Mutual recognition – possible difficulties and solutions

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Mutual recognition benefits

No duplication of work.

Evaluation is:

- cheaper and quicker than standard route for assessement.
- limited expert evaluation.

Attitude, trust is crucial.

Good tool for learning and gain expierence in the area of authorisation of ppp.

Possible problems

Some difficulties in mutual recognition are frequently related to:

- quality of the risk assessment/different national requirements/assessments,
- data protection.

Quality of the risk assessment/different national requirements/assessments

Refinements or updates of dossier can be necessary (because of specific national requirements with regard to following sections of registration report):

- section 3 – toxicology,
- section 4 – residues,
- section 5 – fate and behaviour,
- section 6 – ecotoxicology,
- section 7 – efficacy.

BiH national requirements/assessments

In order not having to refuse systematically applications for mutual recognition, BiH should consider making national requirements available, so that they can be taken into account by the applicant by submission for the application for mutual recognition in the format of national addenda to the dRR.

National requirements (and way of work) should be determined in advance to avoid „case by case” aproach.

Section 3 – toxicology

Exposure for operator (OPEX).

UK POEM, BBA German model are in common use (at least in the Central Zone), **but but OPEX calculations taking into account realistic use conditions**.

It can be necessary to determine characteristic of BiH worker to accordingly change input parameters in models (e.g. **PPE** – using of gloves during mixing and application and coverall and sturdy footwear during application process, **duration of activities** – 6 versus 8 hours, area per day – 20 ha in UK POEM and 50 ha in German model and vice versa in some MS, **body weight** – 60 versus 70 kg etc.).

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Section 3 – toxicology

Exposure for operator (OPEX).

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Table IIIA 7.3.1-1: Input values [Report of RMS-UK (2009a), Vol 3, Annex B6, page 202]

Application method	Tractor-mounted/trailed boom sprayer; hydraulic nozzles
Formulation type	Liquid, water based
Maximum individual dose	1.0 L/ha (250 g a.s./ha) (maximum rate on cereals & oilseed rape)
Water volume	100 L/ha
Container	10 litre HDPE single trip container with 63 mm screw closure
RPE, PPE, hand (gloves)	None
Work rate/day	20 ha (German model); 50 ha (UK POEM model)
Duration of spraying	6 h

Section 4 – residues

2 residue „zones” in Europe

Northern and Central Europe

Sweden, Norway, Iceland Finland, Denmark, United Kingdom, Ireland, northern France, Belgium, The Netherlands, Luxembourg, Germany, Poland, Czech Republic, Slovakia, Austria, Hungary, Switzerland, Estonia, Latvia, Lithuania, Romania, Slovenia.

Southern Europe and the Mediterranean:

Spain, Portugal, Southern France, Italy, Greece, Malta, Croatia, Serbia, Bosnia and Herzegovina, FYROM (Former Yugoslav Republic of Macedonia), Turkey, Bulgaria, Cyprus.

Section 4 – residues

2 residue „zones” in Europe (Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs – SANCO 7525/VI/95 rev.9)

In case of outdoor applications it is assumed that for the carrying out of residue trials, the climatic conditions and weather influences in each country of the region are comparable.

But trial data should be representative of the areas where authorization is granted or envisaged.

Data from different countries even within the same region may reflect different cultural practices and they might therefore be rejected.

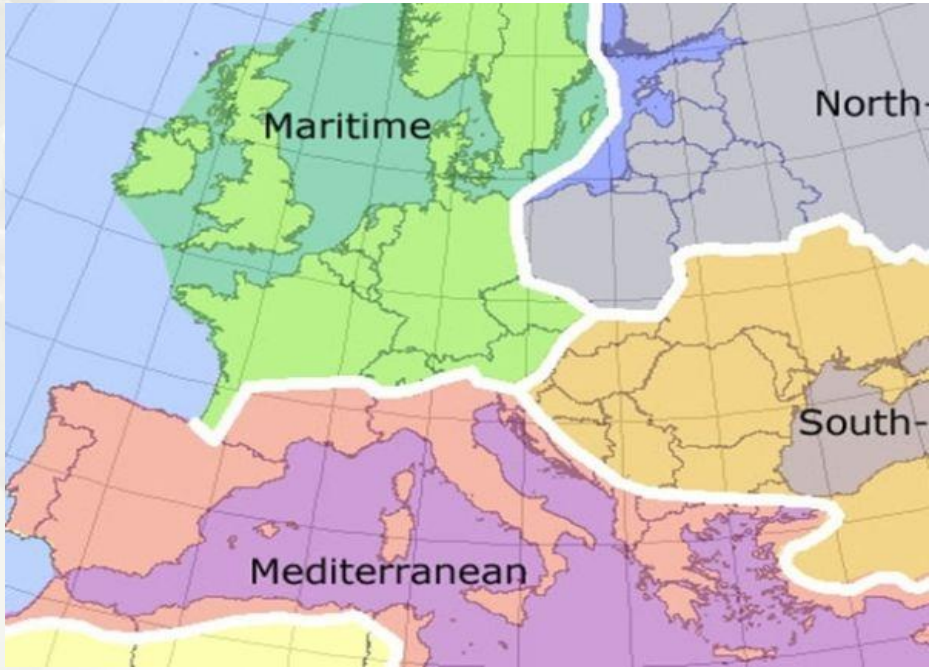
Section 4 – residues

2 residue „zones” in Europe

Studies performed in Northern and Central Europe?

