

Parallel trade in Hungary How to prevent misuse of the system?



1 € / L

Illegal PPPs represent around **10%** of the EU PPP market – but this might be a considerable underestimation of the extent of the problem. (*European Commission, DG Health and Food Safety (2015): Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU*)

Legitimate parallel trade enables price equalisation by importing identical products from a country where prices are lower to other countries.

Illegal parallel trade:

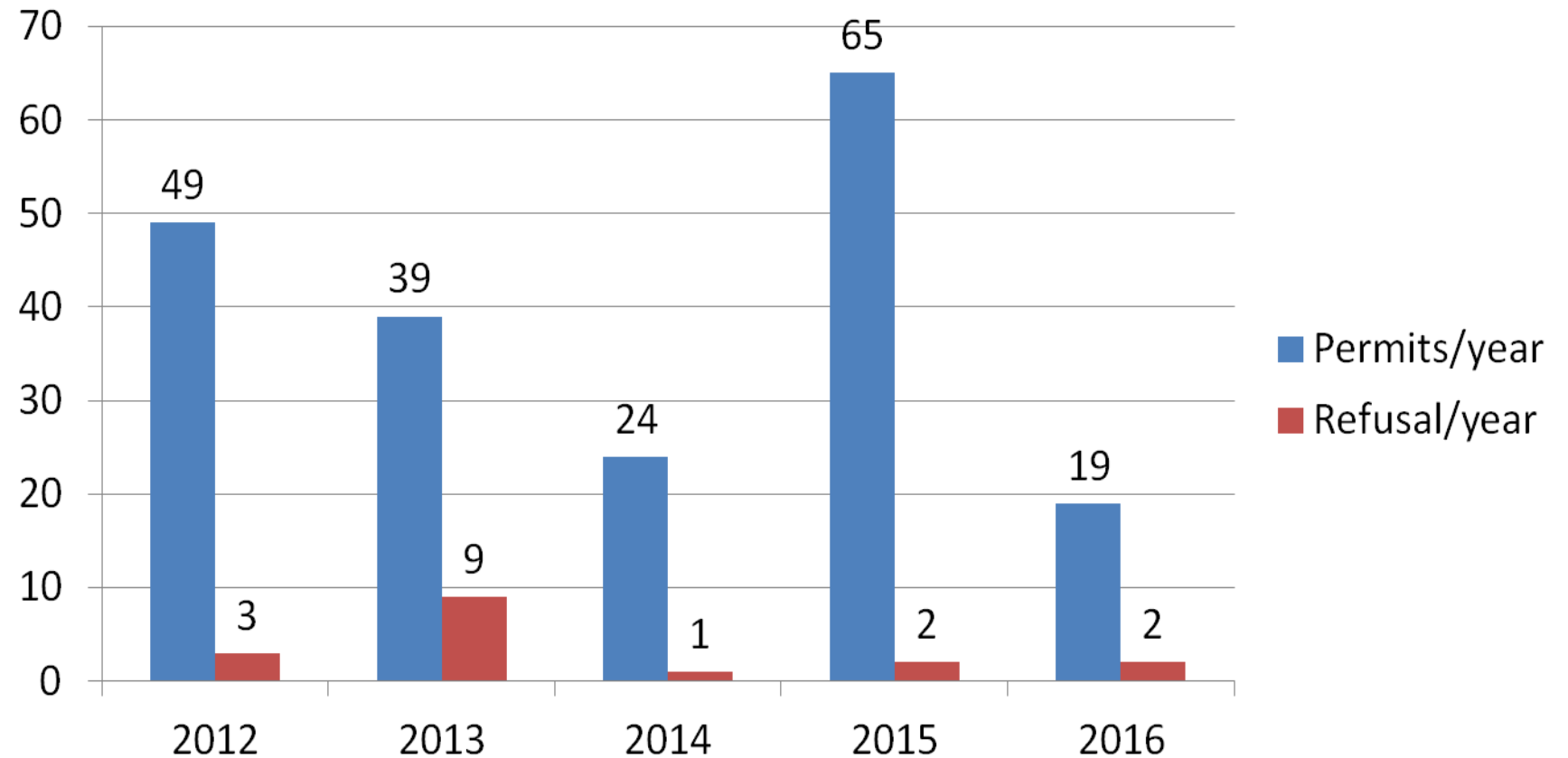
- Legitimate parallel traded products, substituted by counterfeit products
- Formulation of illegal PPPs from legal imports of a.s. and placing on the market through misuse of the parallel trade system

