

*Illegal plant protection products
marketed as parallel import products
Cases in Greece*

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Parallel Import plant protection products

A plant protection product that is authorized in one Member State (MS of origin) is placed on the market or used in another Member State (MS of introduction), if this MS determines that the plant protection product is identical in composition to a plant protection product already authorized in its territory (reference product).

Why to market parallel products?

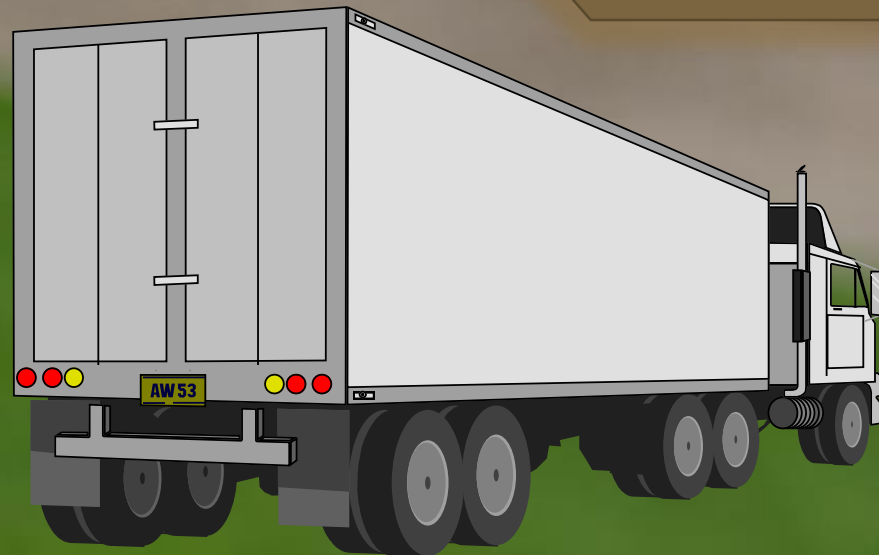
CHEAPER PRODUCTS

Parallel imports

...So it is not a new authorization; it is marketing an authorized product to another Member State...

**Member
State of
introduction**

**Member State of
origin**



Illegal plant protection products

Unknown composition,
Non evaluated products

Risks to humans

Risks to environment

Risks to crop

Jeopardize the safety of the
authorization system

Full contrary to the sustainable use of
ppps

But

CHEAPER PRODUCTS

Official controls structure in Greece

Who are controlled for illegal ppps?

