

WELCOME TO THE UCT CHEMICALS NETWORK DISCUSSION



Division of Environmental Health
School of Public Health and Family Medicine
Isikolo Sempilo Yoluntu kunye Namayeza Osapho
Departement Openbare Gesondheid en Huisartskunde

UNIVERSITY OF CAPE TOWN
UNIVERSITEIT YAKESAPA - UNIVERSITEIT VAN KAAPSTAD

Introduce yourself (name, job title, organization and country) in the **chat section**.

Only the presenter and facilitator will speak. Any comments or questions from attendees should be typed in the **chat section**.

Please kindly keep you microphone muted and cameras off during the discussion

NOTE: If you are having **technical difficulties**, please join the WhatsApp group for assistance:

<https://chat.whatsapp.com/CdEJNdPEva30263AB3KYBq>

Discussion 5 Topic: “Chemicals registration and monitoring.”

- Date: 5th October 2021
- Time: 14h00 – 15h30 (GMT+2)
- Presenter: Mel Biring, Lubrizol Ltd
Irinia Zestanskaya, WHO Europe
Nana Gabriadze, Georgia
Snezana Markovich, Serbia
- Facilitator: Andrea Rother, University of Cape Town

CHEMICALS NETWORK DISCUSSION

CHEMICALS REGISTRATION AND MONITORING



Mr. Mel Biring
Job title



Dr. Irina Zestanskaya
Job title



Dr. Nana Gabriadze
Job title



Snezana Markovic
Job title

BACKGROUND TO QUESTION I

PRESENTED BY: MEL BIRING, LUBRIZOL LTD

REACH = Registration, Evaluation and Authorisation of Chemicals

- **R**egistration: of all in-scope industrial chemicals at > 1tpa
 - **E**valuation: check information submitted and request further information if needed
 - **A**uthorization (and Restriction) of **C**hemicals = Manage the risks of high concern chemicals
-
- 300 pages of legal text + 10,000s of pages of guidance. Put together on basis of knowledge built up over 40 years
 - Implemented over 11 years with high workload at regulator (>500 ECHA staff + MSCAs) and in industry.
 - Specialised expertise in toxicology, risk assessment, and regulation needed.
 - Up to \$20 billion spent so far by industry to comply. High costs for test data and dossier production.

GLOBAL BENCHMARK!

BACKGROUND TO QUESTION 1

PRESENTED BY: MEL BIRING, LUBRIZOL LTD

REACH-like legislation has been implemented in the UK, Turkey and South Korea

- Scope can make regulatory **implementation more onerous** than we saw for EU
- Substantially **less guidance**
- **Less infrastructure** at the regulator + within local industry

Key issue: each company to own or have legitimate access to test data in order for each of them to submit it to the regulator creates several issues:

- Huge cost to try to organise, obtain and share data amongst local companies
- Lack of best practice guidance on how to share data between jurisdictions
- Lack of local availability of data leading to repetition of testing

Ultimately less data submitted than available in the public domain eg via ECHA dissemination website??

BACKGROUND TO QUESTION 1

PRESENTED BY: MEL BIRING, LUBRIZOL LTD

'Quasi-REACH like' legislation used by several countries around the world in which a dossier only has to be submitted for:

- so-called 'new substances' that are not on the national inventory
- specific possible high risk substances that are on the national inventory via screening

'REACH-like' only for a **subset of targeted substances** making up a smaller percentage of the market.

REACH has allowed for data to be generated, collected and disseminated. Use appropriately within regulation:

- By industry within decisions on GHS classification and to inform on safety
- By regulators to inform on which substances they might wish to further risk manage

BACKGROUND TO QUESTION 1

PRESENTED BY: MEL BIRING, LUBRIZOL LTD

Mixture (product) registration used by countries seeking to be informed about hazards of mixtures:

- 'SDS information' typically submitted for in-scope mixtures
- Large numbers on the market, exacerbated by including for example R&D
- Changes happen all the time: products used, classification, composition
- Per GHS and based on protection of IP not all substances are declared in SDSs
- CBI issues also if certain information is published

What information is actually useful – overall hazard vs in-depth detail on compositions?

BACKGROUND TO QUESTION I

PRESENTED BY: MEL BIRING, LUBRIZOL LTD

On previous slides you can see a subset of practical issues for industry

Key before deciding on chemical management approaches

- Impact assessment
- Capacity building
- What is need and how will it help?