Cause: No harmonised approach of the requirements and control of parallel traded products

(e.g. different level of checking procedures, lack of uniform approach to re-packaging, different sanctions)

Overview of parallel trade in HU

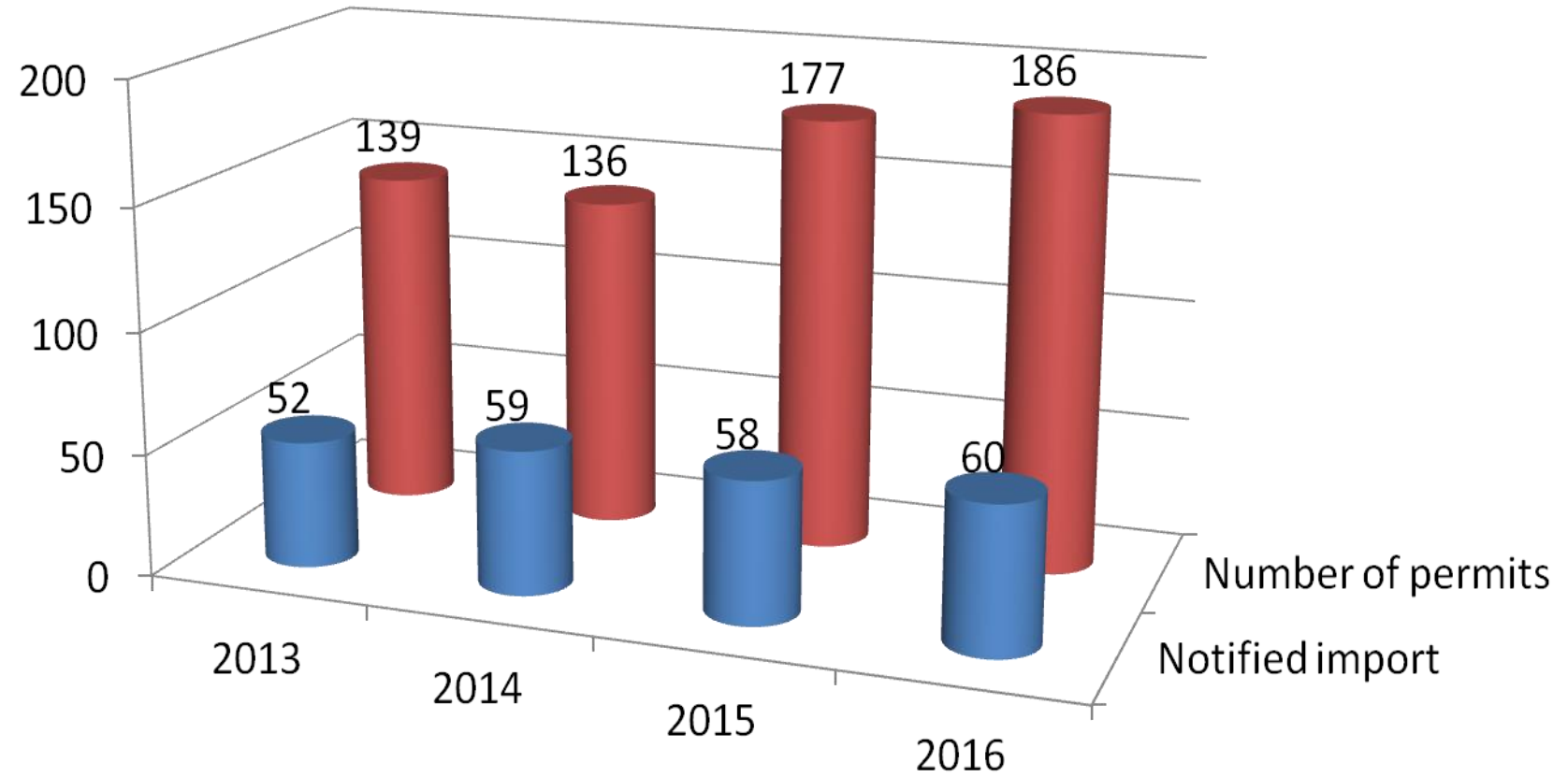
New permits and refusals/year



Reasons of refusal:

- The composition of the PPP is not identical
- The authorisation of the PPP in the MS of origin is not valid
- Misuse of product name (former product name is not allowed)
- On request of the applicant (no answer of the country of origin)

