



# Better Training for Safer Food *Initiative*

**Kyriaki Machera, MSc, PhD, ERT**

*Regulatory Toxicologist*

*Head, Laboratory of Toxicological Control of  
Pesticides*

*Director, Benaki Phytopathological Institute  
8 St.Delta str., 145 61 Kifissia, Attica, Greece  
[k.machera@bpi.gr](mailto:k.machera@bpi.gr), [machera@otenet.gr](mailto:machera@otenet.gr)*

**Towards a Sustainable  
Use of Plant Protection  
Products: "Safe Use -  
Identification of  
hazards and risks to  
humans"**

# Presentation outline

## **A. Hazards and Risks:**

- a.1 Definitions
- a.2 Hazard Identification & Characterisation

## **B. Risk assessment:**

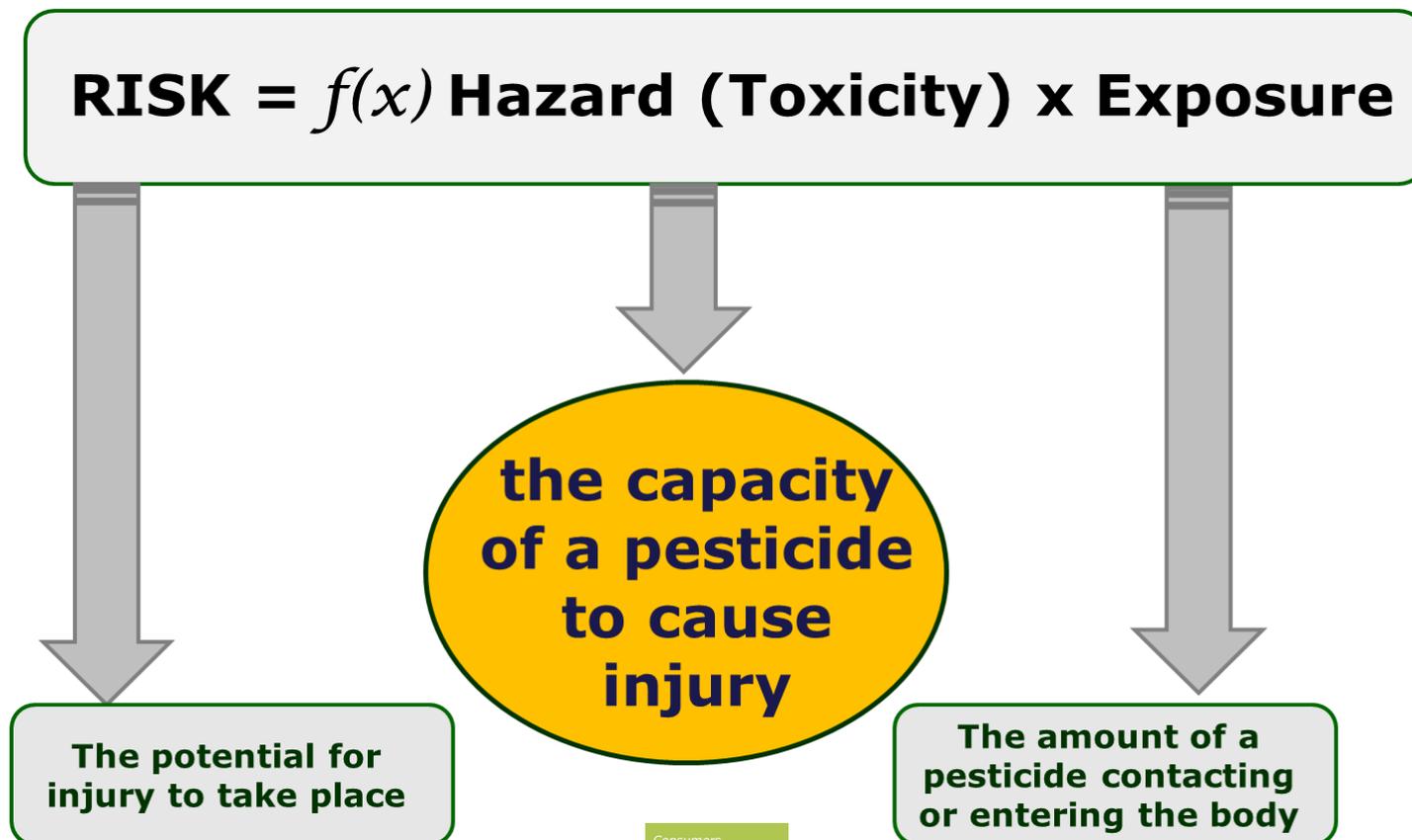
- b.1 R.A.: Consumer & Operator
- b.2 Routes of exposure
- b.3 Operator exposure estimation tools

## **C. Pesticide Label and Safety Data Sheet**

- c.1 Interpretation of label and SDS in relation to classification
- c.2 Interpretation of label in relation to safety precautions & PPE recommendations
- c.3 Interpretation of label in relation to first aid measures