Prioritisation

Best solutions can be found where all stakeholders are involved, to include industry:

- Experiences in practical implementation and consequences
- Lessons learned around the world over decades

QUESTION 1

Do you have any experience with chemicals registration and monitoring in your country?

What challenges are you currently facing in chemicals registration and monitoring?

There will be 20 minutes to discuss this question in the chat section.

Please keep your cameras off and microphones muted.

Make use of the chat function to discuss

For **technical assistance** join the Chemicals Network WhatsApp group using this link:

<https://chat.whatsapp.com/CdEJNdPEva30263AB3KYBq>

BACKGROUND TO QUESTION 2

PRESENTED BY: DR IRINA ZESTANSKAYA,

Information for SMC (view from the strategic level)

the one who owns information
owns the world



the one who has information on
chemicals can manage them safely

The objectives of the Strategic Approach to sound chemicals management with regard to knowledge and information are:

To ensure that **information on chemicals** and chemicals management are sufficient to enable chemicals to be adequately assessed and **managed safely throughout their life cycle**

That information on chemicals throughout their life cycle, including, where appropriate, chemicals in products, is **available, accessible, user friendly, adequate and appropriate to the needs of all stakeholders.**

Appropriate types of information include **their effects on human health and the environment, their intrinsic properties, their potential uses, their protective measures and regulation**

Legislative arrangements

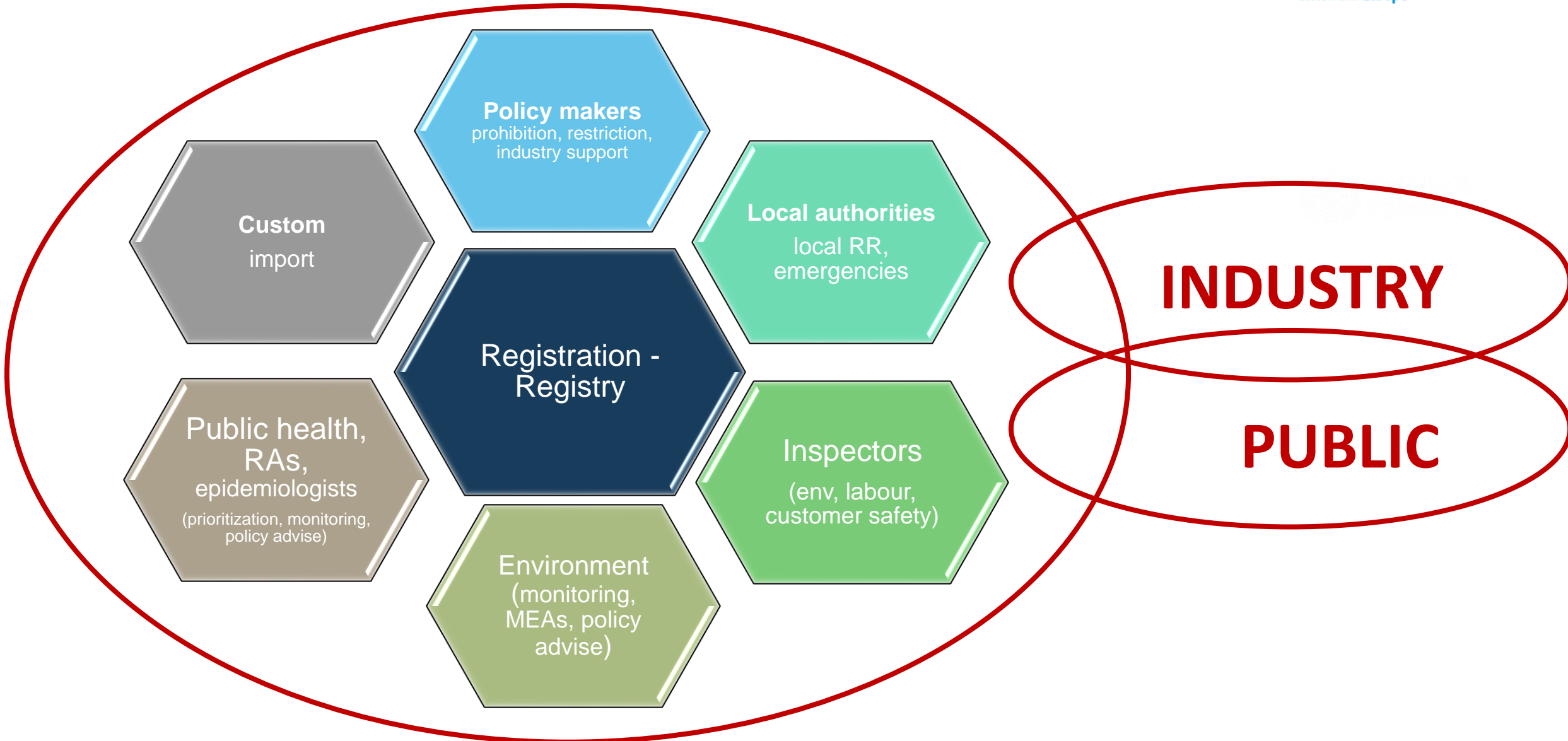
Obligatory (law) (in most cases – the first step)