Parallel products on the market



Less than 40 % of the permitted parallel products is on the market

- ad hoc applications or
- Ignoring of the engagements

Rate of parallel products on the HU market

Continuous increase



Year	PPP trade (tons)	Parallel trade (tons)	%
2013	24 393	123	0,5
2014	29 649	342	1,1
2015	29 770	354	1,2
2016	30 000*	455	1,5

* Preliminary data

Critical issues in the procedure and assessment

Critical points	Problems occur
Complete application is needed	The original label sometimes missing
Name of the product	Name of a former authorised (expired) product, a.s. name as product name – not allowed Parallel traders should pay attention to the intellectual property rights
Request for information from the MS of origin	Long time (more than 10 days) of receiving the request
Identification of the product in the MS of origin: <ul style="list-style-type: none">• Authorisation status• Common origin	Expired authorisation – refusal Parallel trade of parallel traded product – reference to Court case in C-108/13 The manufacturer is not the same (or associated undertaking or under licence) – refusal (The authorisation holders could be different.)

Critical issues in the procedure and assessment

Critical points of the assessment	Problems occur
Identity of the parallel product with the reference product:	
• A.s. specification and content are identical	• Different source of a.s., and equivalence has not been assessed – refusal
• Equivalent or same co-formulants	• Not equivalent co-formulants – refusal Simplified procedure – no detailed assessment!
• Same packaging size, material or form	• Different packaging in the MS of origin – acceptable • Repackaging – not acceptable

Post-permit issues

Ensuring traceability of the products along the trade chain

Avoiding the misuse of parallel trade system and unveiling parallel trade abuse



Ensuring traceability 1

Prohibition of re-packaging

Regulation 1107/2009/EC does not prohibit re-packaging of products but traceability should be ensured.

The most concerns was created by re-packaging outside HU.
Suspicious business: the MS of origin was PL and the repackaging plant was in the UK.

HU provision: **Prohibition of repackaging** from 1 January 2013 and distribution allowed only in original packaging units and material (Presidential Order of NFCSO/NÉBIH)

It appears case by case in the parallel permit:
e.g. „**1 litre in original packaging**”



Ensuring traceability 3

Data base of parallel trade permits – on the NÉBIH website
– to facilitate information exchange

Obligation of the importer:

Announcement of the date of import and volume of the
product within 15 days of the import

(Planned provision: 15 days prior to the import)

Information (leaflets, presentations), trainings



Official controls

Organisations involved:

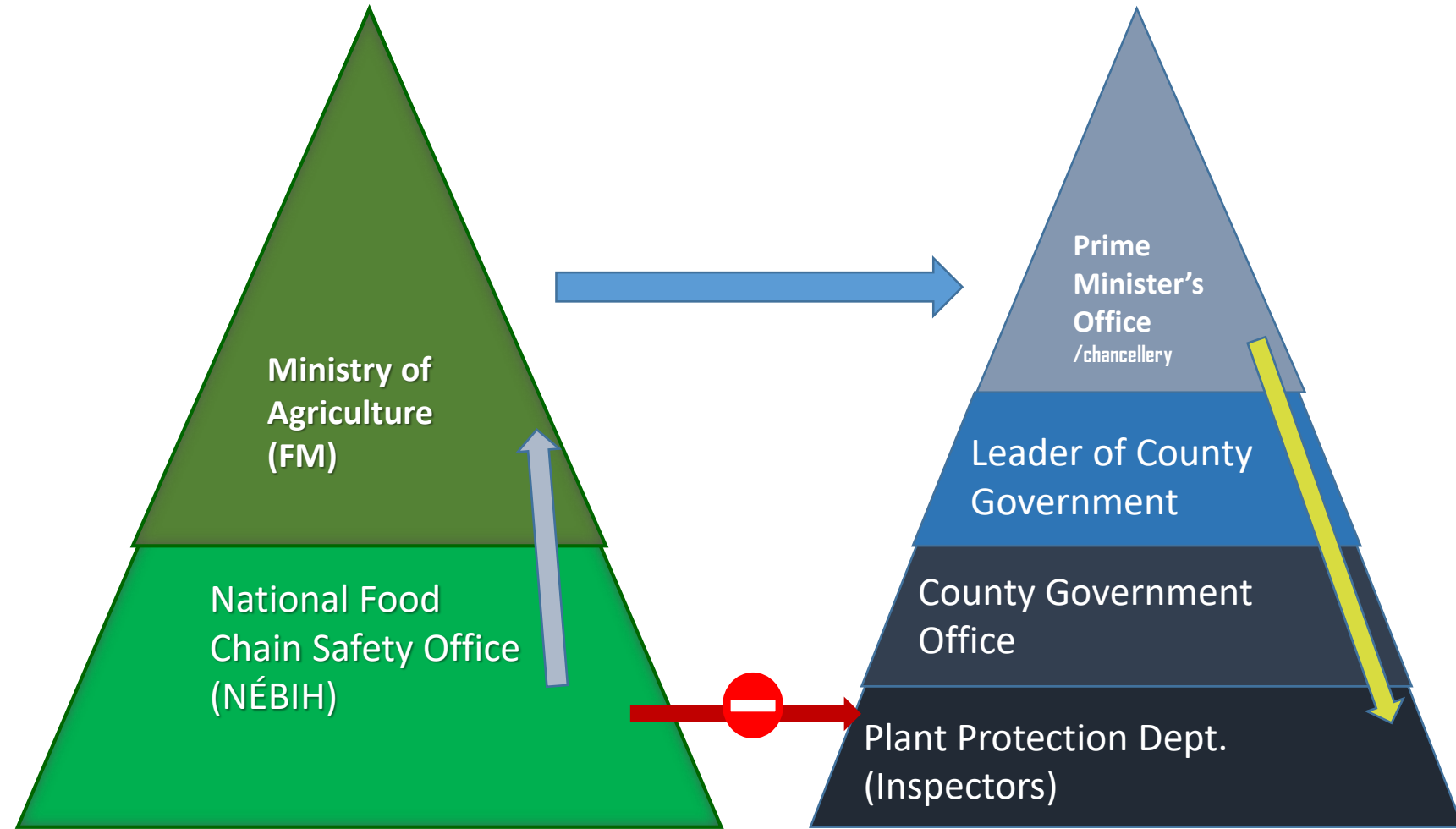
National Food Chain Safety Office (NÉBIH)

