

Institute of Plant Protection – National Research Institute  
Sosnicowice Branch  
29 Gliwicka St., 44-153 SOSNICOWICE, Poland  
phone +48 32 238 75 84, fax +48 32 238 75 03  
e-mail: [stocki@ior.gliwice.pl](mailto:stocki@ior.gliwice.pl), web: [www.ior.gliwice.pl](http://www.ior.gliwice.pl)

**Author: Stanislaw Stobiecki**

# **RISKS OF PARALLEL TRADE OF PLANT PROTECTION PRODUCTS – SELECTED ASPECTS**

**CEUREG FORUM XV**

**Bratislava, Slovak Republic, 6-7.10.2011**



## COUNTERFEIT PESTICIDES

- **Ceureg Forum XIII, Poznan, Rocky Rowe (ECPA) – International Activities against Counterfeiting of Pesticides.**
- **Ceureg Forum XIII, Poznan, Maurice Boureau (France, Min. of Agr.) Outcomes of Control of Parallel Import Products.**
- **Ceureg Forum XIV, Brno, Stanislaw Stobiecki (IPP, Poland) Counterfeit Pesticides – Big Quality Control Problem with Plant Protection Products in Poland.**
- **European Commission Workshop on Illegal Pesticides, DG Markt, Brussels, 11.05.2011**



## ESTIMATION A RANGE OF THE PROBLEM

- **ECPA (2008) estimates that counterfeit and illegal pesticides account for 5-7% of European ppp's market = 400-500 million Euros**
- **2011 estimate: 7-9% European ppp's market**
- **Poland – 10-15% Polish ppp's market = 40-60 thousand Euros**

## PARALLEL TRADE ABUSE

**Legal parallel traded plant protection products are substituted with counterfeit products**



## PARALLEL TRADE – ADVANTAGES

- **Facilitates trade among the EU countries**
- **Makes it possible for farmers to buy the same product at a lower price**
- **Positive impact on the market and price policy**
- **Less bureaucracy thanks simplified system of issuing permits (permits issued 45 days from the application date)**
- **Increases the amount of products sought after by farmers – more products available to farmers**



## PARALLEL TRADE – DISADVANTAGES

- Relays on documentation to determine identity of products
- Repacking and labeling products – improprieties possible
- Used to introduce counterfeit products
- Calls for additional control (using resources)
- Introduces on the market products that are close to their expiration date
- Illegal import from non-EU countries
- Increases difficulty in control and fighting against counterfeit products



# PARALLEL TRADE

- **Introduced in EU in 2000**
- **Guidelines of The European Commission in 2001 different way of providing a legal basis within the EU**
- **2007 parallel trade incorporated into Polish Law**
- **2011 Parallel trade as a part of Regulation 1107/2009, Article 52**



## **GUIDELINES ON PARALLEL TRADE OF PPP'S**

- **Guideline development within the Standing Committee on Plant Health concerning parallel trade of plant protection products within the EU and EEA – Sanco/223/2000 rev. 9 dated 6-12-2001**
- **Guidance document concerning the parallel trade of plant protection products under Regulation (EC) 1107/2009 – Sanco/xxxx/2010 rev.0 on dated 17-8-2011**
- **Criteria for approving the parallel trade of plant protection products by BVL, Germany, valid from 14-6-2011**
- **Parallel Trade Permit procedure by Chemicals Regulation Directorate (CRD, U.K.), Annex A – criteria for identity**



## **REGULATION 1107/2009 ARTICLE 52**

### **PARALLEL TRADE**

- 3. Plant protection products shall be considered as identical to the reference product if:**
- (a) they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;**
  - (b) they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation; and**
  - (c) they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.**





## THE RESPONSIBILITY OF MEMBER STATES

- **To provide necessary checking procedures.**
- **Effective post-registration control.**
- **MS apply varying levels of control of parallel trade.**
- **Non-existent or minimal level of control cause confusion in the market.**
- **This confusion has lead to the abuse of the system by criminals.**

