

**Registration environment
and challenges in Poland
Applicants point of view**

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- **What keeps us busy last 12 months?**
- What is most challenging last 12 months?
- Reflections



Dossier translation the main obstacle in Zonal approach

- ✗** Rapporteur duties transferred from PL to other RMS
- ✗** Reorganization of the submission strategy for many products
- ✗** Mitigations of consequences of PL absence in the Zonal System



- ✓** Understanding of the situation by the Authorities
- ✓** Polish registration experts highly appreciated in EU
- ✓** Polish agriculture is not yet impacted. Negative results expected in near future if changes do not occur.

Requirements changing during ongoing processes

- ✗ Change of efficacy requirements
- ✗ Change of policy on commenting AI-s inclusion
- ✗ Unused space for dialogue preceding introduction of new requirements



- ✓ Willingness of the Authorities to improve the system
- ✓ Proposed also positive changes, which are not balancing damages by other changes

CLP re-classification the least pragmatic approach among EU 28

- ✘ Late decision regarding CLP procedure, expected impact on registration
- ✘ Availability of PPP on the market can be affected
- ✘ Unlike other EU MS, Poland Registration Report is required for CLP
- ✘ Costly and time consuming procedure
- ✘ Polish template creating additional workload (2013)



✔ no comment

Enormous workload expected due to EU regulations

- ✘ High wave of re-registrations expected in 2016-2018 (2-3 times more)
- ✘ Large number of applications queuing for approval



- ✔ Optimization of portfolio pending by the Industry
- ✔ Monitoring of future submission plans in 2015 by the Ministry. Hope to have resource planning 2016 onwards.

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Delays in registration

- ✘ Not all applications under 91/414 completed so far
- ✘ Most of the registration time frames significantly exceeded
- ✘ CLP may affect registration activities in Poland in 2015
- ✘ Prioritization of applications by the applicant not possible



- ✔ In some cases flexible approach towards applicant delays.
- ✔ Change of internal organization of Authority done. Industry is waiting for the results.

Minor uses

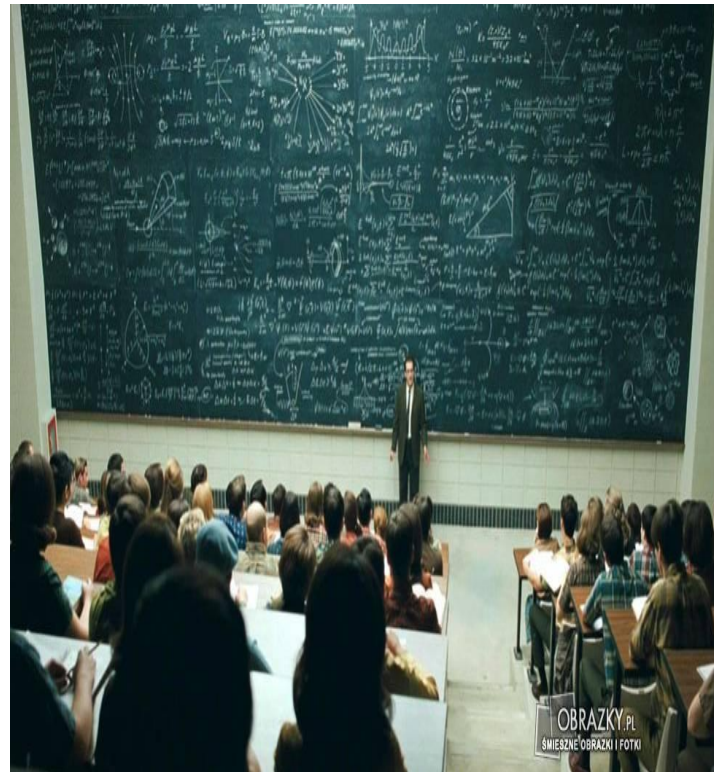
- ✗ Translation of the dossier makes application difficult if not impossible
- ✗ No clear rules for applicant, especially for producer groups
- ✗ No priority treatment
- ✗ Expected impact of comparative assessment



- ✓ Existing dialogue with Authority. We do hope changes are coming.

National requirements

- ✘ Decisions are shifted from Zonal level to national level**
- ✘ National requirements are contradictory with the spirit of 1107/2009**
They make the registration more complicated.
- ✘ Assessment of entire documentation for Mutual Recognition is not foreseen in 1107/2009**



- ✔ Authority does not apply any new national requirements**

Applicant / Authority

Way of co-operation

- ✘ Planning of registration strategy not possible due to frequent changes of interpretation of legal acts
- ✘ Important changes implemented without consultation with industry (e.g. CLP)
- ✘ Website as a communication tool not properly used



- ✔ There is still minor dialogue with Authority. Expected extension of dialogue as per Authority declaration.

- Changes of rules and interpretations of regulations make the life of the applicant difficult
- Dialog better than „go to court” approach
- There is hope to see Poland as a regular member of the Zonal System
- Appeal to the Authority „to take advantage of the good examples form the Zone”



Thank you for your attention

