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eBIOZIDE

MARIA AMON

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CA-MEETING MARCH 2016

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Status quo

- Currently in Austria **no data** are **collected** on **quantities** of biocidal products made available on the market.
- No database or automated assessments on the amounts of biocidal products are installed.

eBiozide

- **eBiozide** is an IT-project for the systematic collection of data on biocidal products with focus on the **quantities** of the **active substances.**

Why is the systematic collection of data essential? What is the benefit?

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Reliable data are the **basis** for

- Sustainable use of biocidal products - *resistances*
- Research and development - *science and industry*
- Strategy development and shaping of law - *a.s. ban*
- Daily politics - *Zika virus, strategies for control*
- Support of enforcement activities – *setting of priorities*

To enable assessments a **unique IT-format** of the data is crucial!

Data collection is a **task for authorities**! (mandatory + confidential)

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What do we want to know?

- the amount of active substances made available on the market in Austria per year.

Examples for assessments

- Amount of **Difenacoum** made available on the Austrian market in 2015

- Amount of **Difenacoum** made available on the Austrian market in 2015 by a **specific authorisation holder**

- Amount of **active substances** for **PT 5** made available on the Austrian market in 2015

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Further examples for assessments

- Amount of **biocidal products** for **PT 8** made available on the Austrian market in 2015

- Authorised products **not** made available on the Austrian market in 2015

- Amounts of a specific **active substance** made available on the Austrian market in **2015, 2016 and 2017 (time series)**

- **Biocidal products** of **PT14** made available on the Austrian market for **private users** in 2015

How shall it work

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- The Austrian CA has all **authorisations** of biocidal products containing e.g. difenacoum
- The Austrian CA has the **SPC** and the **composition** (not visible for the Authorisation holder) of these products available in a database
- The Authorisation holders **report** electronically once a year the amounts of the products which they made available on the market to the Austrian CA
- The data on the composition (active substance) and the reported amounts are processed and an **assessment** e.g. of the amount of difenacoum of all biocidal products made available on the market in a specific year can be derived.

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Legal basis - Art. 22, 66 and 68 BPR

Content of the Authorisation; Art. 22 (2) lit. q

„Without prejudice to Articles **66** … where relevant, **other information** about the biocidal product." – *a reporting obligation on request of the authority is content in Austrian product authorisations*

Confidentiality; Art. 66 (2) lit. b

"the **precise tonnage** of the **active substance** or **biocidal product** manufactured or **made available** on the market;"

Record-keeping and reporting; Art. 68 (1)

"Authorisation holders shall **keep records** of the biocidal products they place on the market for at least **10 years after placing on the market**, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier. They shall **make available** the relevant **information** contained in these records **to the competent authority on request**."

Project Cost and follow-up projects

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Cost: € 300,000.- to € 400,000.- (basic version)

Time frame: basic version to be released Oct. 2017

Follow-up projects:

depending on priorities, e.g. where additional monitoring is required concerning human health and environmental effects of biocidal products

- reports down the supply chain
- in addition information on the areas of the use (combined with geographical systems) by professional/industrial users, e.g. hospitals; urban areas, where rodenticides are used; areas, where insecticides are applied by helicopters, …

Follow-up projects would require **legal amendments**

Confidentiality

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Data access:

- **Authorisation holder:** Access only to the data of his products and the amounts he reported to the application (no composition), no possibility for assessments;

- **Competent Authority:** Access to data and assessments

Art. 66 (2) BPR Confidentiality

Basically confidentiality of the data is guaranteed.

"However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph."

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Request for COM support

- The COM should recommend the usage of an IT-system where the processing data are based on a **harmonised format**
- Only **minor extension** of current data formats (IUCLID/SPC) necessary in coordination with ECHA and other MSCA
- **Harmonisation and publication** of data format specification prior to any implementation efforts in MS supported by COM
- **Data exchange interface reasonable** for automatic data transfer (SPC)
- Amendment of **ECHA contract** to these points

BMLFUW presentation ceremony – June 2015

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Thank you for your attention!

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