Placing in the market

Use

Parallel import traders

Retailers and wholesalers

Professional users

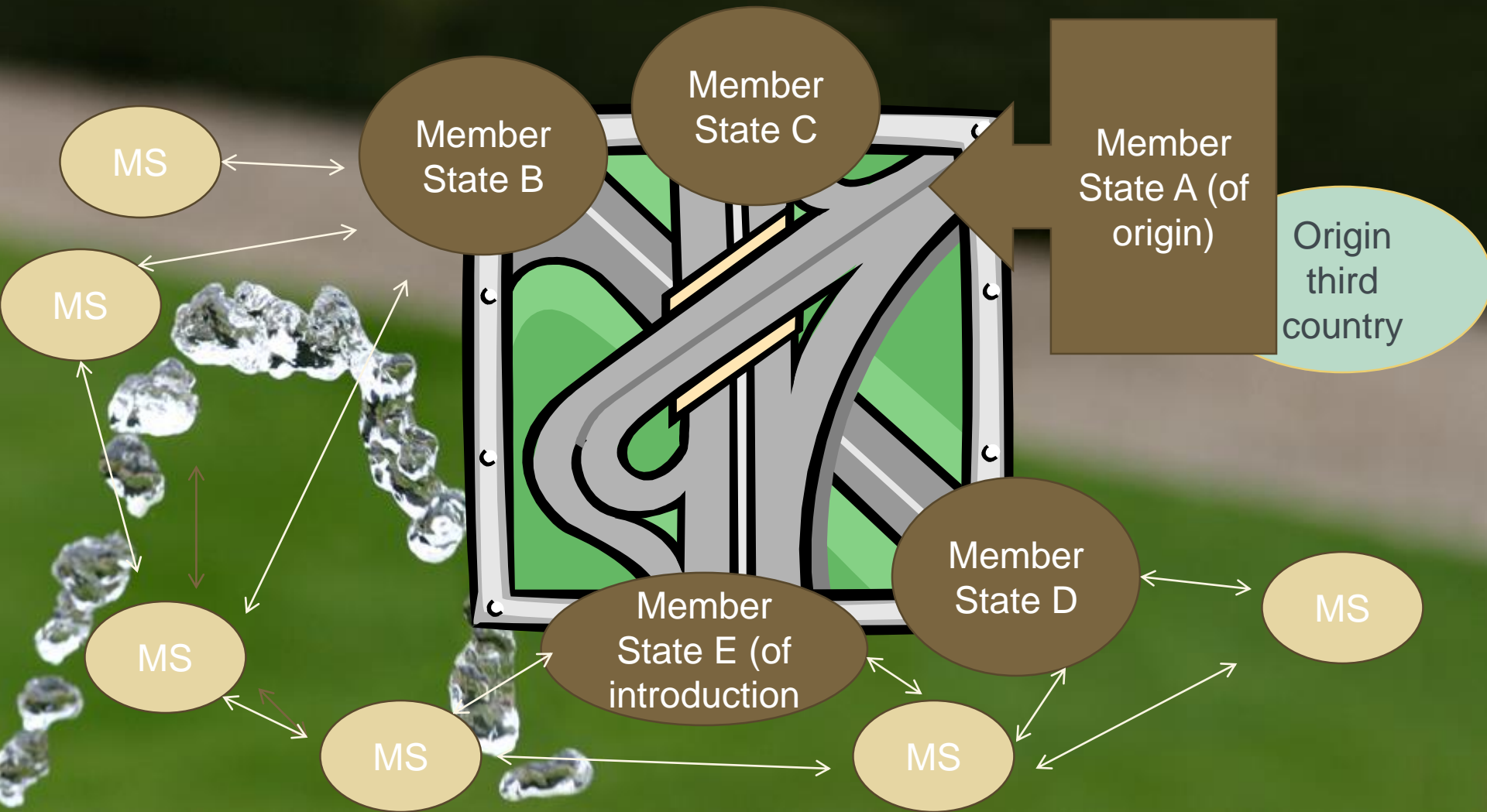
Official authorities for PI controls

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- ❑ Coordination of inspection authorities and sanctions proposal: Directorate of Plant Produce Protection, Ministry of Reconstruction of Production, Environment & Energy
 - ❑ On site inspection authorities: Directorates of Rural Economy and Veterinary Medicine of Regional Unities (DREVM of RU)
 - ❑ Chemical controls Laboratories: (Benaki Chemical Control Lab)

PI controls

- ✓ Controls during the imports of ppps in EU to avoid distribution of import products as PI. Good coordination among MS, as the MS of import is not usually the MS of origin.
- ✓ Documentary checks: Check invoices of the PI product in order to prove that is originated by the authorization holder of the MS of origin (*problem – almost always impossible*)
- ✓ **Sampling and comparative analysis**

In fact sometimes instead of transfer from a MS to another



Sampling and analysis of PI

- ✓ Sampling of 1 batch of PI product and 2 batches of reference product from the market (randomly)
- ✓ Full chemical analysis
 - ❑ Analysis for the content of active substance
 - ❑ Analysis for the inerts
 - ❑ Analysis for the physicochemical properties



Sampling and analysis of PI

- ✓ Second analysis (counter analysis) conducted with the presence of experts of the PI permit holder and the authorization holder
- ✓ Second expert opinion on the procedures and the results
- ✓ Reporting results and evaluating the compliance with the provisions, meaning the similarity of the two products

Sanctioning system

- ✓ Request for opinion express on the infringement
- ✓ Administrative sanctions: Fines up to 30,000 euros (double in case of a repeat), recall of the batch from the market
- ✓ Punitive sanctions: imprisonment for three months up to one year
- ✓ Publicity of the sanctioning decision in the free access “Diavgeia” website.



Cases in Greece

Learning from our experience...