- Chemical law (any other legislation)
- No information, no market
- Roles and responsibilities are clearly defined
- Sustainability - resources are reserved
- Industry support (obvious benefits)
- XXX

Voluntary (possible but in most cases not that successful)

- At least high-level decision
- No values for producers/importers
- Somebody initiative
- More efforts with less results (commonly)
- Industry resistance (more work)
- XXX

Who will use and benefit – determinant of types of information to collect and share



Other considerations

| | | |
|--|----|---|
| On-line | VS | Hard copies |
| Verification of information | VS | No verification (postponed) |
| Centralised | VS | Not centralized |
| Financial support from government | VS | Self-funded (industry pay for registration) |
| All in one (pesticides, industrial, etc....) | VS | Separate (but harmonised) |
| Limitations (use, tonnage, etc.) | VS | Everything and all |
| Periodic (annually) | VS | Once |

QUESTION 2

What do you feel your country would need to establish a chemicals registration and monitoring system?

Please state the country you are from and elaborate on how a chemicals registration and monitoring system could look in your country.

If your country has a registration system, what are the needs to make the system efficient?

There will be 25 minutes to discuss this question in the chat section.

Please keep your cameras off and microphones muted.

Make use of the chat function to discuss

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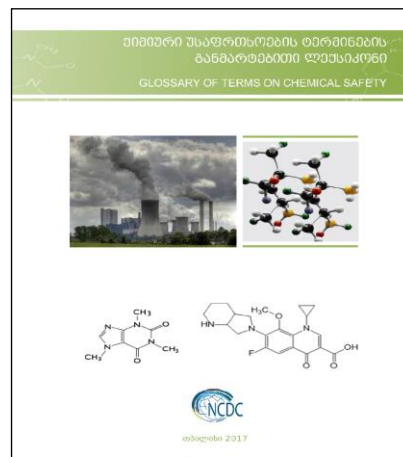
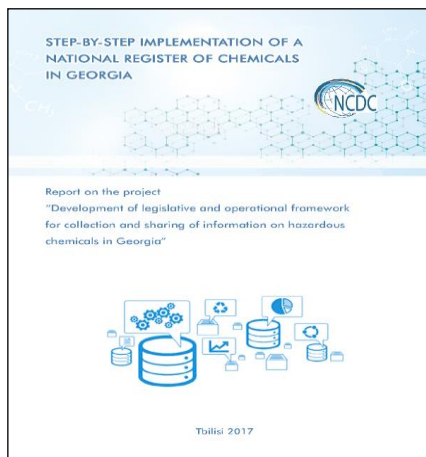
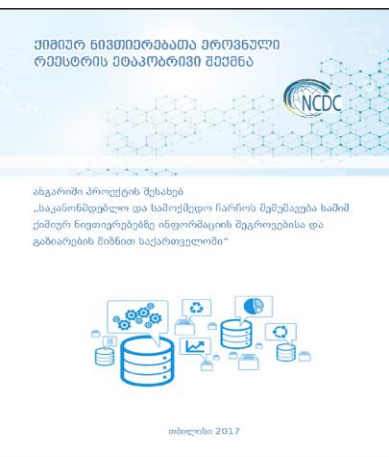
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CASE STUDY I

PRESENTED BY: NANA GABRIADZE, GEORGIA

The Association Agreement of Georgia with EU, into force from July 2016, postulates Georgia to harmonize legislation and implement reforms in the main areas of the Agenda, including public and environmental protection (art.301). Article 302 of the Agreement lists the areas of interest, that includes chemicals management (REACH,CLP,BPR, ED on Safety of toys, Regulation on Cosmetic products, Regulation on detergents etc).