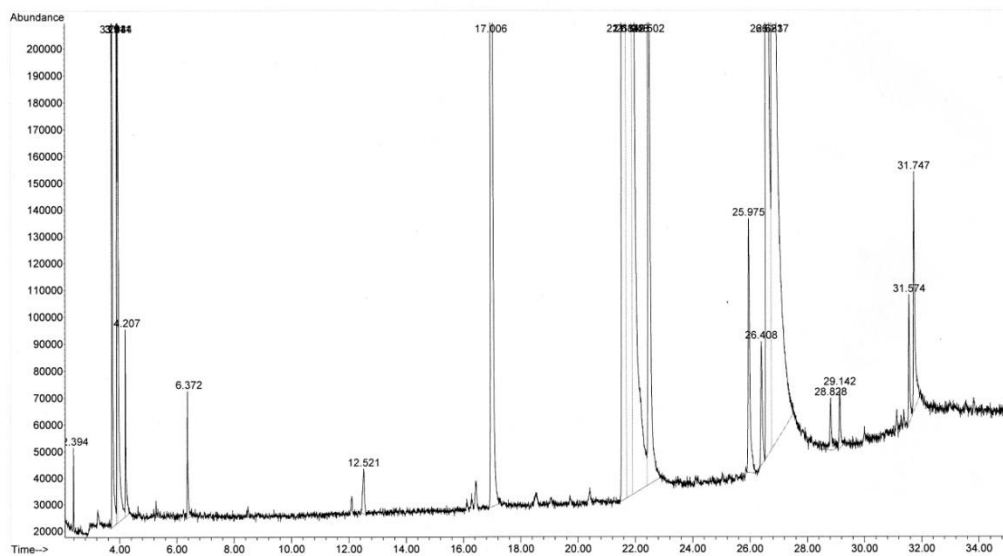
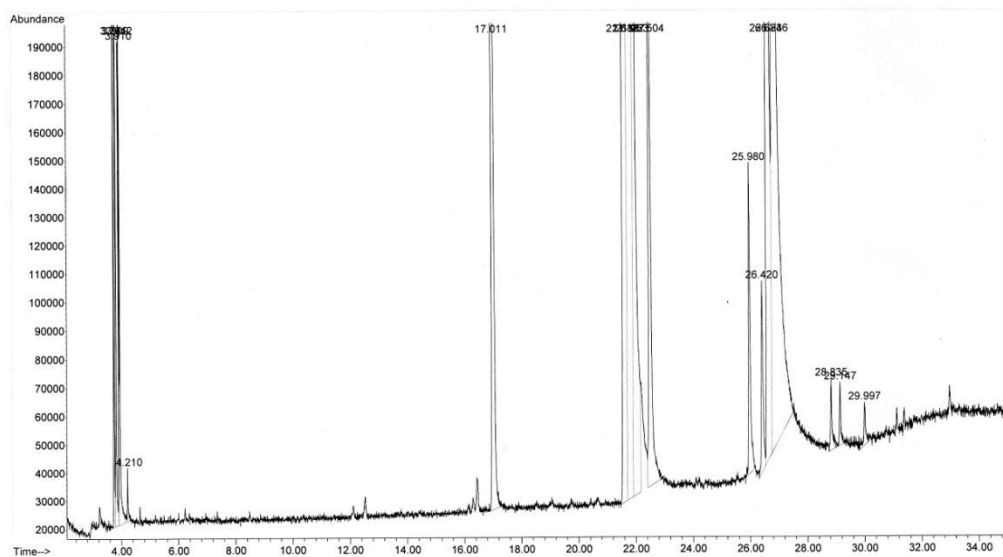