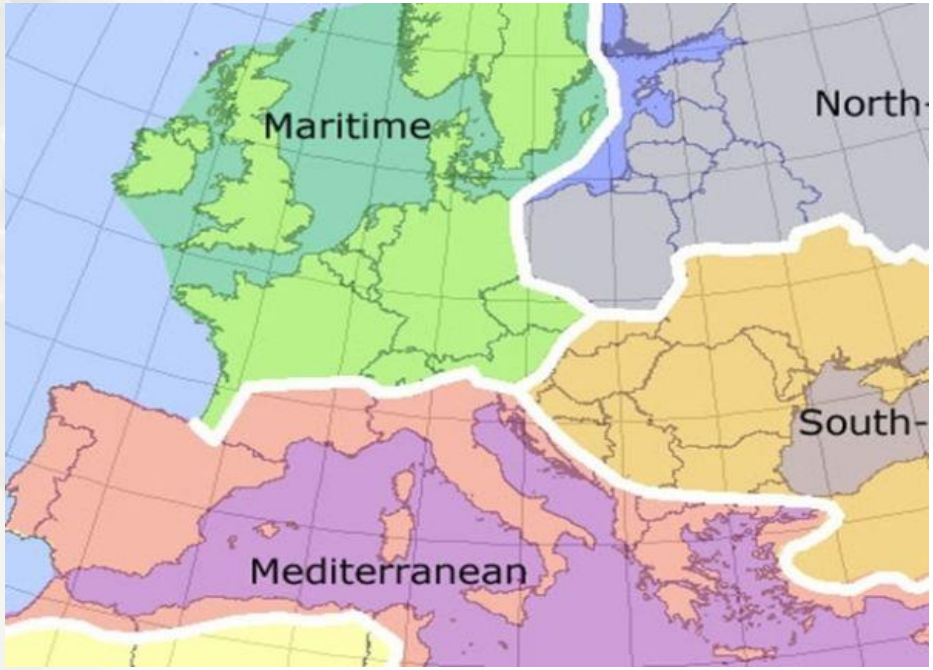
Possible request for bridging study/ies (conducted on the territory of BiH or in the Southern Europe and the Mediterranean).

Section 7 – efficacy



Efficacy studies should be performed according to EPPO standards, regarding number of trials, distribution of trials (location), etc. (data requirements regulation 284/2013).

Section 7 – efficacy



Studies performed in other EPPO zones?

Possible request for bridging study/ies (conducted on the territory of BiH or in the same EPPO zone).

Data protection

Data protection - protection means “the temporary” right of the owner of a test or study report to prevent it being used for the benefit of another applicant.

According to art. 59 of regulation 1107/2009 the period of data protection is 10 years starting at the date of first authorisation in that Member State (only in EU or in the countries where „data protection” is defined in similar way).

Data protection

Applicants shall be exempted from supplying the test and study reports where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access or that any data protection period has expired.

Data protection

In the case of using "off protected" data registrations reports usually contain only references to other reports, prepared for purpose of authorisation of reference product.

Mentioned approach makes procedure of mutual recognition useless from point of view of the country who doesn’t have physical access to „original” report and dossier.

PART A – Risk Management

1 Details of the application

1.1 Application background

AgriGuard Ltd submitted an application for approval of 'Achieve', a new suspension concentrate (SC) formulation containing 250 g/l azoxystrobin for use as an agricultural fungicide on cereals (wheat, barley, rye, oats and triticale).

The applicant requested approval of their new product on the basis of comparability to the approved product 'Amistar' (M10443), to which they claim their proposed formulation of 'Achieve' is comparable, and hence the proposed GAP is within that approved for 'Amistar' - and hence within the risk envelope in risk areas.

In support of this application, phys/chem data on the formulation were submitted, along with compatibility trials to support the efficacy of the product.

However it was requested that the risk to operators / workers / bystanders and the ecotoxicological risk posed by 'Achieve' be extrapolated from 'Amistar'. As such, toxicology and ecotoxicology specialists are required to compare the two formulations.

Additionally, it is necessary for the proposed formulation of 'Achieve' to be classified as a sum of the toxicological properties of its components.

1.2 Annex I inclusion

IIIA 7.1.7 Supplementary studies for combinations of plant protection products

No information provided. No information is required.