# A. Hazards and Risks:

## a.1 Definitions



## a.2 Hazard Identification & Characterization

**«The dose makes the poison»**

*.... applies in most of the cases for pesticides also.*



**Paracelsus, 1493-1541,  
Swiss alchemist & doctor**



## a.2 Hazard Identification & characterization

### Studies of pesticide effects on mammals

PURPOSE

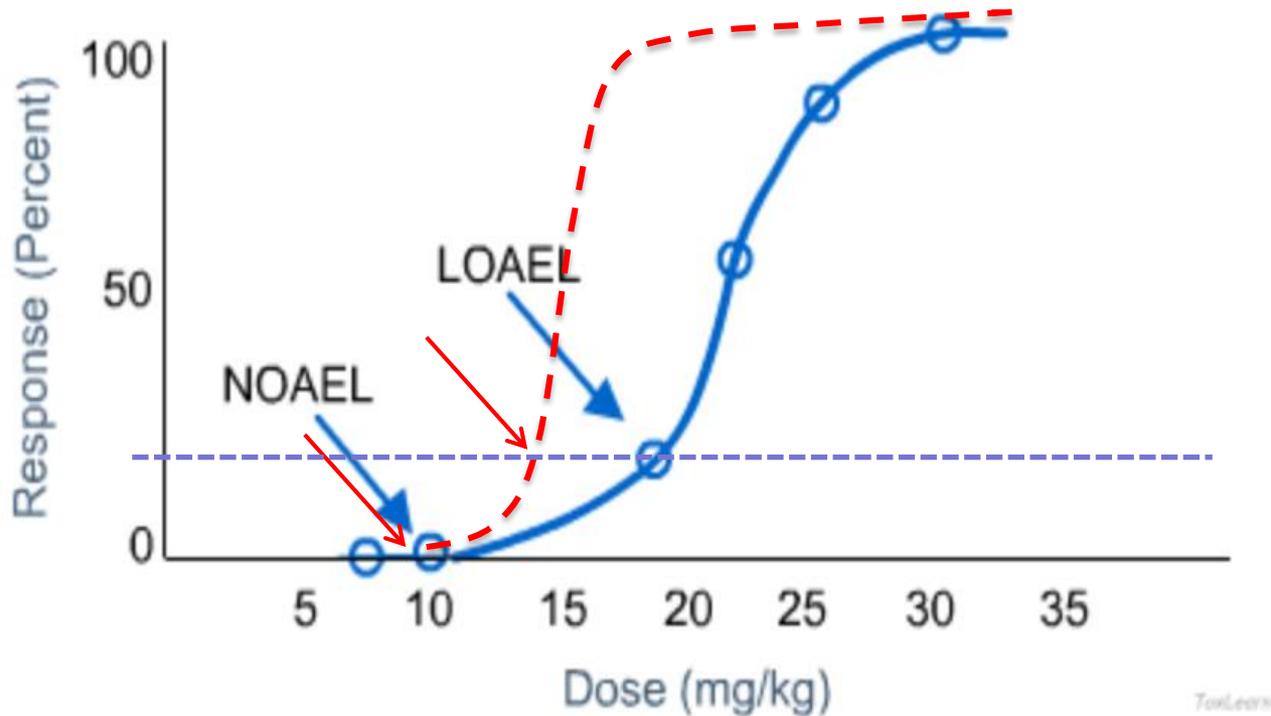


*Prediction of effects in humans*



European  
Commission

# The dose – response curve



**NOAEL: Non Adverse Effect Level**  
**LOAEL: Lowest Adverse Effect Level**



European  
Commission

# Types of studies

## Plant Protection Product

- Acute Oral, Dermal, Inhalation
- Skin & Eye Irritation
- Skin Sensitization
- Supplementary studies  
(e.g. combinations of PPPs)
- Exposure data
  - Operator
  - Bystander & Resident
  - Worker
- Dermal absorption
- Toxicological data relating to  
formulants

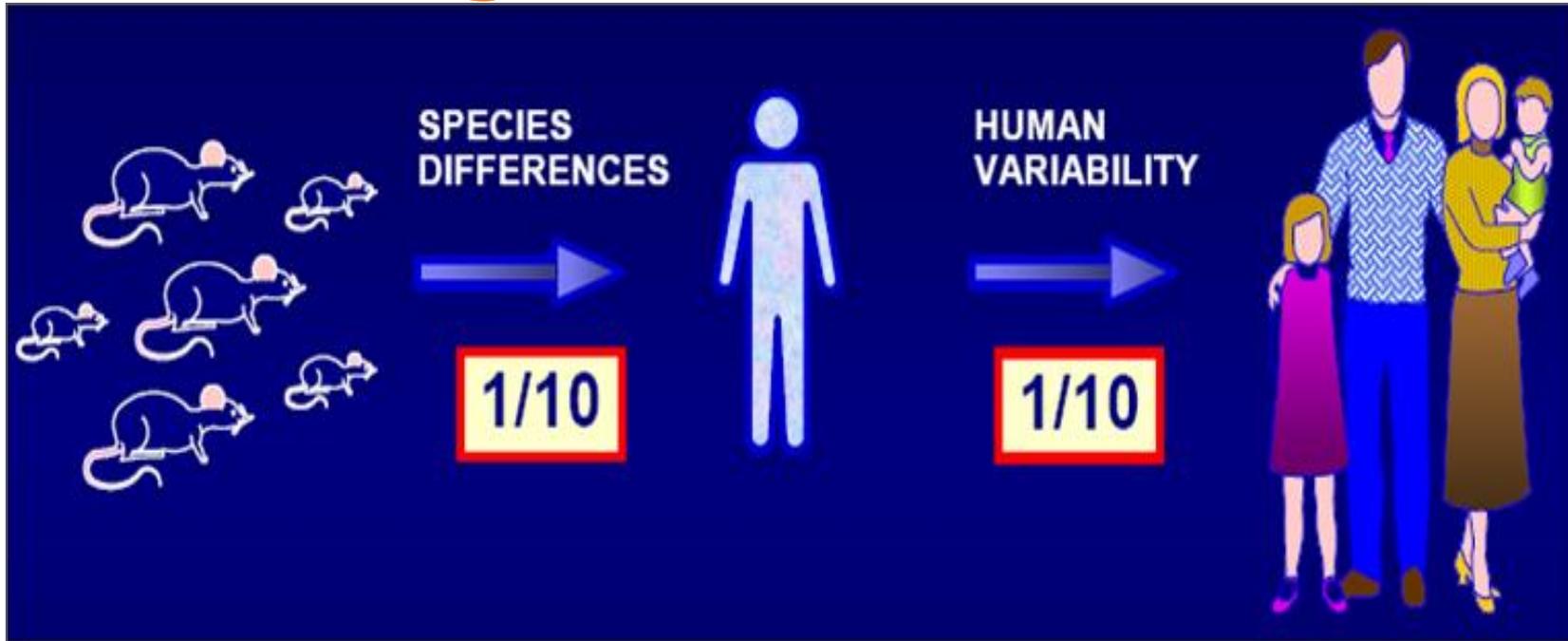
## Active & other substances

- Absorption, Distribution, Metabolism,  
Excretion
- Acute Oral, Dermal, Inhalation
- Skin & Eye Irritation
- Skin Sensitization & Phototoxicity
- Short term toxicity
- Genotoxicity
- Long term toxicity & Carcinogenicity
- Reproductive toxicity  
[Multi-generation – Developmental]
- Neurotoxicity
- Other toxicological studies [Toxicity  
studies of metabolites or supplementary  
studies on the active substance, e.g.  
mechanistic studies]
- Medical data



European  
Commission

# Setting of threshold values



**NOAEL**

÷

**Assessment  
Factors (100)**

=

**Toxicological  
thresholds:  
[ADI, AOEL,  
ARfD, AAOEL]**

## Toxicological Thresholds

**ADI: Acceptable Daily Intake** – Threshold for lifespan dietary exposure.

**ARfD: Acute Reference Dose** – Threshold set for compounds that pose risk for effects following single or short term dietary exposure, e.g. acute or subacute effects.

**AOEL\*:** **Acceptable Operator Exposure Levels** – Threshold for repeated non dietary exposure.

**AAOEL\*\*:** **Acute Acceptable Operator Exposure Levels** – Threshold for compounds that pose risk for effects following single or short term non dietary exposure (development of GD for AAOEL setting, priority for EFSA and the Commission).

