Parallel Trade:
A Trader's Perspective

Informa Conference

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Basic Purpose of 1107/2009

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

(9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.

history of 1107/2009 (1/2)

- Initially traders saw the advantage of complete harmonisaton
- In the objective of a larger harmonisation wished by member States and stakeholders, the Commission notably integrated an article 49bis on parallel trade into its second project Regulation of March 11th, 2008.
- The common position adopted by the Council on August 20th, 2008, radically modified this article by an article 52 which:
  - Conflicts with the most recent and constant jurisprudence of the ECJ and restricts considerably the scope of application of article 34 TFEU to plant protection products.
  - Misses the target of total harmonisation.

[article 34 TFEU (ex article 28): Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member states.]

history of 1107/2009 (2/2)

- Adopted by EU Parliament in second reading on January 14th 2009
- Published in Official Journal on November 20th 2009
- Entry into force date: December 14th 2009
  - At this point, member States could have implemented changes in accordance with the new regulation

Have they ?

- Application: June 14th 2011
  - Member States competent authorities MUST comply with all provisions included in the new regulation

Will they ?

p. 2: timelines

45 days for decision on permit plus 10 days response time from MS

- **improvement** ☑

- Shortens processing time of the current practice
  - To that extent the applicant benefits from increased certainty,
  - and this puts the applicant more at ease in its relation with the national competent authority.
- Will it be fully complied with by all parties, even if improvements to that effect have sometimes been clearly visible in advance of the 14th June 2011 deadline ?
- However, why did the Council remove the obligation which was "*The Member State of introduction shall inform the applicant of this request*" (project of March 11th, 2008 - article 49bis - § 2 - last sentence),

p.2: timelines-example

Representative of current practices:

> "*In our legislation there is not a time limit (12 months) for handling an application. The delay in handling in many cases depends on how quickly we get information from another MS. After we have got the information, we will make the decision as soon as possible*".

> *"We have many applications for parallel import and 'normal' registration. The handling time of the 'normal' applications is quite long as well, so the handling time of parallel import applications is in line with that".*

[source: Overdue response from a national competent authority to an applicant on October 20th 2010.]

p.3: criteria for identity

➢ **more limitations**

“they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process”;

- Common origin
- Definition ‚*associated undertaking*‘ or ‚*under licence*‘
- Who is to know if ‚*associated undertaking*‘ or ‚*under licence*‘ are relevant attributes of a particular application ?
- Can the reference registration holder be trusted to give complete and accurate information when asked by the competent authority ? Is abuse of dominant position (e.g. Losec-case) an effective deterrent ?
- Transparency?

p.3: criteria for identity

➢ **more limitations**

> *„they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation“;*

- What does „*identical in specification*“ mean?
- All active substances soon to be on Annex I.
- Interpretation is the enemy of harmonisation!

p.3: criteria for identity

➢ **more limitations**

> *„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*“.

- These criteria of identity relating to packaging were always considered by the Court as being disproportionate and amounting to a measure having equivalent effect to a quantitative restriction within the meaning of article 34 TFUE.
- Neither the extensive jurisprudence on this matter in the area of human medicine nor judgments relating to plant protection products (C-100/96 – C-260 and 261/06 – C-201/06) allow for such a condition of identity of the packaging including when it is mitigated by the option “*or equivalent*” obviously not applicable in the case at hand because a 5 litres packaging will never be equivalent to a 10 litres packaging as for its “*dimension*” or its “*form*”.

p.3: criteria for identity

The common position adopted by Parliament and the Council does not retain that:

" *The applicant for a first parallel trade permit may demonstrate by means of all available and accessible information that the plant protection product intended to be introduced is identical in terms of paragraph 3, 4 and 5 to the reference product* (...) " (Commission project of March 11th, 2008 - article 49bis - § 7).

- Henceforth, the applicant is thus deprived of any possibility of appeal further to a decision of refusal.

p.4: application data

➢ **more limitations**

- original label: Definition? Every MS can decide in a different way.
- instruction for use: Definition?
- translation: additional burden
- product sample: additional burden

➢ All these potential requirements create additional costs and require additional time and effort. They are effectively limitations and can be regarded as redundant requirements that contradict p. 5!

p.4: Successive applications & own use

- The absence of those provisions demonstrates the will not to harmonise
- Current practices at member State level, 3 years after the binding decision in the case "*Bonnarel-Escalier*", further demonstrate member states` will not harmonise fully.

p.5: PI =reference product

„ A plant protection product for which a parallel trade permit has been issued shall be placed on the market and used only in accordance with the provisions of the authorisation of the reference product...”