## IDENTICALITY – KEY ELEMENTS

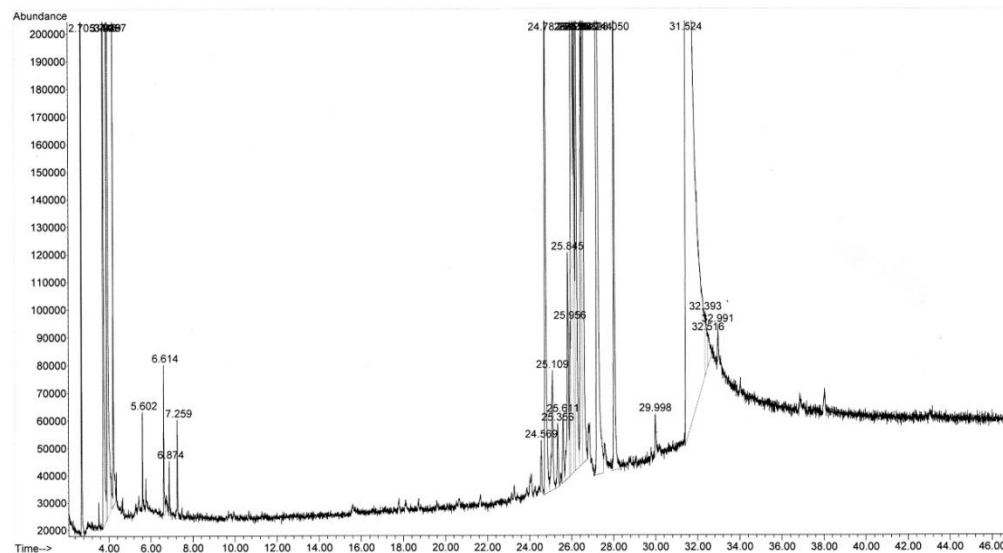
- **Identical method of synthesis of a.s.**
- **Identicality of composition of additional substances, isomers**
- **Identical “impurities profile”**
- **Identical composition and amounts of significant impurities (amounts greater than 1 g/kg)**
- **the same formulation**
- **Identical physical and chemical properties of the plant protection product**



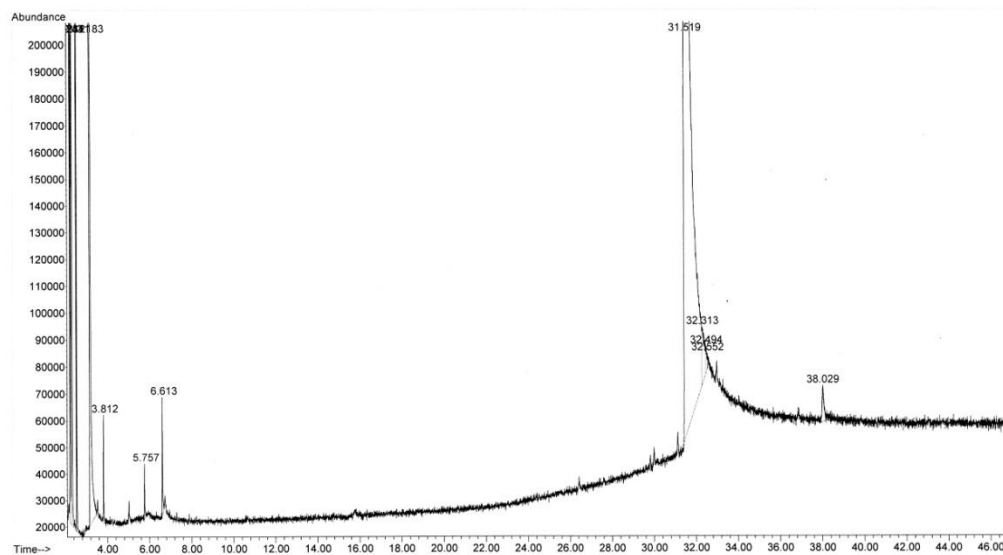
# SMALL DIFFERENCES (GC-MS)