\* In EFSA calculator renamed to: Reference value non acutely toxic active substance (RVNAS)

\*\* In EFSA calculator renamed to: Reference value acutely toxic active substance (RVAAS)



European Commission

# Plant Protection Product database

[http://ec.europa.eu/sanco\\_pesticides/public/?event=homepage&language=EN](http://ec.europa.eu/sanco_pesticides/public/?event=homepage&language=EN)

European Commission

EU Pesticides database

European Commission > Food Safety > Plants > Pesticides > EU Pesticides Database

HEALTH FOOD ANIMALS **PLANTS**

PESTICIDES

EU rules

**EU Pesticides database**

Search active substances

Search products

Search pesticide residues

Download MRLs data

Sustainable use of pesticides

Approval of active substances

## EU Pesticides database

**ACTIVE SUBSTANCES**  
Regulation (EC) No 1107/2009

**PESTICIDES EU-MRLs**  
Regulation (EC) No 396/2005

### Latest active substance updates

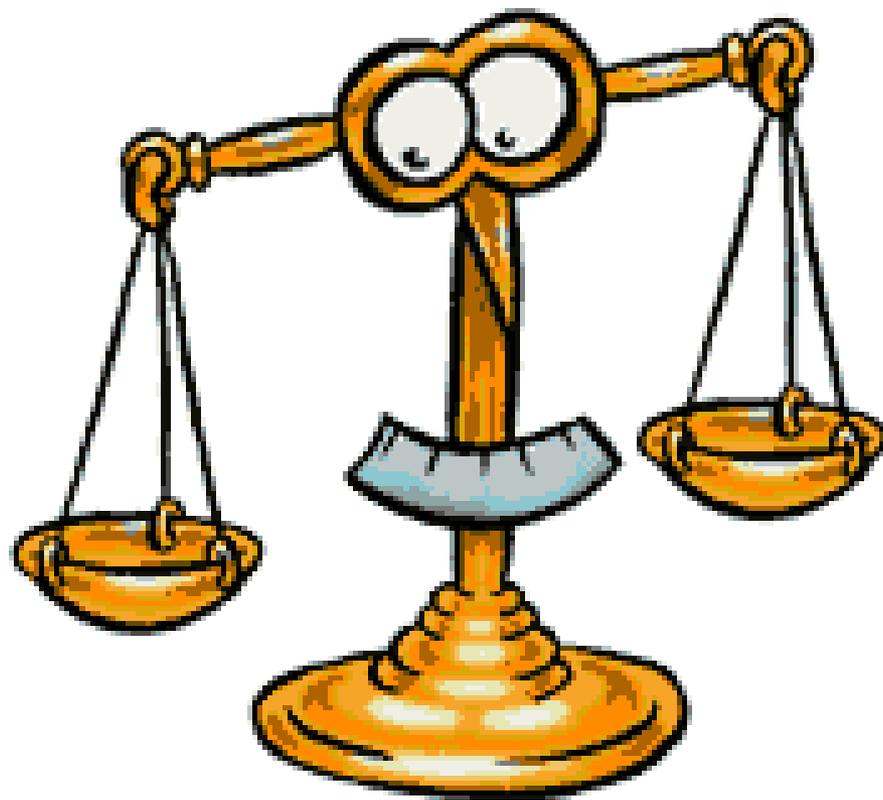
- Update of national authorisations (except FR and CZ) **02/02/2015**
- Correction of several approval dates **16/12/2014**
- Upload of Review Reports taken note of by the PAFF in October 2014 (Section A) **08/12/2014**
- Upload of Review Reports taken note of by the PAFF in July 2014 (Section B) **27/10/2014**
- Correction of the AOEL for oxamyl **22/10/2014**

### Latest MRL updates

- Insertion of MRLs for Commission Regulation (EU) No 1127/2014 of 20 October 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amitrole, dinocap, fipronil, flufenacet, pendimethalin, propyzamide, and pyridate in or on certain products **12/12/2014**
- Insertion of MRLs for Commission Regulation (EU) No 1096/2014 of 15 October 2014 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the **20/11/2014**

## B. Risk Assessment

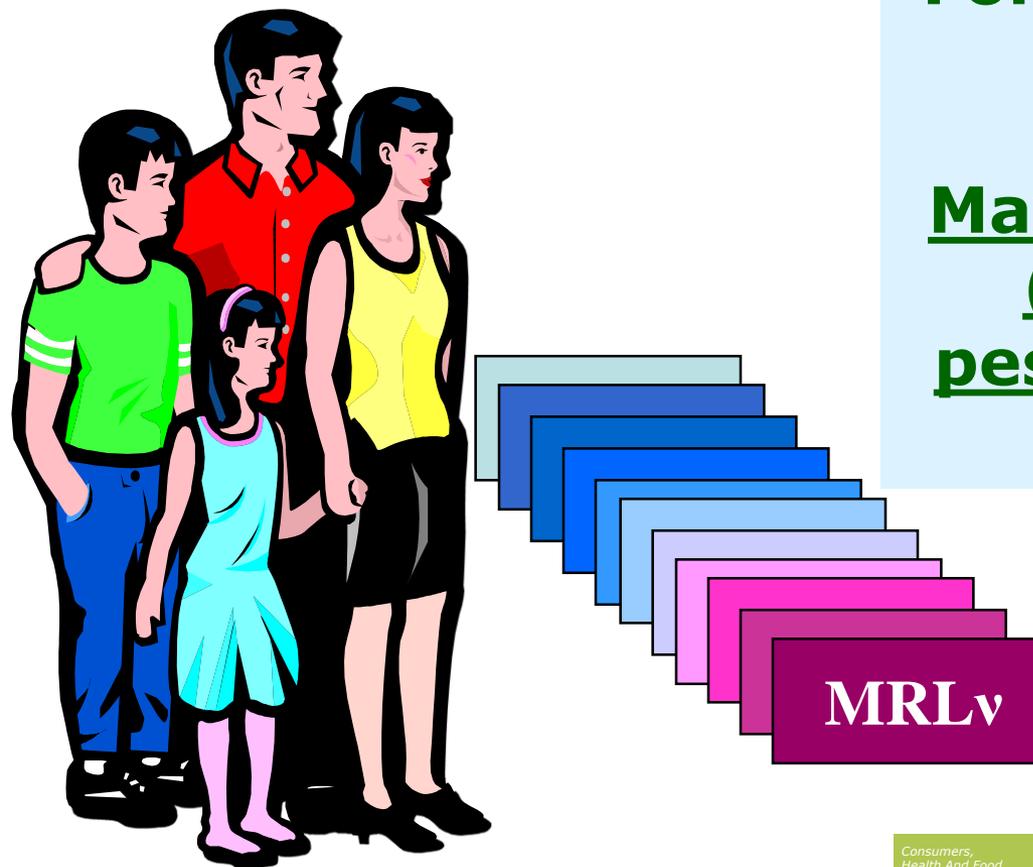
**RISK**  
**Acceptable or**  
**Not acceptable**  
**?**



## b.1 Consumer Risk Assessment

For consumer protection:  
Compare the  
ADI to the sum of  
Maximum Residue Limits  
(MRLs) of a specific  
pesticide in the different  
foods consumed