With the support of the WHO European Centre for Environment and Health (ECEH), (Bonn, Germany) and the German Federal Environment Agency (UBA), the National Center for Disease Control and Public Health implemented the project "Development of legislative and operational framework for collection and sharing of information on hazardous chemicals in Georgia" in 2015-2017. Demo version of the registry of hazardous chemicals was developed;



დაავადებათა კონტროლისა და
საზოგადოებრივი ჯანმრთელობის
ეროვნული ცენტრი
GEORGIAN NATIONAL CENTER FOR DISEASE
CONTROL AND PUBLIC HEALTH

CASE STUDY I

PRESENTED BY: NANA GABRIADZE, GEORGIA

Taking into account all mentioned above, the overall goal of the project was to develop legislative and operational framework for collection and sharing of information on hazardous chemicals as well as to develop a model of register/inventory and to test its applicability in relation to the stakeholders' needs.

- Main steps of the project implementation

1. Situational analysis of collection and sharing information on hazardous chemicals and stakeholder's information.
2. Development of a model and operational framework of a national chemical register.
3. Development of proposals for legislative framework for setting a national register of chemicals

Needs for information on hazardous chemicals to ensure implementation of sound chemical management in Georgia: multi-stakeholders' workshop (29-30 October 2015)



CASE STUDY I

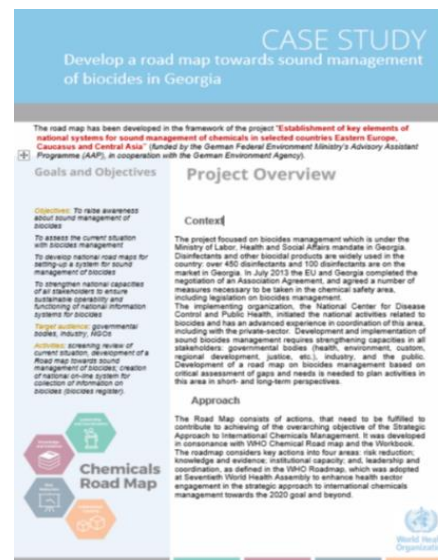
PRESENTED BY: NANA GABRIADZE, GEORGIA

Online registry of biocides of chemicals has been launched since 2020

Within the project "Establishment of key elements of the sound chemicals management systems in selected countries of Eastern Europe, Caucasus and Central Asia - Belarus, Georgia, Kazakhstan" (2018-2020), supported by WHO and the German Federal Environment Agency online registry for registration of chemicals was developed, introduced and launched. So called "Help desk" of biocide products was established aimed to provide relevant information and guidance on biocides to all stakeholders.

National Roadmap towards sound management of biocides in Georgia

A national roadmap has been developed towards sound management of biocides in Georgia. Information on the roadmap is available on the WHO website: <https://apps.who.int/iris/handle/10665/338376?locale-attribute=pt&>



Registered Data (21.09.2020- 15.01.2021)

Registered Companies

- Company - 48

Registered Products

- Registered Biocide – 22
- Old registered Biocides - 33
- Rejected – 10
- Not required registration - 5
- Active Substance - 3