# LARGE DIFFERENCES (GC-MS)



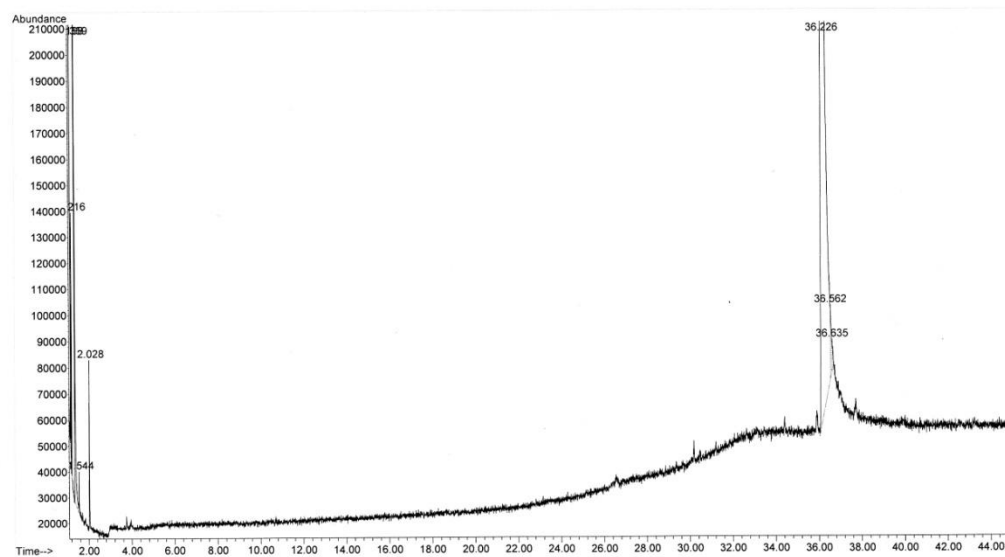
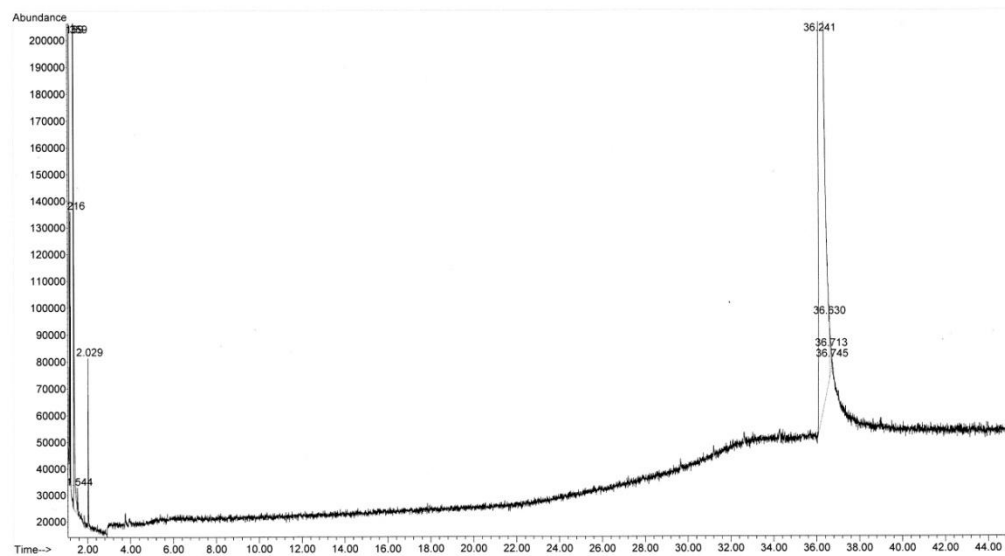
test product