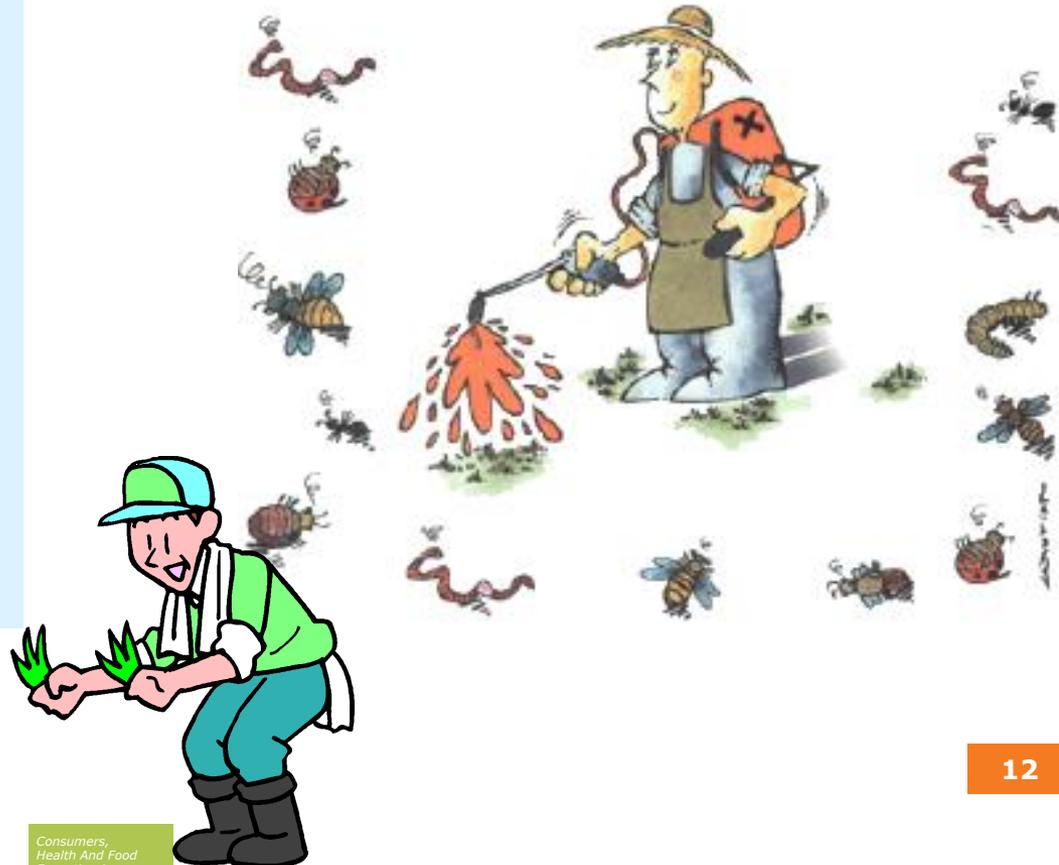
$$\sum MRL \leq ADI$$



## b.1 Operator, Worker, Bystander, Resident Risk Assessment

For the protection  
of the operator,  
worker, bystander  
and resident:  
Compare the  
AOEL to the  
Exposure