CASE STUDY 2

PRESENTED BY: SNEZANA MARKOVIC, SERBIA



Ministry of Environmental Protection
Republic of Serbia

CHEMICALS REGISTRY IN THE REPUBLIC OF SERBIA

UCT's Chemical Network Discussion Forum

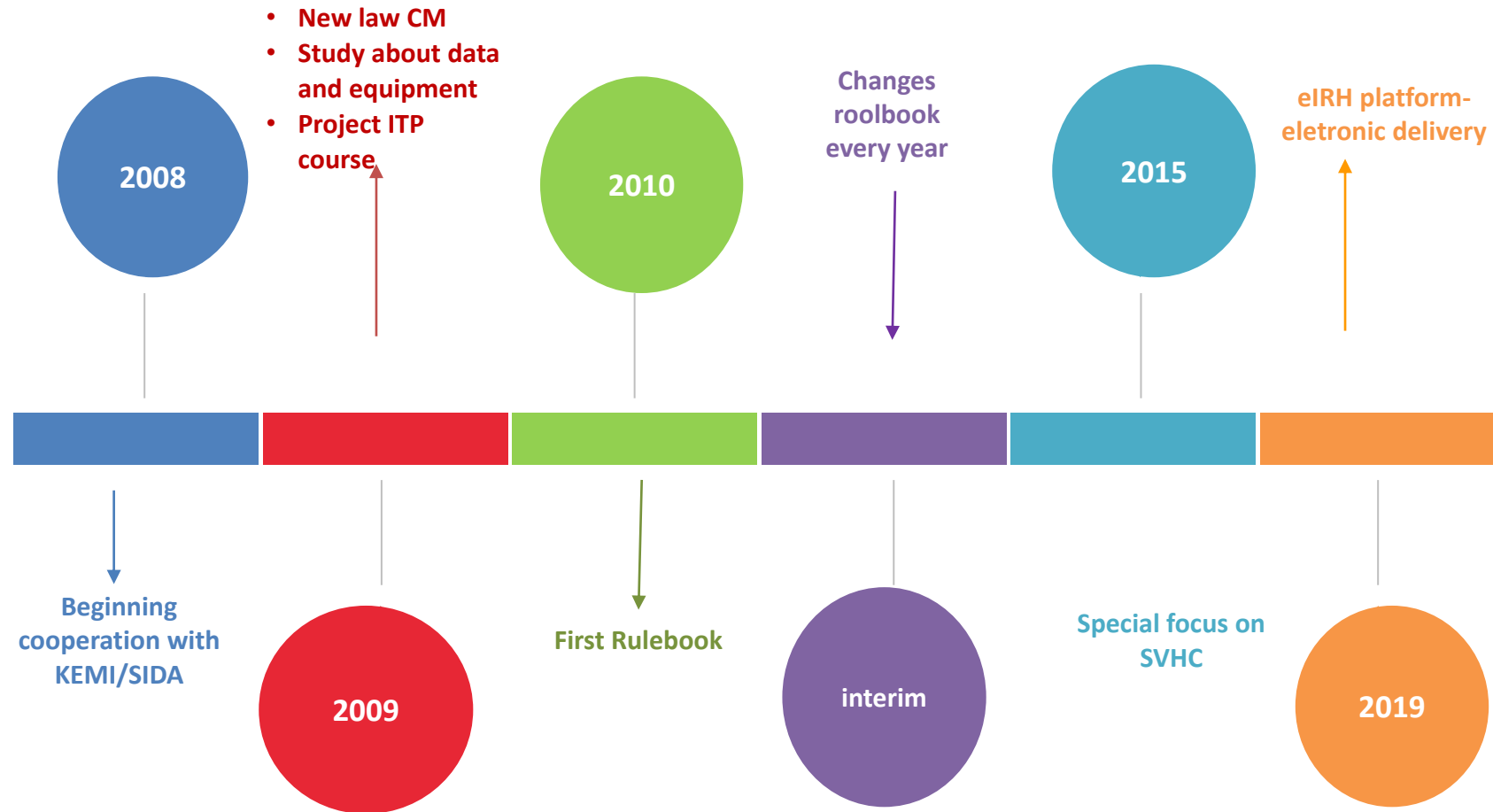
Chemicals registration and monitoring

05. October 2021

On-line from Belgrade, Republic Serbia

MSc chem.eng. Snezana Markovic

IRH Timeline





**INTEGRATED
CHEMICALS
REGISTRY**



Ministry of Environmental Protection
Republic of Serbia

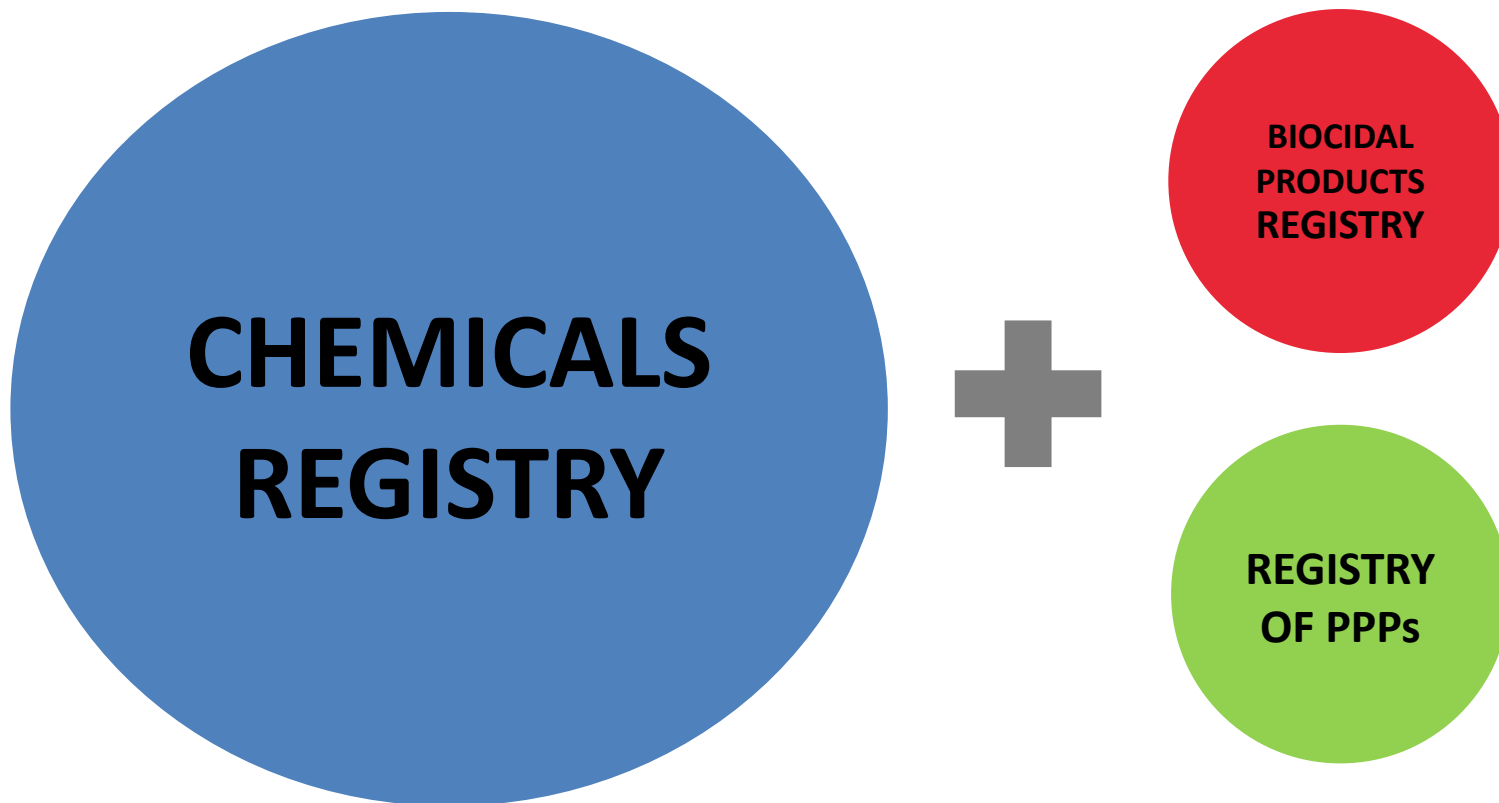
**CHEMICALS
REGISTRY**

**TOXICOCIDAL
PRODUCTS
INDUSTRY**

**INDUSTRY
OF PPPs**



Ministry of Environmental Protection
Republic of Serbia





Ministry of Environmental Protection
Republic of Serbia

**CHEMICALS
REGISTRY**

- Data submitted by importers, producers and downstream users

**BIOCIDAL
PRODUCTS
REGISTRY**

- Data received from Division for Biocidal Products Risk Management

**REGISTRY ON
PPPs**

- Data received from competent authority in charge of Plant Protection Products



Ministry of Environmental Protection
Republic of Serbia

CHEMICALS REGISTRY

- Law on Chemicals
- Rulebook on Chemicals Registry

BIOCIDAL PRODUCTS REGISTRY

- Law on Biocidal Products

REGISTRY OF PPPs

- Law on Plant Protection Products

RULEBOOK ON CHEMICALS REGISTRY

Rulebook on Chemicals Registry prescribes:

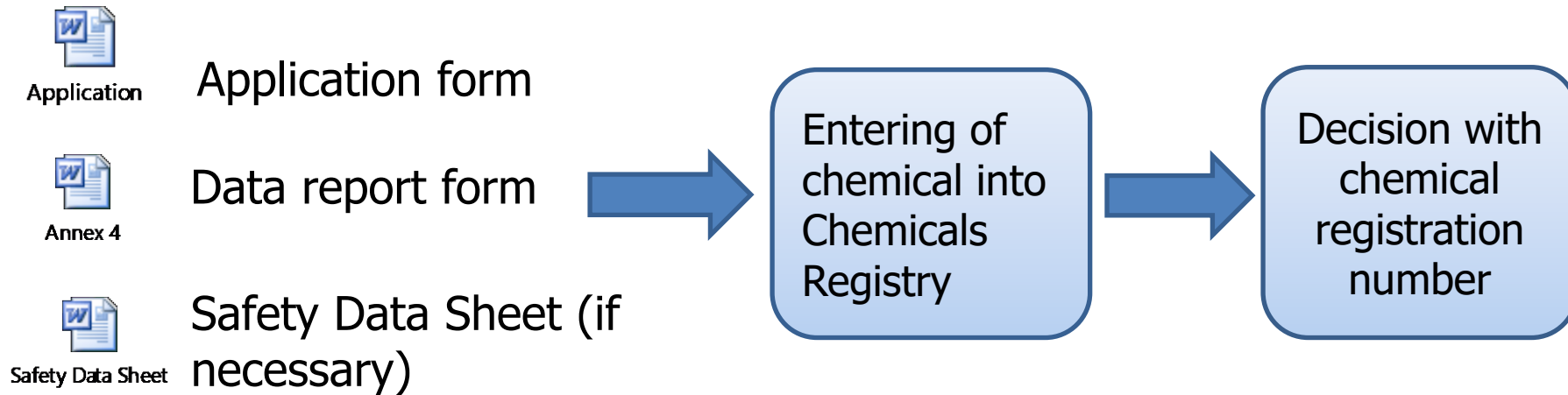
- ✓ Minimum quantity limit of the chemical for reporting (≥ 100 kg/year)
- ✓ Detailed data on each chemical reported into the Registry
- ✓ Content of the Report forms

- 1) General data on chemical
- 2) Origin of chemical
- 3) Intended use of chemical
- 4) Labelling of chemical
- 5) Chemical composition (optional – surfactants)
- 6) Content of Volatile Organic Compounds (optional)
- 7) Description of the intended use, description of the risk reduction measures and proposal of the system monitoring of use
- 8) Suggested safer alternative

RULEBOOK ON CHEMICALS REGISTRY

- ✓ Annex 1: List of Customs Tariff Headings of Chemicals
- ✓ Annex 2: List of codes for category of use
- ✓ Annex 3: Report form: List of Trade Names of all chemicals from the group of chemicals
- ✓ Annex 4: Report form: Chemical Dossier
- ✓ Annex 5: Report form: Chemical Dossier for chemicals that are already entered in the Registry
- ✓ Annex 6: Report form: Chemical Dossier for SVHC's and mixtures containing SVHC's

APPLICATION PROCEDURE



So what are benefits having data from Chemicals Registry for Chemical Management in Serbia

- Data about companies which import, produce and use chemicals
- Data about chemicals
- Adequate implementation of the Law on Chemicals especially regarding:
 - ✓ Bans and restrictions
 - ✓ Classification and labelling
 - ✓ Safety Data Sheet
 - ✓ Provisions regarding detergents
 - ✓ Provisions regarding VOC content
- Enforcement
- Monitoring
- Generating statistical reports