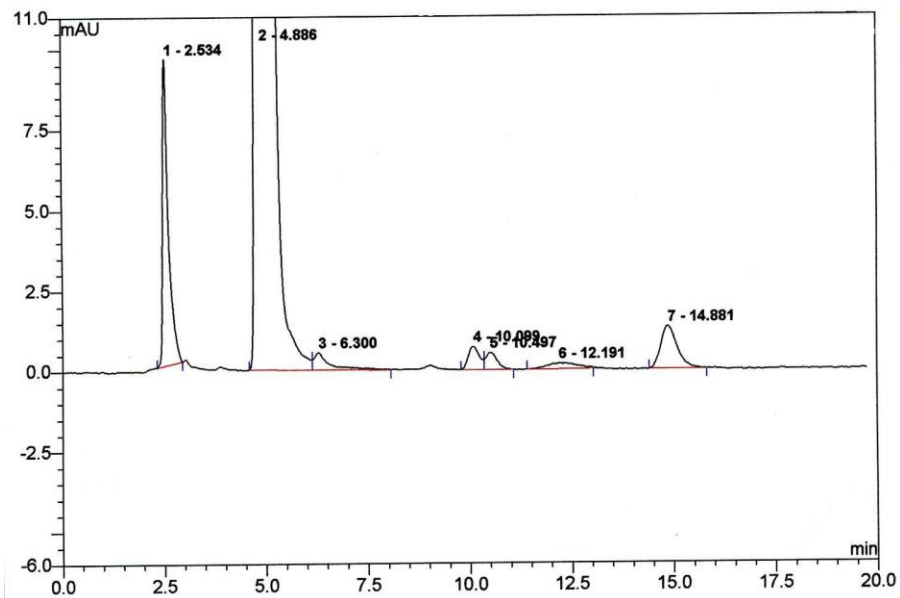
reference product



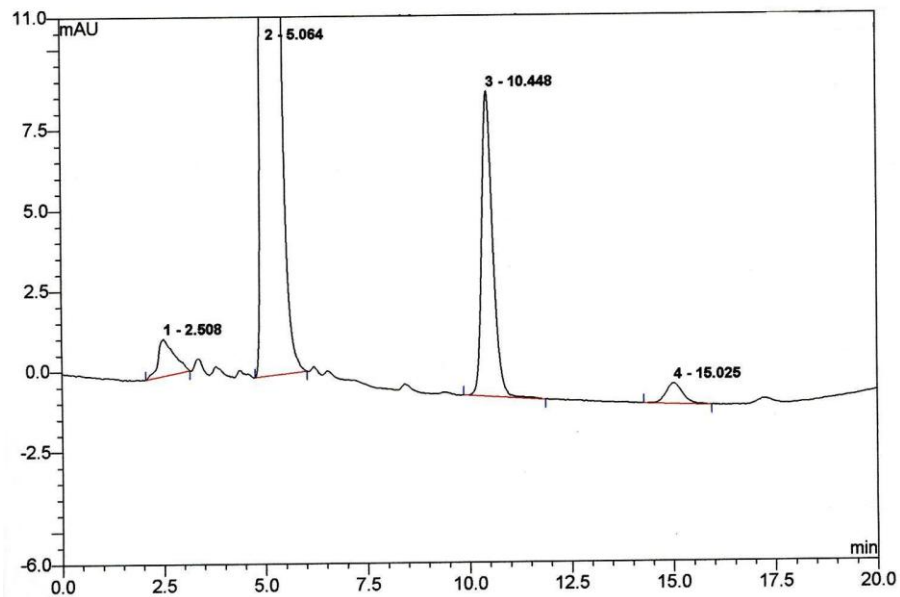
# NO DIFFERENCE (GC-MS)