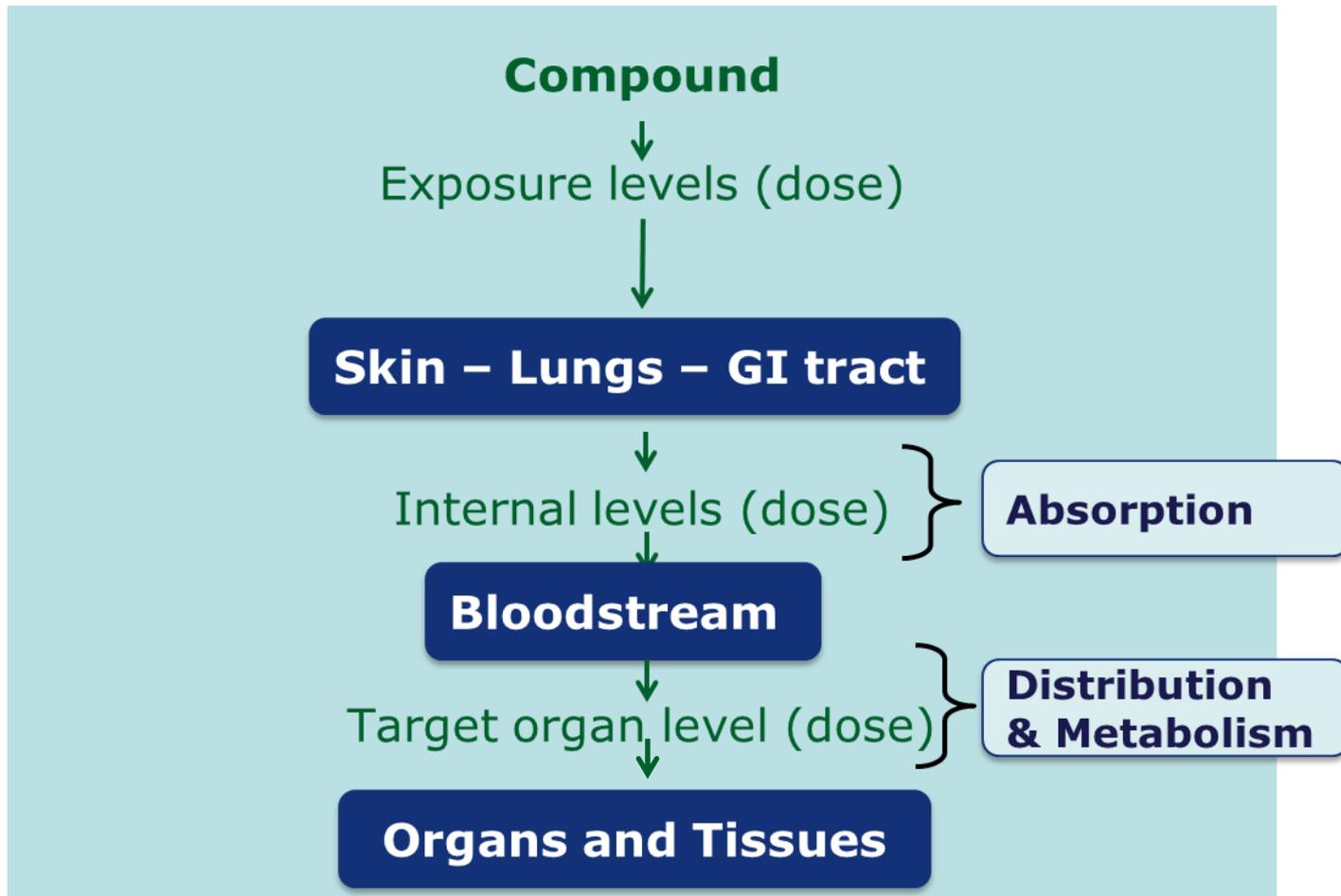
$$E < AOEL$$



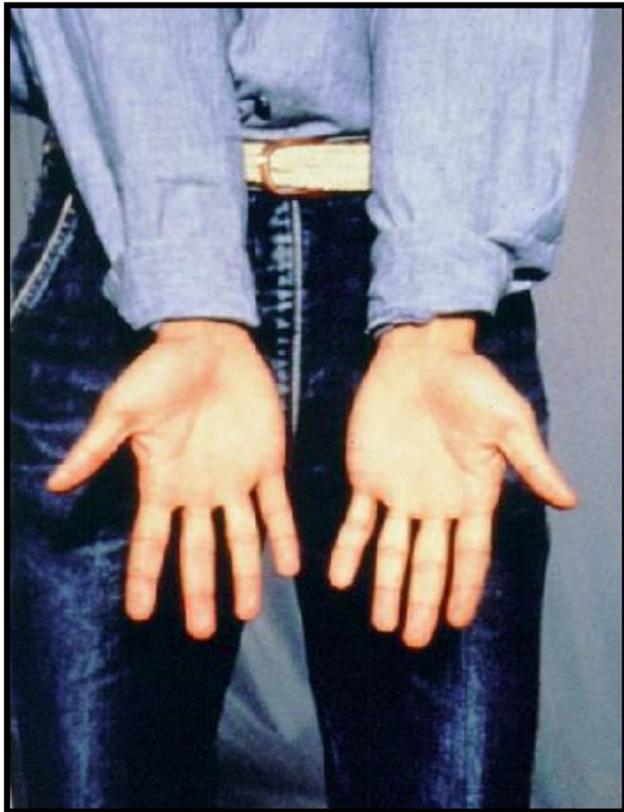
## **b.2 Routes of exposure to pesticides and their entrance in the organism**



# Exposure v.s. internal dose



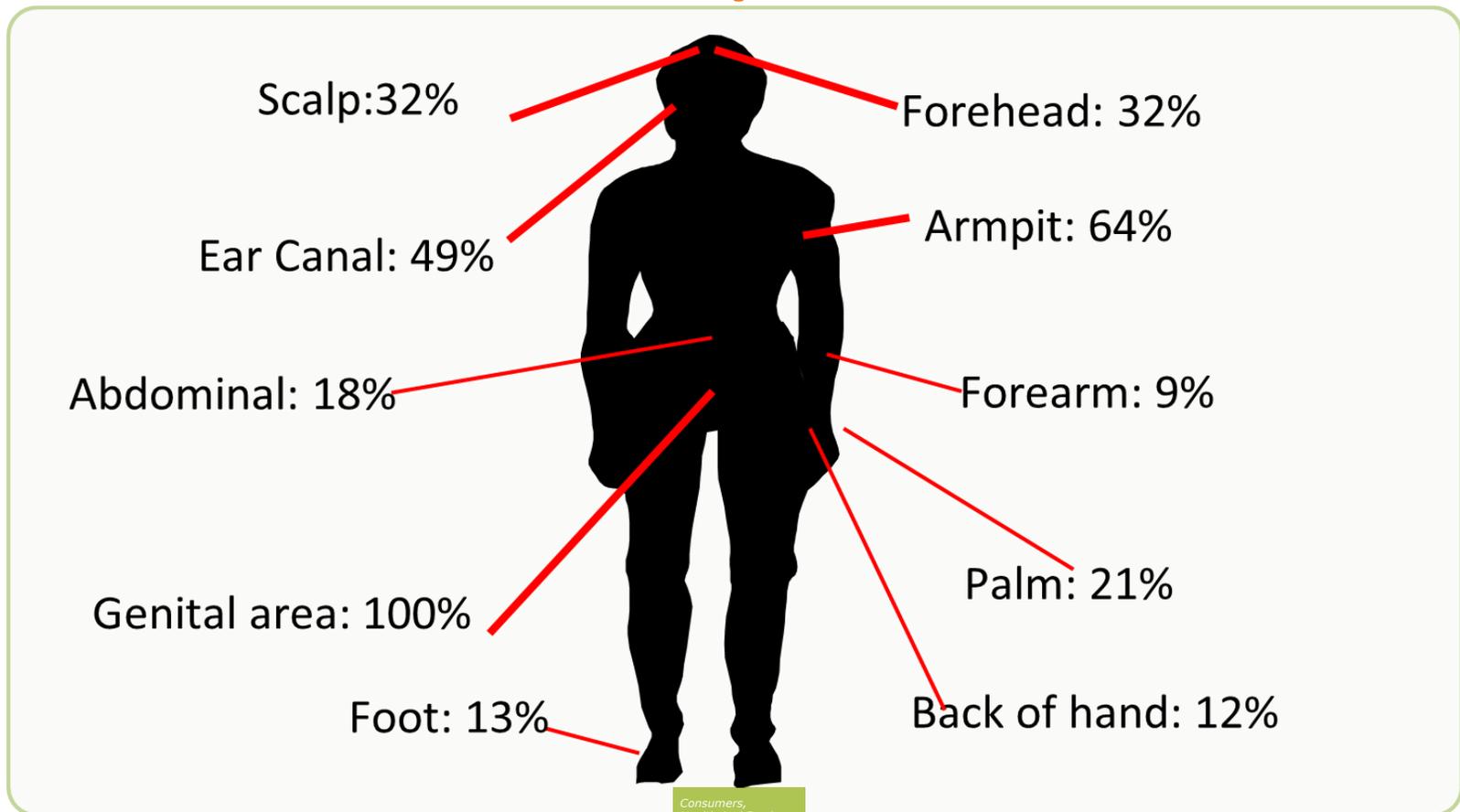
## SKIN: Dermal route of exposure\*



97% of all body exposure during application is by skin contact.