IIIA 7.2 Short-Term Toxicity Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 7.3 Operator Exposure

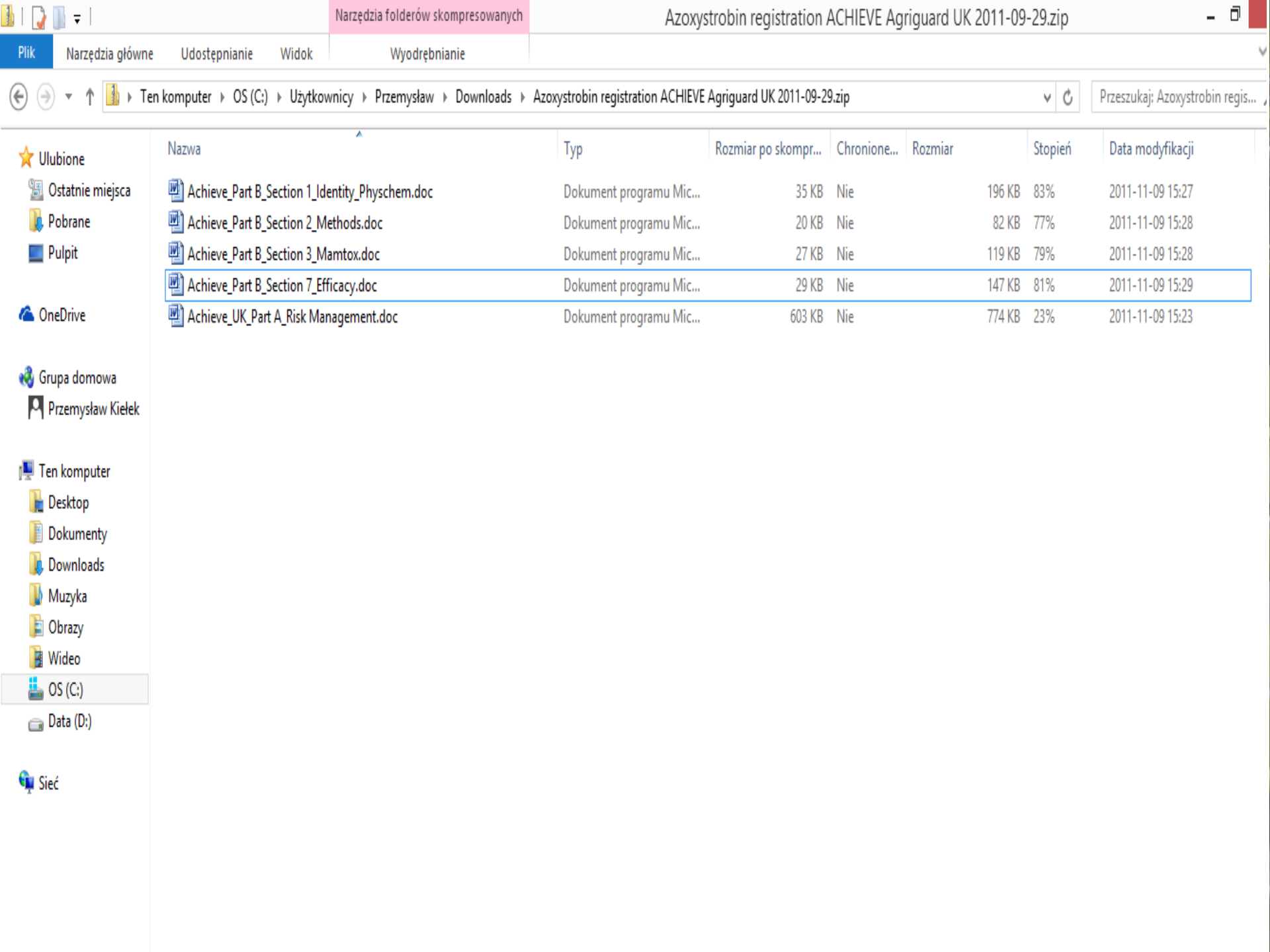
No Operator Exposure assessment was carried out under this evaluation, the risk to operators / workers / bystanders is considered within that currently approved for the reference product 'Amistar'.

IIIA 7.6 Dermal Absorption

The preparation 'Achieve SC' is a very similar formulation to 'Amistar' and to 'Priori'; 'Priori' was evaluated during the EU review of azoxystrobin. The solvent and co-formulants are comparable to 'Achieve' Hence the dermal absorption values proposed for 'Amistar' can be used 'Achieve'.

Table 7.6-1: Dermal absorption of azoxystrobin. EU Annex 1 end-points for the risk assessment

Concentrate: 0.3%	250 g/L SC formulation	based on *in vivo* rat study
Spray dilutions: 0.5%	1:600 spray dilution (0.42 g a.s/L)	based on an *in vivo* rat study and *in vitro* data in rat and human skin.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Data protection

Possible solution??

Each application for mutual recognition in BiH has to be supported by complete dossier (physically submitted) which is a property of the applicant – legal obligation (even if letter of access is available).