16/6/2015

Illegal ppps

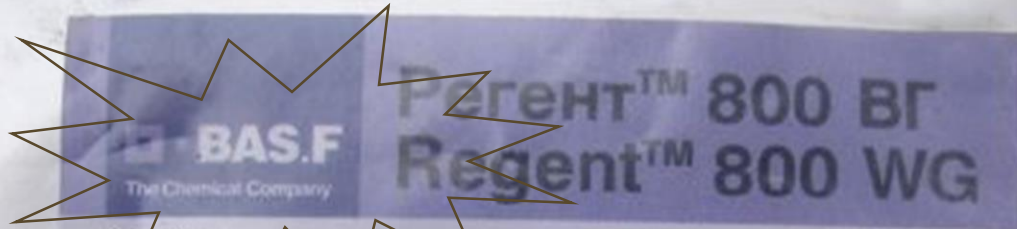


16/6/2015

Achievements - example



Illegal copy of fipronil ppp



ОПАСНИ
ПРОИЗВОД ЗА ЗАШТИТА НА РАСТЕНИЈА 404349
Пред употреба внимателно прочитајте етикетата
За да се избегнат ризиците за здравјето на луѓето и животната средина,
почитувајте ги упатствата за употреба!

Широко инсектицидите со систематски и контактен план за борба
против непријатели на пченица, ечимик, компир, слънчогед, пченка, памук, тутун
и шеќерна репка.

| Култура | Непријател | Доза - г / дха |
|-----------------|--|----------------|
| Пченка | сива тченкарен хоботник | 18 |
| Сончоглед | сива тченкарен хоботник | 18 |
| Шеќерна репка | цветкови хоботници | 18 |
| Пченица, ечимик | житна пивалца | 2,5 |
| Пченица | штетна житни грешка - парки | 2,5 |
| Компир | колорадски трамбовка | 2,0 |
| Тутун | праска листа вошки тутунски трипс | 3,5 3,5 |
| Памук | памукова листа вошки тутунски трипс | 3,5 3,5 |



10 грама
TM-търговска марка на BASF



Achievements

- ✓ Ability to deal with emerging risks related to illegal pesticides.
- ✓ Modernized and sharpened control tools,
- ✓ Efficient cooperation with industry satisfying the corresponding expectations
- ✓ Gained experience
- ✓ Improvement of cooperation among national control authorities

PI infringements – Cases in Greece

- Different chromatographic tops representing the different synthesis of the controlled formulations.
- Decrease in active substance concentration (e.g. 3 samples of deltamethrin 2,5%EC found to contain even 0,95% deltamethrin)



PI infringements – Cases in Greece

- Linkage of formulation due to different diluents
- Traces of endosulfan in deltamethrin 2,5%EC PI formulation
- Differences in the type of formulation (for example lambda cyhalothrin 10% Capsulated formulation where capsules had different appearance in comparison to the authorized product)



What were the common characteristics of the cases

- All cases were introduced from the same wholesaler of the same MS.
- The sender had supplied the receivers with self-issued “certificates” about the genuinity of the products and his responsibility to pay any fine in case of infringement.
- The receivers were buying the products with a lot of invoices of small quantities paying in advance of by dispatch.



What were the common characteristics of the cases

- The invoices never mention the tradename (e.g. “DECIS”) but only the a.s. (e.g. deltamethrin 2,5%EC)
- The batches always arrived in Greece with “white”-not labeled bottles & boxes.
- Almost always the second expert is denying everything in the laboratory analysis.

Infringement Defense

- Laboratory methods are not accredited, not even developed in house and tested.
- Laboratory report cannot always result to the conclusion of the difference of the two (three) preparations.
- Differences are not described in any EU Guidance Document, as enough proof for PI infringement.

How we deal PI cases...

- Good cooperation with other Member States in order to exchange experience, to supply assistance and keep our information achieves always updated.
- Communication with industry. Information exchange and selection of analysis aims.
- Close cooperation with our main laboratory (Benaki) in order to cope any needs, to manage the aggressions of PI and develop best practices.

How we deal PI cases...

- Severe fines (doubled in case of repeat)
- Publicity of the decisions
- Planning to forbid the introduction of PI products without having the label of the MS of origin and keeping samples of each batch.
- Changing law and supplying 70% of registration fees to Benaki Institute for evaluation and **control** purposes.

How we deal PI cases...

- We created a new Common Ministerial Decision describing the procedures for the controls of plant protection products.
- We are about to issue a new Ministerial Decision the chemical controls procedures and the evaluation of their results will be clearly described...

What we have succeeded...

Independent survey organized by
EU and presented to the working
group recognized Greece and
Benaki Laboratory for Chemical
Controls as

BEST PRACTICE

The greatest challenge

To create an effective control system, based on risk analysis, cooperation with all stakeholders and low resources able to control marketing and use of illegal ppps.

To keep and update the efficiency of our official laboratories in order to ensure the reliability and consistency of official controls in Greece.

Thank You



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