## LARGE DIFFERENCES (HPLC)



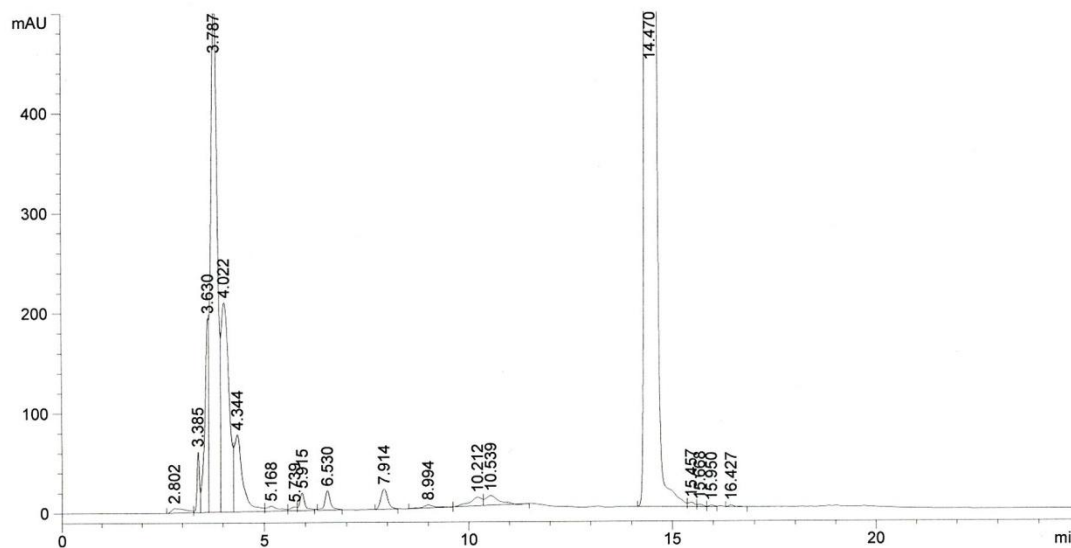
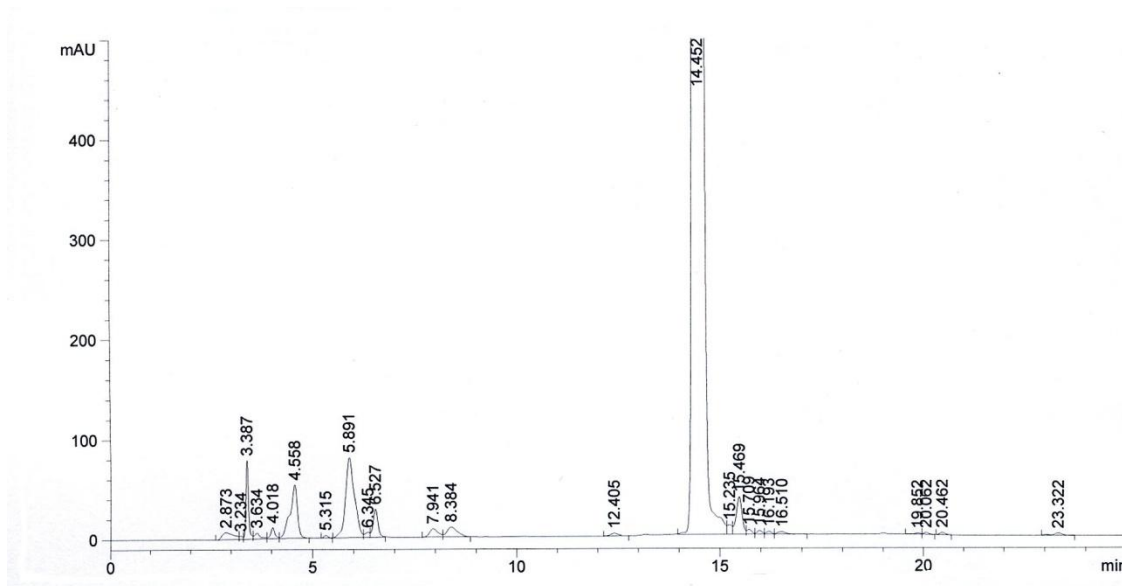
test product