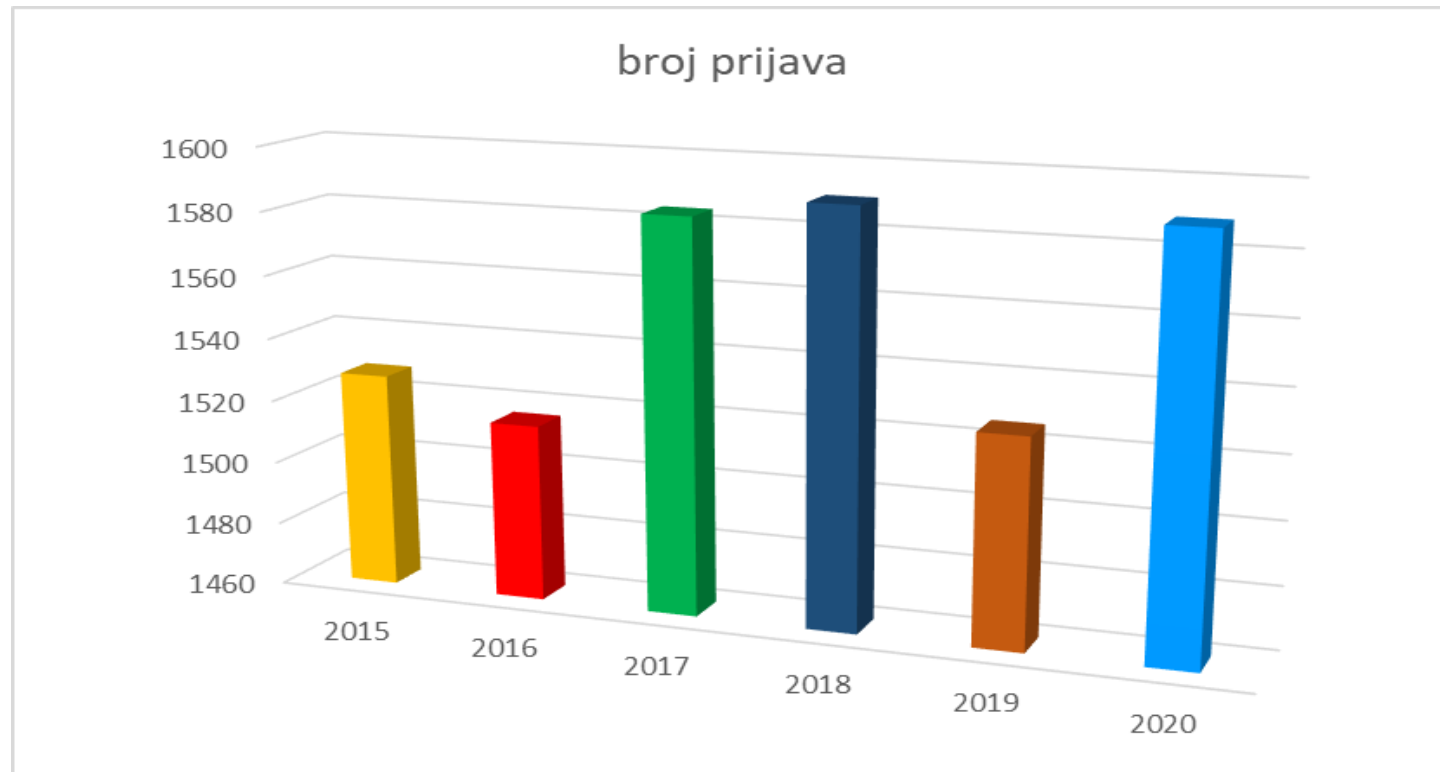
Some usual reports generated from Chemicals Registry:

- Report on number of chemicals placed on the Serbian market;
- Report on number of chemicals placed on the market manufactured or imported from non/EU countries in quantities above 1t per year;
- Report on number and quantities of detergents placed on the market;
- Report on total number of produced and imported chemicals;
- Report on main types of industry in Serbia;
- Report regarding POPs substances;
- Report regarding SVHC substances;
- Report on distribution hazard class of chemicals, sector and category of use, quantities,...and other useful information about them;
- Various reports for inspection;

Some reports generated from Chemical Registry on demand of other state bodies:

- Report on substances under Chemicals Weapon Convention;
- Reports about companies that place chemicals on the market;
- Based on the request of the Ministry for interior affairs - Sector for Emergency Situations, reports about certain hazardous chemicals placed on market;
- Report on companies that place substances which are subject to PIC Procedure;
- Report on substances which are included in Rotterdam Convention;
- Report on companies and chemicals classified as CMRs placed on the market, based on request of the Ministry of Health;
- Report on chemicals which are used in production of feeding stuff, based on request of Ministry of agriculture- Veterinary Directorate;

Number of applications per years





Ministry of Environmental Protection
Republic of Serbia

THANK YOU FOR YOUR ATTENTION



MSc chem.eng. Snezana Markovic, Senior
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snezana.markovic@ekologija.gov.rs

CASE STUDY DISCUSSION TIME

There will be 15 minutes to discuss these case studies in the chat section.

Please keep your cameras off and microphones muted.

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THANK YOU FOR JOINING UCT'S CHEMICALS NETWORK DISCUSSION

**Save the date:
Chemicals Network
Discussion 6
Date: 7th December 2021
Time: 14h00 – 15h30
(GMT+2)**

This network has been produced with financial assistance from Sweden, through the Swedish International Development Cooperation Agency, Sida, which has been arranged by the Swedish Chemicals Agency (KemI).

The views herein shall not be taken to reflect the official opinion of Sida or the Swedish Chemicals Agency.