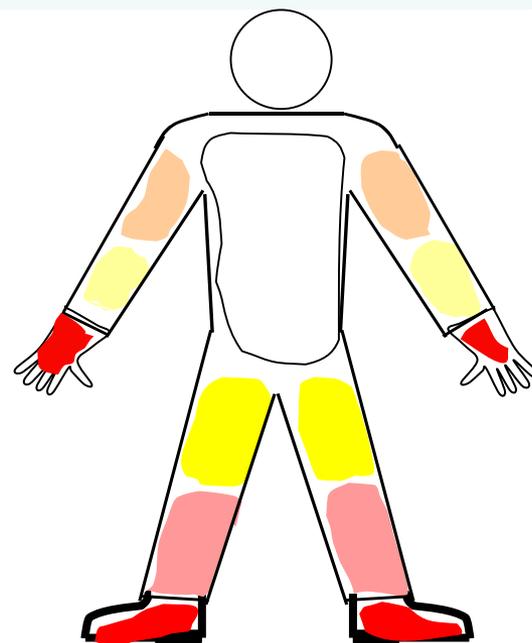
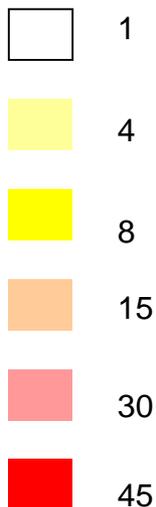
## Different parts of the body vary in their ability to absorb pesticides\*



# Distribution of spray solution in the different body parts

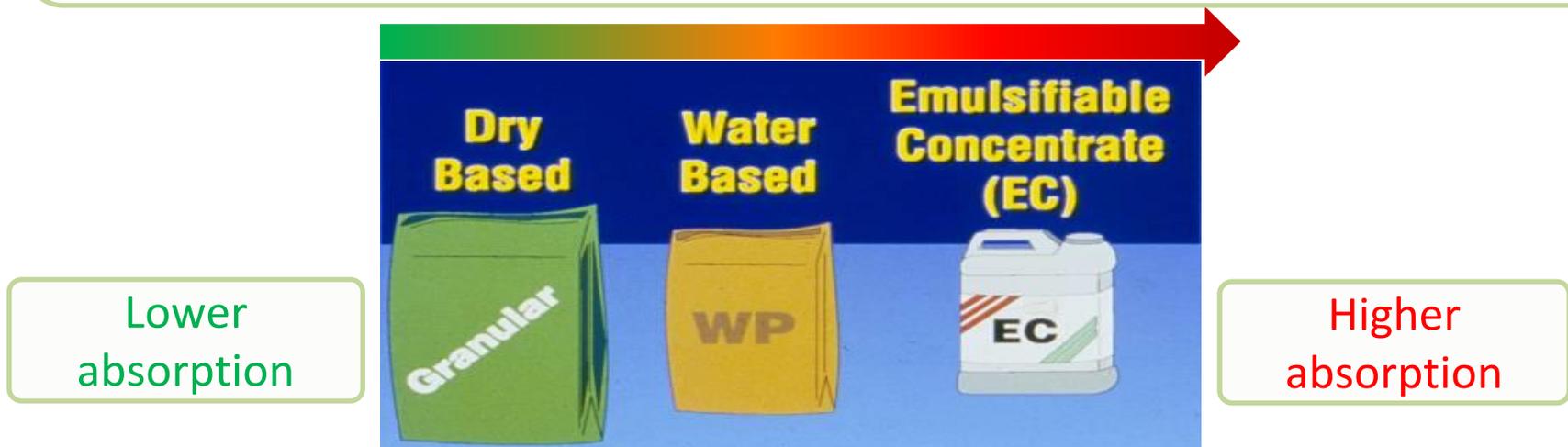
## Measurements after herbicide application

% total exposure



## Factors that influence the dermal absorption\*:

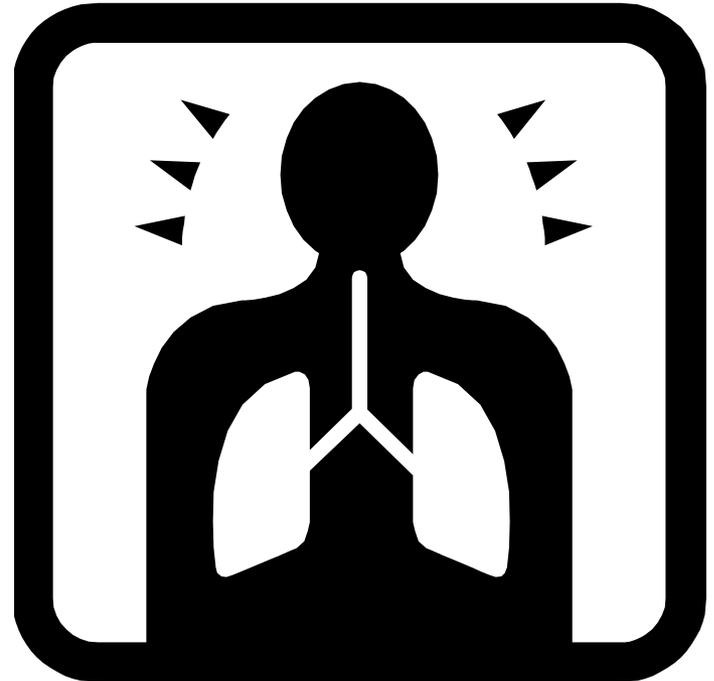
- Different anatomical sites...
- Warm and moist areas with increased blood vessels
- Skin condition such as cuts, abrasions and rashes
- Type of pesticide formulation



## LUNGS: Route of entry *via* inhalation\*

Exposure *via* Inhalation can occur:

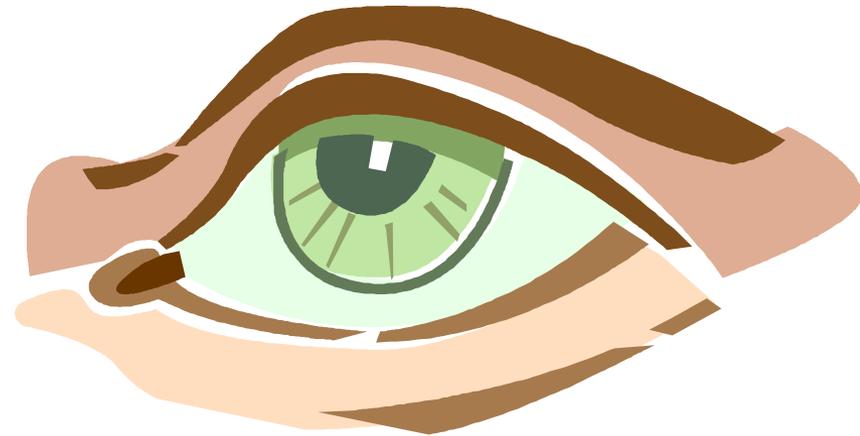
- When using wettable powders, dusts, gases, vapors and sprays
- While mixing and loading pesticides
- During application



## EYES\* :

### **Entry *via* mucous membranes and microcapillaries**

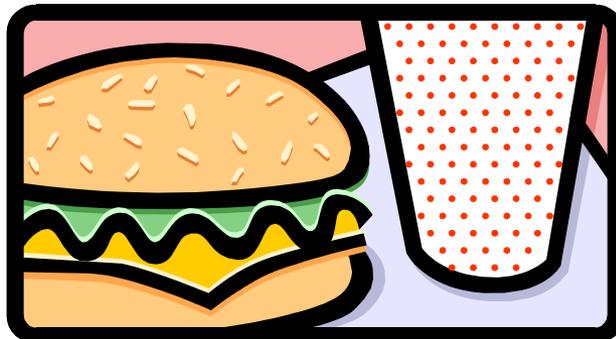
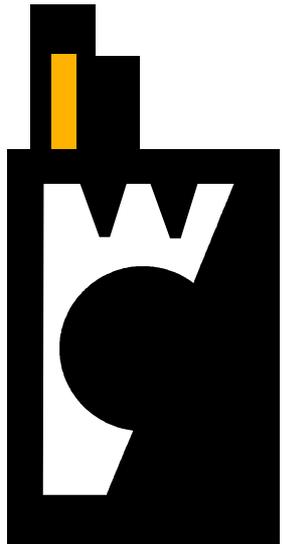
- Eyes are able to absorb surprisingly large amounts.
- Local effects can be produced, from irritation to irreversible injuries.