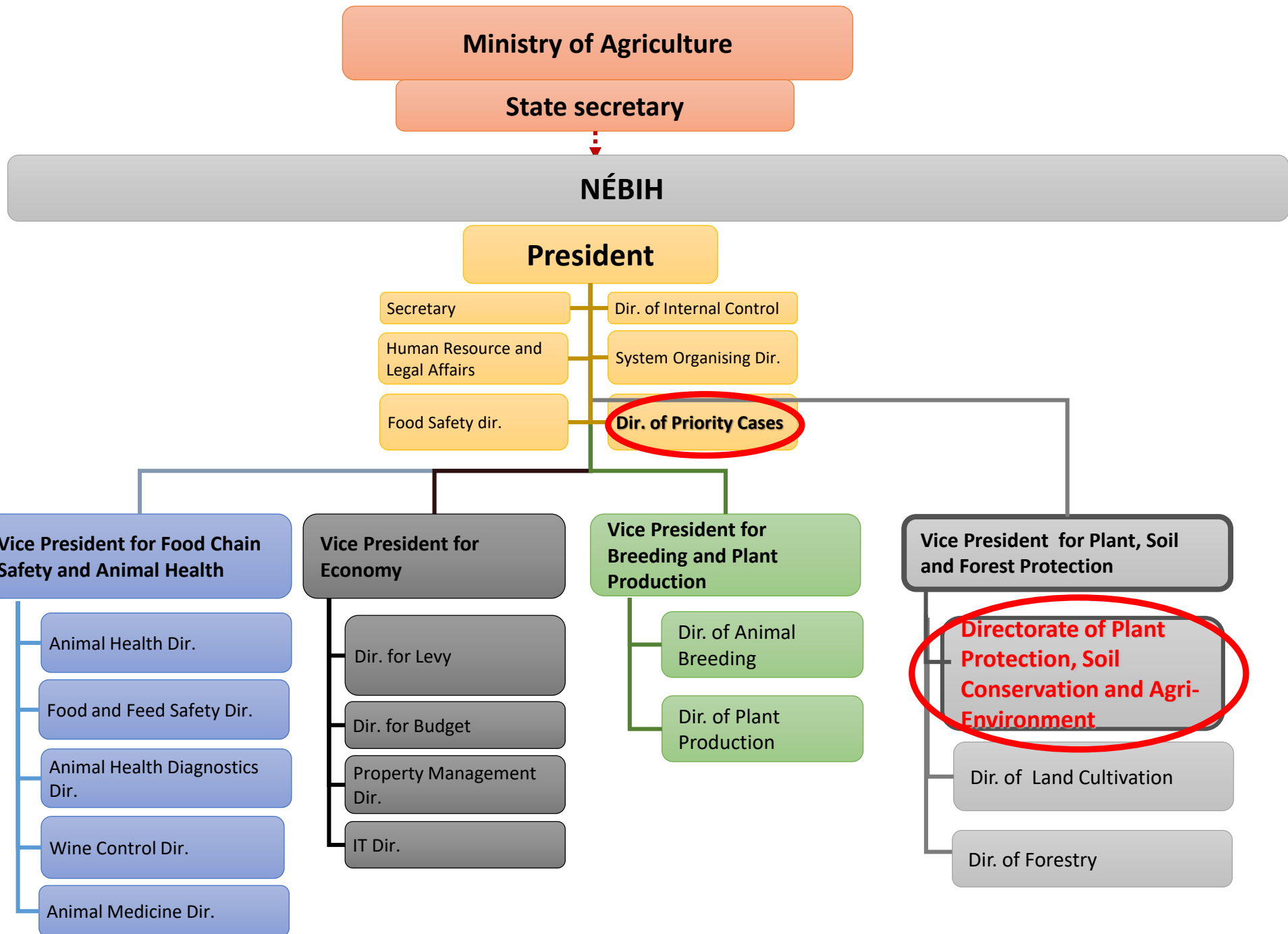
- Directorate of Priority Cases – inspections of great importance issues
- Directorate of Plant Protection, Soil Conservation and Agri-environment – information for the inspections on the products