- **improvement** ☑

but:

- Why are the extensive data and samples from the country of origin required? According to this p. 5 only the authorisation of the reference product is relevant for the PI-product in the import market.

p. 6: expiry date of permit

- **improvement** ☑

- Permit renewal? (incomplete harmonisation)
- Problems in cascade when registration numbers of reference products ore potential source products are frequently changed (notably in the United Kingdom)
- Can an application be filed after the reference PPP was withdrawn for commercial purposes but before the initial expiry date?

fees for a PI-permit

- UK: 1020 €
- DE: 300 € (range 160-1840 €)
- FR: 600 €
- IT: 680 €
- HU: 1100 €
- SI: 18 €

(all cited fees are approximate values)

further costs related to placing a PI-product in the market

- trademark protection
- sample for registration holder
- label translation
- label creation
- providing the original label from country of origin
- ...

➢ further costs can be up to a few thousand € (per provenance)

theoretical costs of free trade

- example 1: one MS (e.g. UK)
  - PI-permit for one origin appr. 1000 €
  - PI permit for 26 provenances (=MS of origin) : **26.000 €**

- example 2: whole EU

  average price of a PI permit: 500 €

  two multinational trademarks per MS

  13 MS with lower prices than target-MS
  - one MS: 500 € x 2 (trademarks) x 13 (origin MS)=**13.000 €**
  - all MS: 13.000 € x 13 (origin MS) = **169.000 €**

example: Austria

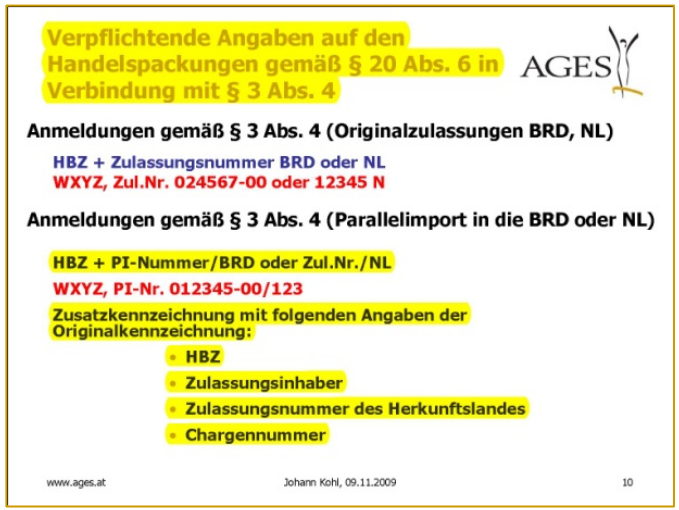
Presentation held by AGES, Vienna, 09.11.2009