# MOUTH: oral route of exposure\*

**WASH YOUR HANDS!!** →

→ Before eating, drinking, smoking or going to the bathroom, at breaks and before using your mobile phone.



## Routes of exposure to pesticides and their entrance in the organism

1. SKIN: dermal exposure (COVERALL & GLOVES)
2. RESPIRATORY TRACT: exposure by inhalation (MASK)
3. MOUTH: exposure by swallowing (MASK, FACE SHIELD & BASIC PRECAUTIONS )
4. EYES: via mucosal membranes (PROTECTIVE GOGGLES & FACE SHIELD)

### REDUCTION OF THE AMOUNT THAT ENTERS INTO THE SYSTEMIC CIRCULATION:

Thorough washing of the whole body with water & soap after the pesticide application (reduction of exposure >60%).

# Presentation outline

## A. Hazards and Risks:

- a.1 Definitions
- a.2 Hazard Identification & Characterisation

## B. Risk assessment:

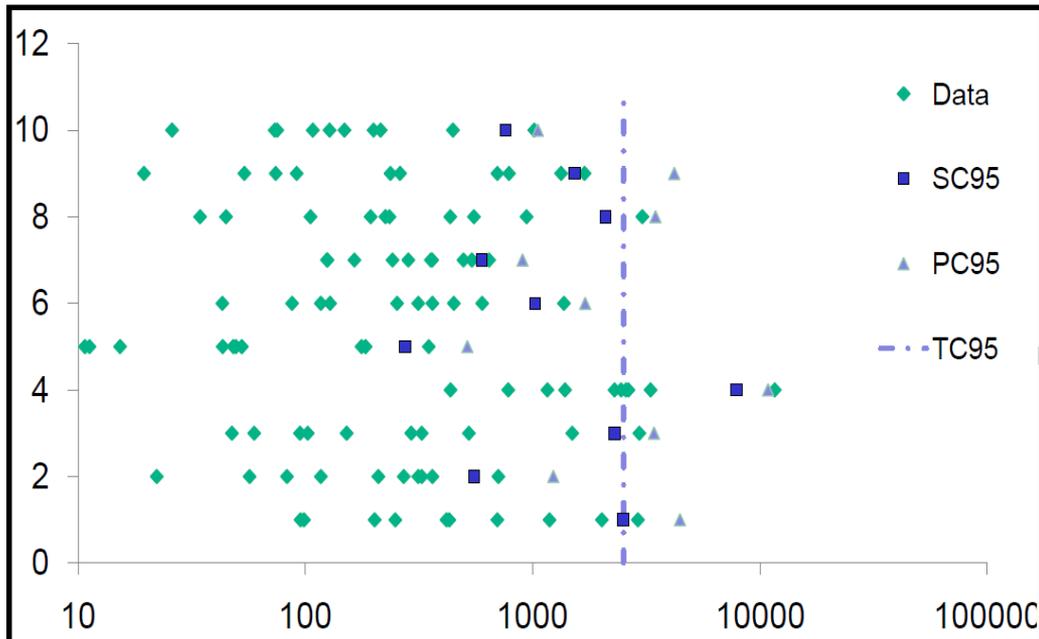
- b.1 R.A.: Consumer & Operator
- b.2 Routes of exposure
- b.3 Operator exposure estimation tools**

## C. Pesticide Label

- c.1 Product labelling & classification
- c.2 Interpretation of label in relation to safety precautions & PPE recommendations
- c.3 Product safety data sheet and First aid measures

## b.3 Operator exposure estimation tools

The **operator exposure levels** to pesticides can be estimated either with mathematical models of measured from field studies.



# The currently used OPEX estimation models

German Model  
outdoor

UK POEM  
outdoor

**EUROPOEM data (outdoor & indoor)**

**Dutch Greenhouse Model**

**ECPA Southern European Greenhouse Model**

**Seed TROPEX** (seed treatment & loading calibration bagging,  
sowing of treated seeds)

**Higher tier data:** Exposure measurements from relevant studies (type of PPP's & application pattern, mixing loading)

# New exposure estimation tool, Operator, Worker, Bystander & Resident

## EFSA Calculator

EFSA Guidance, 2014

■ Background document:

*EFSA, 2008b. Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents, EFSA AGREEMENT NUMBER: EFSA/PPR/2007/01, FINAL REPORT, 28 NOVEMBER 2008.*



European  
Commission

## Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products

EFSA Journal 2014;12(10):3874[55 pp.] doi:10.2903/j.efsa.2014.3874

European Food Safety Authority

Acknowledgment ▾

Contact ▾

**Type:** Guidance of EFSA

**On request from:** European Commission

**Question number:** EFSA-Q-2011-01062

**Approved:** 17 October 2014

**Published:** 23 October 2014

**Last updated:** 24 April 2015. This version replaces the previous one/s.

**Affiliation:** European Food Safety Authority (EFSA), Parma, Italy

[Article](#)  (1.0 Mb)



 [Send](#)  [Print](#)  [Cite](#)

[Excel calculator](#)  (0.1 Mb)



### Abstract

Regulation (EC) No 1107/2009 ensures that the residues of plant protection products (PPPs), consequent to application consistent with good plant protection practice and having regard to realistic conditions of use, shall not have any harmful effects

Sub  
to th  
EF

Sec

- ▶ M
- E
- G
- P
- w
- b
- ▶ P
- ▶ P
- P
- R
- ▶ M
- ▶ C
- C
- d
- E

# C. Pesticide Label and Product safety Data Sheet





European Commission

# Example of a PPP label

Product type:  
Wettable Powder

Directions for use

**Product name** **DWP**

**PUBLIC HEALTH INSECTICIDE**

A WETTABLE POWDER FOR INDOOR RESIDUAL SPRAYING FOR THE CONTROL OF MALARIA VECTOR MOSQUITOES AND OTHER HOUSEHOLD PESTS. SUITABLE FOR ROTATION WITH OTHER CLASSES OF INSECTICIDE IN RESISTANCE MANAGEMENT PROGRAMMES