19 County governmental offices – inspections at producers, distributors, users etc.

Difficult communication with county offices

New structure





Co-operation with Customs Office

Agreement between the competent authorities:

National Food Chain Safety Office

and

National Tax and Customs Office

- Updated yearly since November 2012
- Custom officers and plant protection inspectors are involved
- Focused on the PPPs



Control program of parallel trade

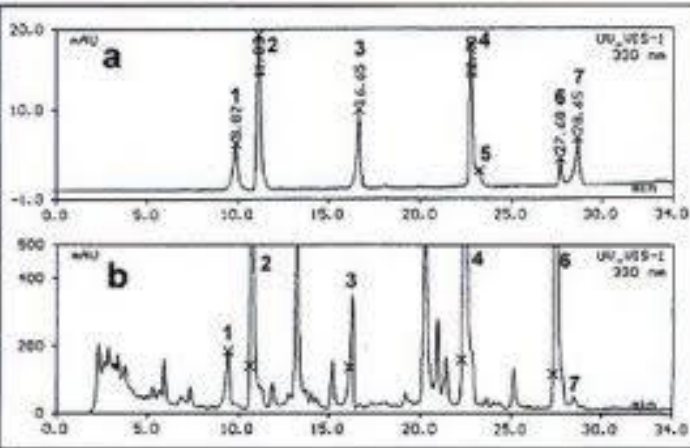


- 3 year control program started in 2015:
priority sampling of parallel trade products together with the reference products
- limited result: **parallel products are not available in shops**– direct distribution

Counterfeit parallel traded product case

Investigation on parallel traded products :

- A registration holder (Becesane) haven't reported the import volume during 2012-2015
- 5 suspicious products of this company were announced to the authority
- Control in the warehouse , sampling
- Sample analysis
- Batch number control, checking of packages
- Manufacturer of the reference product contributed to the checking



Counterfeit parallel traded product case

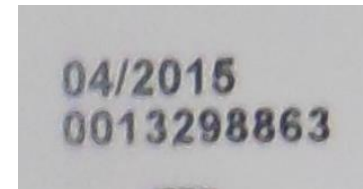
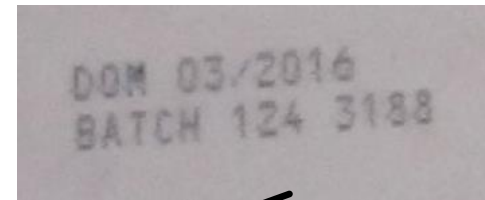
Findings:

- Country of origin was different
- The manufacturer of the reference product couldn't identify the batch number (unknown form)
- The packaging material was different
- Analytical results: the quality was acceptable but different from the reference product

Fake product



Package, position of the batch number and date, format of batch number



Follow-up actions

CONCLUSION

- Parallel trade and number of authorised products are increasing
- Contact the authority in case of product is suspicious
- PPP with very low price may be not original
- Co-operation with the manufacturer of the reference product is useful
- Co-operation with other offices are indispensable
- Repackaging is a main way of fake products



*Thank you
for attention*