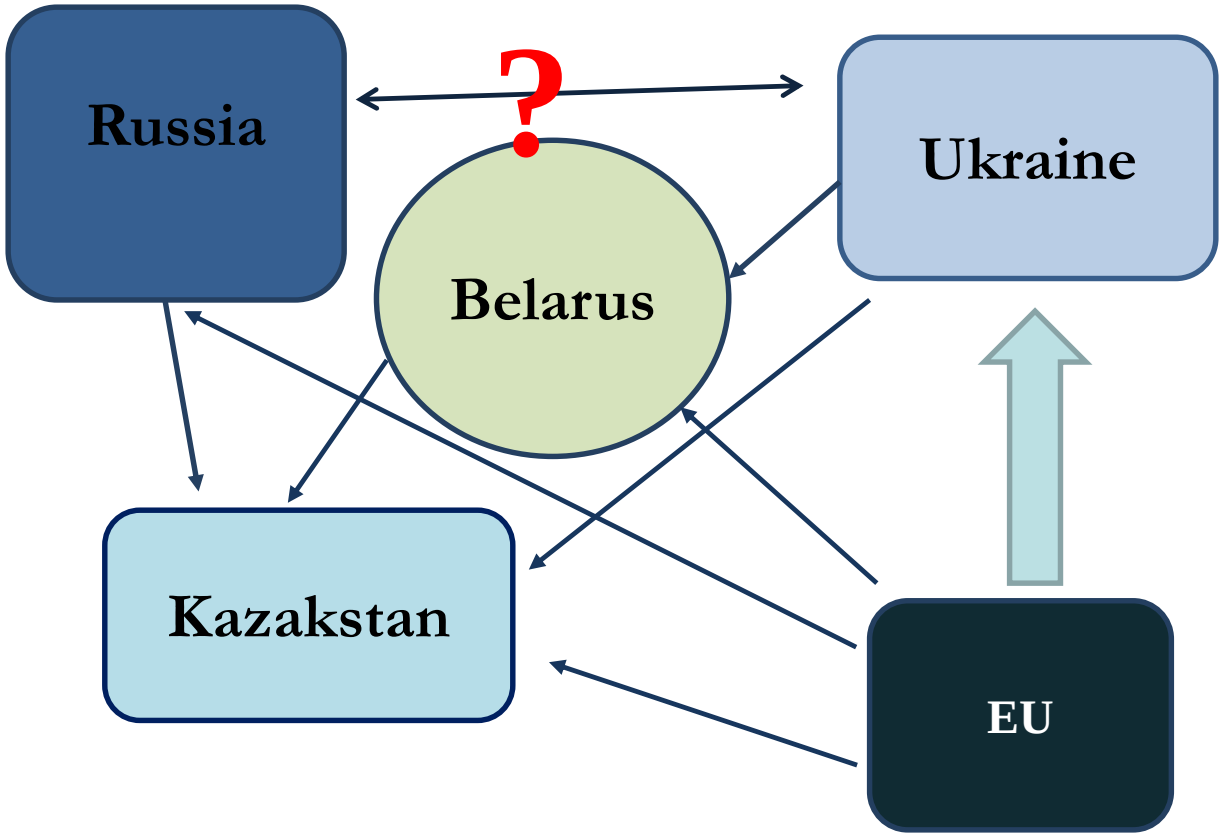
Under discussion

- Mutual recognition for tox studies



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Recent changes. Situation in the MoE

1) State sanitary service, previously issuing state sanitary conclusion, was dissolved in March 2017 and their functions were transferred to State commodity safety and consumer protection service , but the right of approval remains with the MoH. Thus, there is no clear distribution of function – delays in registration
2) Frequent changes in the department of pesticides and agrochemicals of MoE. At the moment – 2 leaders. And new appointment expected.
   Every new head of department introducing new requirements.
3) Registration in the country of production:
   «Обов'язковою умовою завезення та застосування незареєстрованих в Україні пестицидів для цих цілей є документальне підтвердження їх державної реєстрації в країні, де вони виробляються.»
   - Law is not new
   - Interpretation is not correct !
   - Changing requirements
4) Group of ecologists currently responsible for eco tox assessment shall be dissolved, functions transferred to some institutions (which?), new requirements expected

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Re-registration of actives

1. All new active were registered by a first notifier at the Committee of state hygienic reglamentation of the Ministry of Health
2. This procedure was not directly connected to the registration of PPPs with the Ministry of Environment
3. It happened, that when registration of Ais at MoH expired, the MoE did not take this into account and did not check this
4. However, at the moment this situation got attention. A check up was performed: registrations for most AIs expired, for some – never happened. And it is not clear what the procedure will be
5. We are asked to register also bacteria, viruses, even amino acids (product contains various amino acids – 11.000 USD(!))

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Industry feedback

What is industry asking for:

1) Reconsidered application of the Law on pesticides and agrochemicals in terms of product registration in the country of origin: to be replaced by manufacturing license, for example
2) List of institutes in CIS whose study results (if quality complies) would be accepted
3) More communication between MoH and MoA concerning re-registration of Ais.

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2) List of institutes in CIS whose study results (if quality complies) would be accepted
3) More communication between MoH and MoA concerning re-registration of Ais.

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Thank you

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