Mandatory data on the packaging …

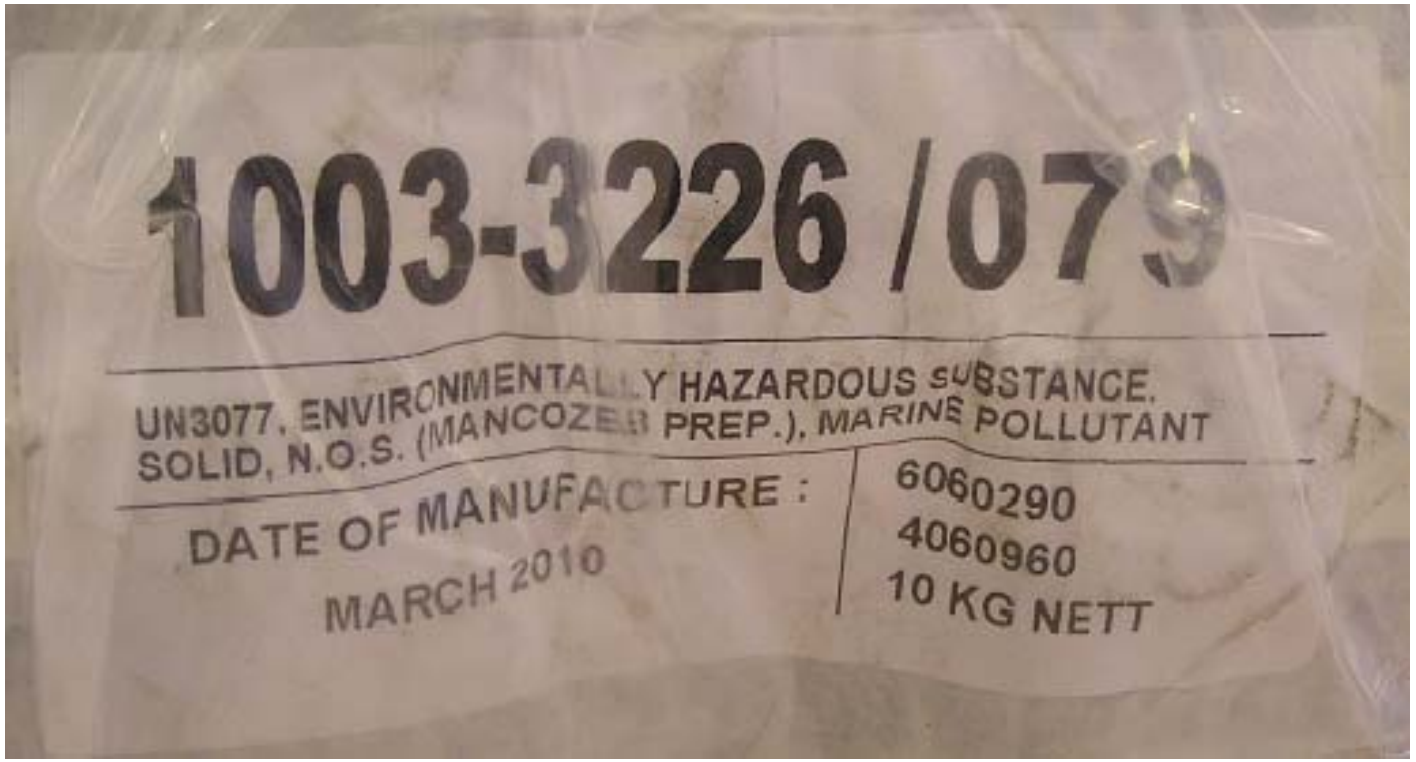
trade name + parallel import no. (DE) or registration no. (NL)

Additional labeling with following data from the original labeling:

- **-trade name**
- **-approval holder**
- **-registration number in country of origin**
- **-batch number**

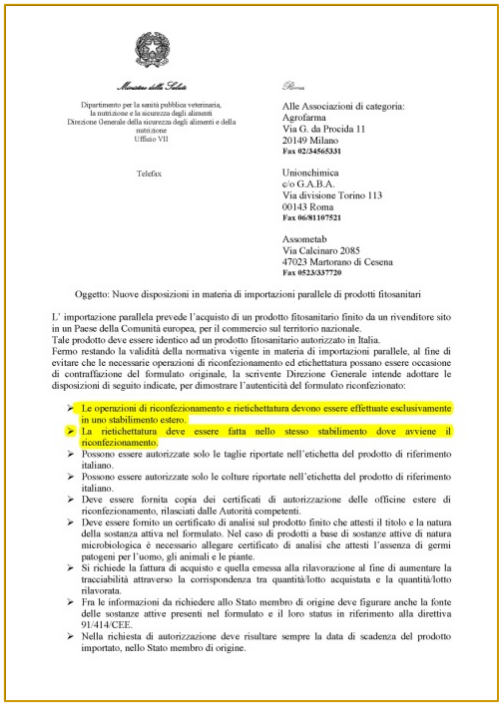


batch number!?!



example: Italy

New rules on parallel imports of plant protection products
(notification of the Italian Ministry of Health, spring 2010)



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Oggetto: Nuove disposizioni in materia di importazioni parallele di prodotti fitosanitari

L' importazione parallela prevede l'acquisto di un prodotto fitosanitario finito da un rivenditore sito in un Paese della Comunità europea, per il commercio sul territorio nazionale.
Tale prodotto deve essere identico ad un prodotto fitosanitario autorizzato in Italia.
Fermo restando la validità della normativa vigente in materia di importazioni parallele, al fine di evitare che le necessarie operazioni di riconfezionamento ed etichettatura possano essere occasione di contraffazione del formulato originale, la scrivente Direzione Generale intende adottare le disposizioni di seguito indicate, per dimostrare l'autenticità del formulato riconfezionato:

- Le operazioni di riconfezionamento e rietichettatura devono essere effettuate esclusivamente in uno stabilimento estero.
- La rietichettatura deve essere fatta nello stesso stabilimento dove avviene il riconfezionamento.
- Possono essere autorizzate solo le taglie riportate nell'etichetta del prodotto di riferimento italiano.
- Possono essere autorizzate solo le colture riportate nell'etichetta del prodotto di riferimento italiano.
- Deve essere fornita copia dei certificati di autorizzazione delle officine estere di riconfezionamento, rilasciati dalle Autorità competenti.
- Deve essere fornito un certificato di analisi sul prodotto finito che attesti il titolo e la natura della sostanza attiva nel formulato. Nel caso di prodotti a base di sostanze attive di natura microbiologica è necessario allegare certificato di analisi che attesti l'assenza di germi patogeni per l'uomo, gli animali e le piante.
- Si richiede la fattura di acquisto e quella emessa alla rilavorazione al fine di aumentare la tracciabilità attraverso la corrispondenza tra quantità/lotto acquistata e la quantità/lotto rilavorata.
- Fra le informazioni da richiedere allo Stato membro di origine deve figurare anche la fonte delle sostanze attive presenti nel formulato e il loro status in riferimento alla direttiva 91/414/CEE.
- Nella richiesta di autorizzazione deve risultare sempre la data di scadenza del prodotto importato, nello Stato membro di origine.

- *The repackaging and relabeling operations must be performed in a foreign establishment.*
- *The relabeling must be done in the same establishment where there is the repackaging.*

example: pack size differences

thiophanate methyl 700 WDG: UK vs DE

CONDITIONS OF PLACING ON THE MARKET (pursuant to regulation 5(6) of PPPR)

Without prejudice to the requirements set out in regulation 18 of PPPR, this product must be placed on the market in a cardboard carton holding 1 kg of product.

Wirkstoff:
704 g Thiophanat-methyl /kg
Wasserdispergierbares Granulat (WG)
Gefahrensymbol: Xn, N
Bienen: nicht bienengefährlich (B4)

Versandgebinde:
1 x 5,5 kg Eimer **=5,5 kg bucket**
1 x 16,5 kg Sack **=16,5 kg bag**

Increase of competition by PT?

before 1107/2009:

- A certain degree of competition was present but even the EU-officials were aware of the fact that there were severe obstacles on the free movement of goods, competition and the single market

after 1107/2009:

- Due to the lack of harmonisation the new regulation will most likely not have any significant impact on the competition (only exceptions are the timelines that will give more chance to short term trading opportunities during the running season and the partially harmonised expiry dates after withdrawal of the registration for commercial purposes)

Increase of competition by PT?

- number of registered PI-products in selected EU-countries

MS	no. of issued PI-permits	MS	no. of issued PI-permits
FR	>300	IT	28
DE	appr. 3400	GR	102
UK	667	HU	93
CZ	appr. 500	PL	89

Example: PT in Germany

- total PPP market turnover in DE in 2009: **1.262 mil. €**
- PI-ratio between 8-10 % (as per IVA)
- turnover of the PI-segment: **100-125 mil €**

Lower input prices for agriculture?

before 1107/2009:

- general trend are lower input prices especially for commodities and specialities that face generic competiton in certain MS
- PT is especially in combination with generic competition an instrument to increase competition and to decrease the input prices.
- in selected markets a price decrease for certain agrochemicals could be observed and directly related to PT

after 1107/2009:

- no positive changes to be expected

AUDACE position on a specific regulation

- Proposition of a specific regulation for all regulated products, pharma-, veterinary-, plant protection products and biocides.
  (To include a very extensive case law relating to IP)

- In the absence of a single community marketing authorization, parallel trade contributes to harmonising the single market in accordance with the objectives laid down in the regulation

- In this situation where agricultural productions MUST move freely across the EU single market, consumers, and not just parallel traders, will not understand why a product authorised in a member State could not be authorised in another one because it puts at great risk public health and the environment.

conclusions

- 1107/2009 includes an abuse of the principle of subsidiarity

  regulation 1107/2009 does not regulate PT sufficiently-too many crucial details are not yet regulated or are left to the MS
- missed opportunity for harmonisation
- conflicts with constant jurisprudence of ECJ
- conflicts with its own provisions for mutual recognition
- constitutes unacceptable limitations of the scope of article 34 TFEU
- most conspicuously fails to meet the aim and objectives of Regulation 1107/2009 enumerated in its ninth preamble