Special tool: acceptable operator exposure level (AOEL)

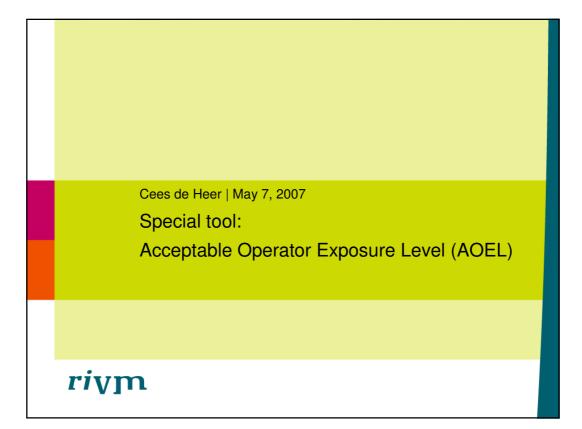
Cees de Heer, Betty C. Hakkert, Peter M.J. Bos

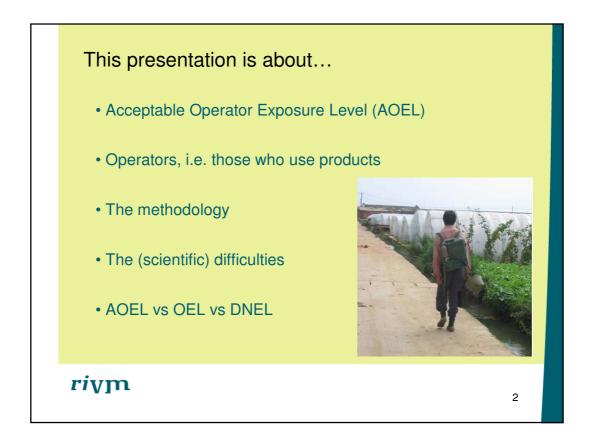
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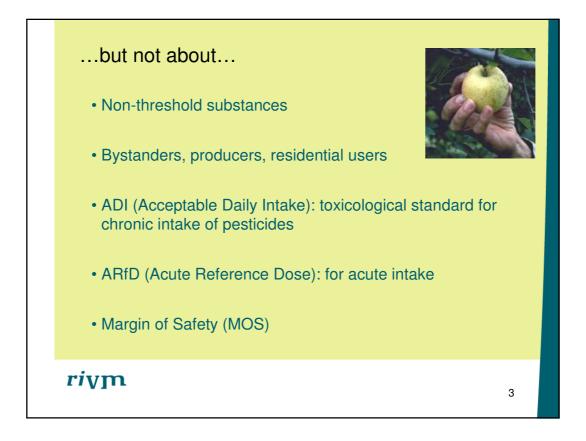
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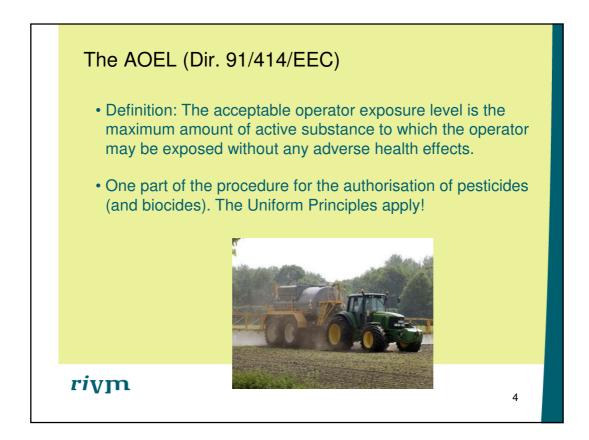
The Acceptable Operator Exposure Level (AOEL) is applied in the assessment and review of pesticides and biocides within Europe. The AOEL is a healthbased limit-value and is established on the basis of the full toxicological package required for pesticides respectively biocides. The default AOEL represents the internal (absorbed) dose available for systemic distribution from any route of absorption and is expressed as an internal level (in milligrams/kilogram body weight/day). The concept of the AOEL as such has relevant legislative consequences and serves primarily as an important tool for operator risk assessment. Exposure estimates exceeding the AOEL do e.g. not allow an inclusion of active substances in Annex I of Directive 91/414/EC.