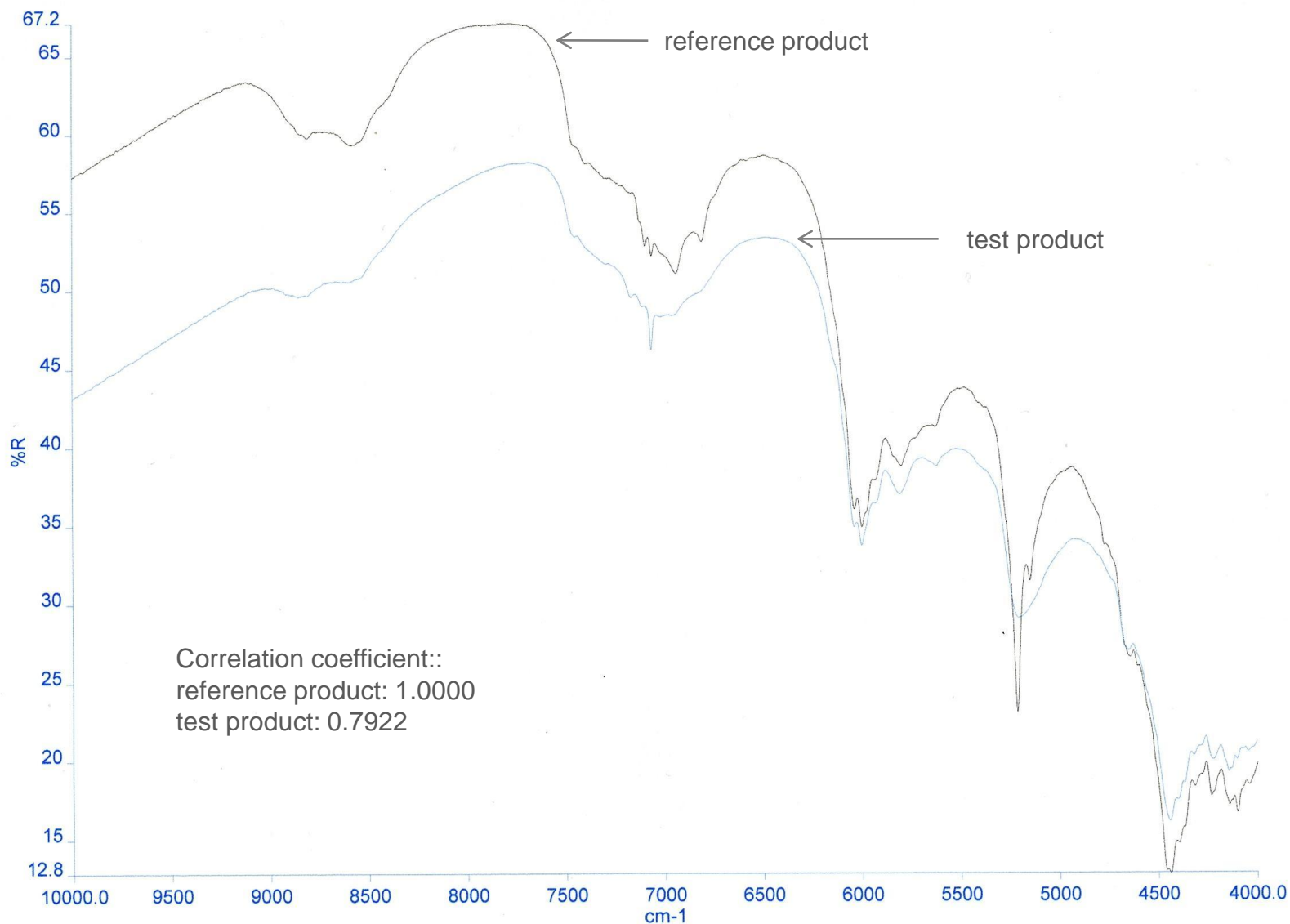
reference product



# LARGE DIFFERENCES (HPLC)



## LARGE DIFFERENCES (NIR)





## NUMBER OF COUNTERFEIT SAMPLES OF PLANT PROTECTION PRODUCTS TESTED BY IPP-NRI, SOSNICOWICE BRANCH

<b>Year</b>	<b>Number of samples – intervention controls</b>	<b>Number of samples found to be counterfeit</b>
2008	69	31
2009	45	32
2010	78	12
<b>TOTAL</b>	<b>192</b>	<b>75</b>



## DIFFICULTIES FOR THE CONTROL LAB

- **Lack of documentation (full composition of the ppp, results of 5-batch analysis, analytical methods for a.s. and impurities)**
- **Lack of a reference product of adequate quality**

**A reference product must come directly from the manufacturer and must be accompanied by a certificate of analysis**

- **Unknown allowable differences between the production batches at the original manufacturer**
- **Overuse of technical resources (apparatus efficiency, time)**
- **Constantly changing topics – variety of problems**



## CONCLUSIONS – POSTULATES – RECOMMENDATIONS

- **It is necessary to provide a more accurate definition of identity of ppps in the law**
- **Introduce an obligation to provide a sample of the ppp, intended for parallel trade**
- **Establish rules regarding packaging and labels of parallel traded products**
- **Obligation to submit documentation to the control lab (composition, results of 5-batch analysis) – signing confidentiality agreements.**



## CONCLUSIONS – POSTULATES – RECOMMENDATIONS cont'd

- **Providing a reliable reference product**
- **Stricter national post-registration control system, directed at uncovering counterfeiting and other impropriates**
- **Creation by the EC of an international team of experts to fight counterfeiting**
- **Better exchange of information between institutions and member states**
- **Creation of an internet webpage devoted to the issue of counterfeit ppps.**