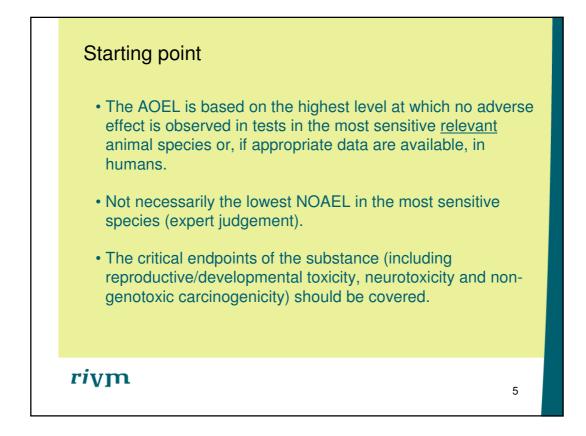
Although a draft guidance was published in 2005, there is no formal harmonized method for the derivation of AOEL in Europe yet. A number of aspects in the AOEL approach are still subject to discussion at the EU-level. Major points of discussion are the number of AOELs to be set in a default procedure (one or three (acute, short-term, and long-term AOELs), whether external route specific AOELs should be set (such as an AOELinhalatory or an AOELlocal dermal), and which assessment factors to be used for the working population. Similar discussions take place at the moment in REACH Implementation Project 3.2 where the Derived No Effect Level (DNEL) approach is being developed for risk assessment under REACH. The presentation will highlight the similarties and differences between the AOEL, DNEL and OEL approach as the three 'types' of limit values set for workers within Europe.

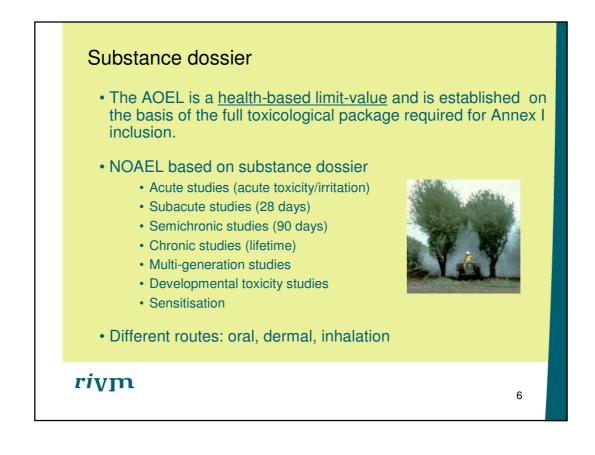


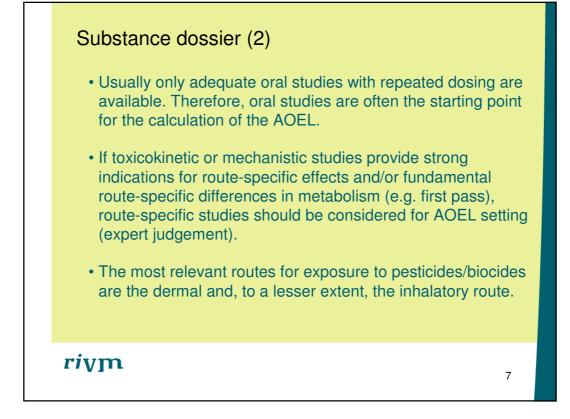


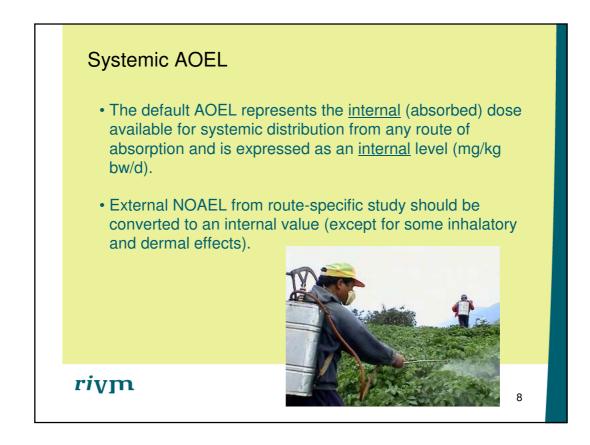


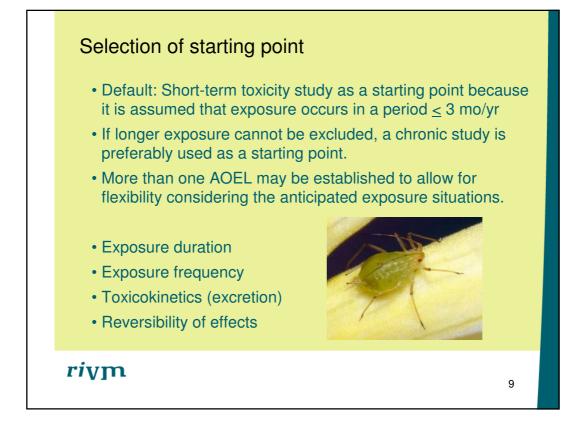


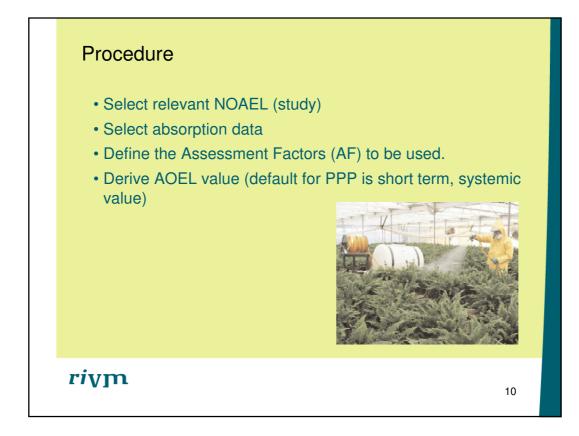


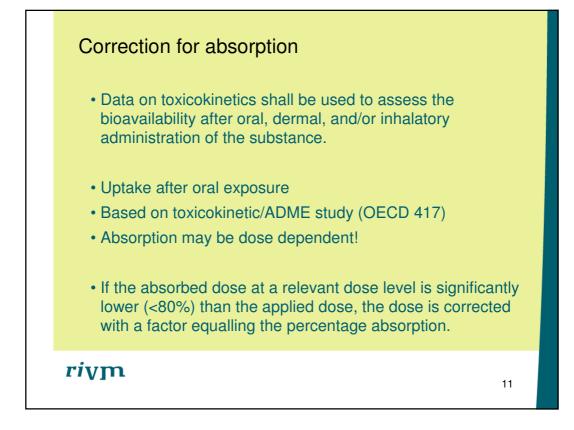


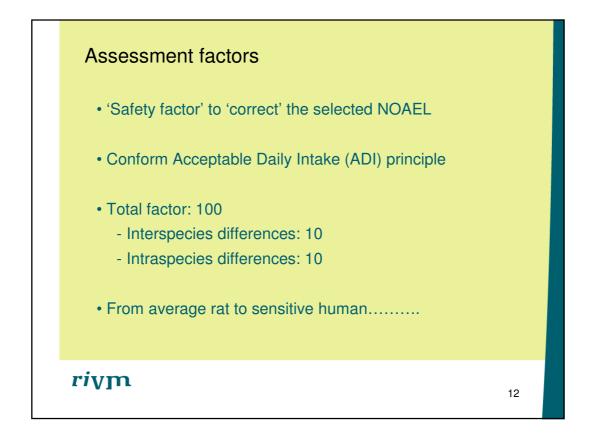


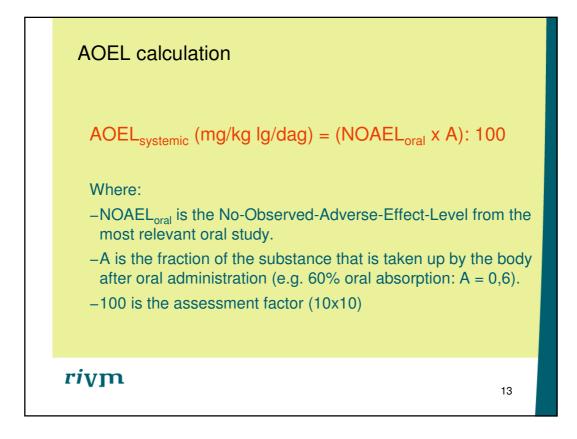


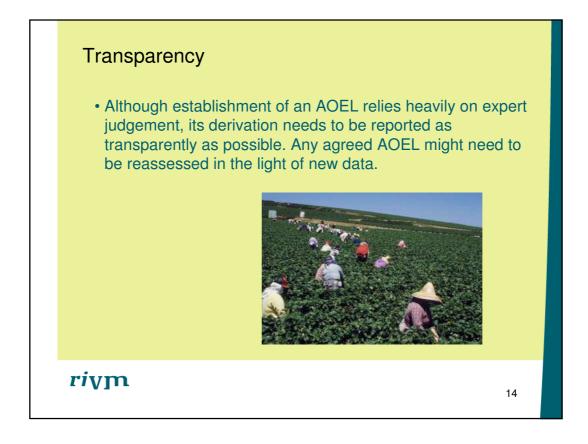


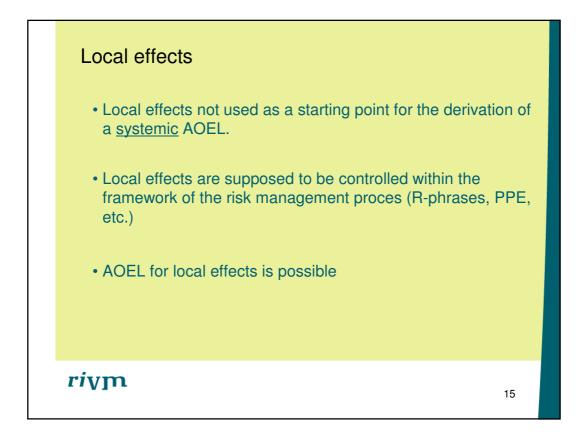


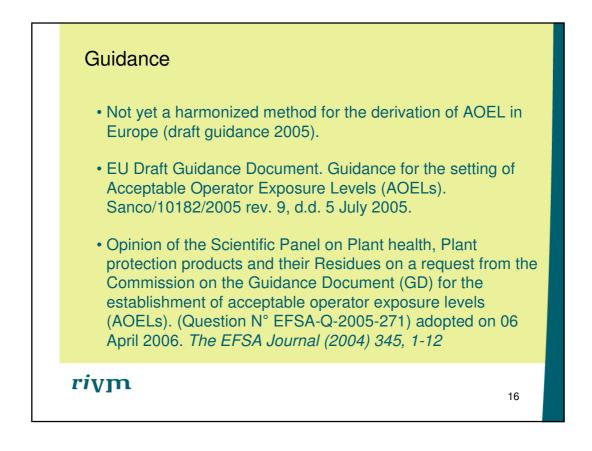


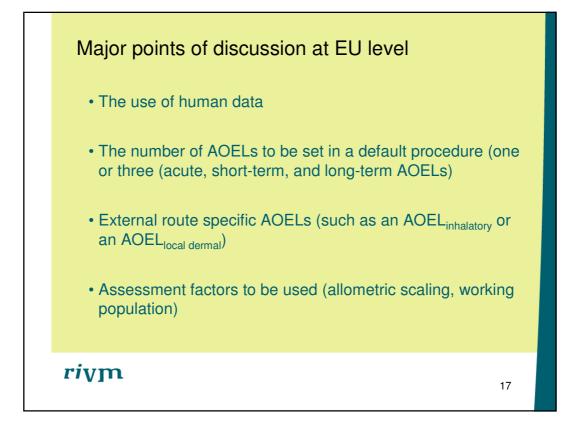












	AOEL	OEL	DNEL
Basis	Health based	Health based	Health based
Database	Full data package	Available public literature	Tonnage dependent
Population	Workers	Workers	Workers, genera population
Route	Inhalation, oral, dermal	Inhalation	Inhalation, oral, dermal

	AOEL	OEL	DNEL
Default exposure period	Short term (<u>≤</u> 3 mo/yr)	Chronic	Chronic?
Internal vs external	Internal (External)	External	External
AF	10x10	Case-by-case	Default value
Local effects	Included?	Important endpoint	Included