**Active Ingredient:**  
Propoxur (Carbamate).....800 g/kg

Contents: 310g

Batch No:.....  
Date of Manufacture.....7/2009  
Date of Expiry.....01/2011

**Formulated by:**  
Name & contact details

**DIRECTIONS FOR USE**  
USE ONLY AS DIRECTED

**Mixing instructions for spray:**  
Pre-mix ProGuard 80WP in a bucket with a small volume of water and mix into a smooth paste. Add approximately 5 litres of water, mix thoroughly and pour the mixture into the sprayer. Fill the sprayer with water to the 10 litre level and shake the sprayer well to ensure proper mixing and agitate regularly to ensure product remains in suspension. Prepared spray mixture must not be left in the spray tank for any length of time e.g. overnight

**Warnings**

- Handle with care
- Concentrate is poisonous when swallowed and moderately toxic by skin contact.
- Toxic to bees, various other beneficial pest parasites and predators and fish under field conditions, provided the product is used as directed
- Do not spray over or allow drift to contaminate drinking water and water bodies such as dams, ponds, rivers, streams or fish hatcheries
- Moderately toxic to wildlife
- Store in a cool place away from food and foodstuffs.
- Keep concentrate out of reach of children, uninformed persons and animals
- Do not apply directly onto animals
- Do not apply to surfaces where food is handled
- ProGuard 80WP may leave visible deposits on dark surfaces

**Precautions**

- Avoid eye splashes, skin contact by and inhalation of spray mist
- Wear protective clothing: overall, gloves and face shield when handling the powder concentrate or diluted spray mixture
- Avoid spray drift when spraying
- Wash contaminated clothing
- Wash with soap and water after use or after accidental skin contact
- Do not eat, drink or smoke while mixing or spraying or before washing hands and face
- Prevent contamination of food, feedstuffs, eating utensils and drinking water
- Remove pets and aquaria or cover aquaria
- Thoroughly wash and rinse the spray equipment/containers/basins after use and dispose of wash water where it will not contaminate crops, grazing, rivers and dams
- Destroy empty container and do not re-use for any other purpose

**TOXICOLOGY**  
Propoxur is a reversible cholinesterase inhibitor with moderate toxicity. It may be absorbed from the gastrointestinal tract, through the intact skin and less commonly by inhalation of spray mist

**SYMPTOMS OF POISONING:**  
Early symptoms of poisoning may include excessive sweating, headache, weakness, giddiness, nausea, vomiting, stomach pains, blurred vision, constricted pupils, slurred speech and muscle twitching. More severe symptoms include convulsions, coma and loss of reflexes

**FIRST AID:**  
Carbamate poisoning requires immediate treatment. The affected person should stop work immediately, remove any contaminated clothing, wash the affected skin with soap and clean water and flush area with large quantities of clean water

**NOTE OF PHYSICIAN:**  
This product is a cholinesterase inhibitor. Propoxur is quickly metabolised and symptoms are short duration. Atropine is the specific antidote and should be administered by a physician. Oximes should not be given in cases of poisoning with carbamates.

**MALARIA VECTOR CONTROL**

**ADULT MOSQUITOES**  
(including malaria and other disease of insecticide)

Who recommended dosage rate: 1-2g a.l./m<sup>2</sup>

**DILUTION**  
Mix one 310 g sachet to contain 1 g a.l./m<sup>2</sup>

For longer residual control mix two sachets to 10 l water to give 2g a.l./m<sup>2</sup>

Several months of control can be expected indoors. The length of control is determined by the type of treated surface. Apply as an even spray to indoor wall and roof/ ceiling surfaces by using a WHO approved compression sprayer fitted with an atomiser. The spray should be applied to the area to be treated to obtain a target deposit of 1g active ingredient per m<sup>2</sup> or the higher rate to give 2g a.l./m<sup>2</sup>

Ensure even coverage to all inside walls and ceiling of houses, outside eaves and out buildings such as animal shelters. For good results the area should be sprayed. Spraying activity should be completed within 2 hours of sunset. Allow spray to dry on treated surfaces before re-entering.

Some operators should be suitably trained on the correct spray technique according to WHO recommended procedures for Indoor Residual Spraying.

Type of PPP →

Pictograms →

Warnings

Precautions

Toxicology

Symptoms of poisoning

First aid

Note of physician

# The Product Safety Data Sheet (SDS)

L 132/8

EN

Official Journal of the European Union

29.5.2015

COMMISSION REGULATION (EU) 2015/830

of 28 May 2015

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the  
Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)



**Guidance on the compilation  
of safety data sheets  
according to the requirements  
in place from 1 June 2015**

[http://echa.europa.eu/documents/10162/13643/sds\\_en.pdf](http://echa.europa.eu/documents/10162/13643/sds_en.pdf)



Guidance on the  
compilation of  
safety data sheets

Version 3.0  
August 2015

# What is a **PRODUCT SAFETY DATA SHEET**

## 2.1 Definition of a Safety Data Sheet (an SDS)

- An SDS is aimed to provide information about a substance or mixture for use in workplace.
- It is used as a source of information about hazards, including environmental hazards, and to obtain advice on safety precautions.
- To be used: at workplace (e.g. professional use of pesticides), consumers, for transport of dangerous goods, in emergency situations (including poison centers)

# **c.1**

## **Interpretation of label and SDS in relation to product classification**

# The legal framework for Hazard Classification

## *...the new CLP (GHS) system*

REGULATION (EC) No 1272/2008 of The European Parliament and of the Council of the 16<sup>th</sup> December 2008  
*on Classification, Labelling and Packaging (CLP Regulation) of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1097/2006*

With this Regulation (CLP) the internationally agreed criteria in the Globally Harmonized System are incorporated into Community Law

### Entry into force

Substances: 1 December 2010, Mixtures: 1 June 2015

## Essential elements on a PPP Label

|                                 |  |   |
|---------------------------------|--|---|
| <b>Hazard pictograms</b>        |  flammable  explosive  flammable & explosive  fatal toxic  Allergen CMR STOT |  gas under pressure  Corrosive to metals skin burns eye dmg  harmful irritant allergen  allergen CMR STOT |
| <b>Signal words</b>             | Danger   |   |
| <b>Hazard statements</b>        | H200 - H290: hazard statements for physical hazards<br>H300 - H373: hazard statements for health hazards<br>H400 - H413: hazard statements for environmental hazards   |   |
| <b>Precautionary statements</b> | P101 – P103: precautionary statements – general<br>P201 – P285: precautionary statements – prevention<br>P301 – P391: precautionary statements – response<br>P401 – P422: precautionary statements – storage<br>P501 : precautionary statements – disposal   |   |

## c.2

# Interpretation of label and SDS in relation to safety precautions and PPE recommendations

# What are the determinants for PPE recommendations?

a

The hazardous properties of active ingredient(s) and co-formulants (C,M,R, EDs)

b

Risk for the operator & worker

PPE recommendations on Pesticide Label



European  
Commission

**Signal word:**

Warning

**Hazard class (health effects):**

Causes serious eye irritation

Suspected of causing cancer

**PPE (statement of prevention):**

Wear protective gloves / protective clothing / eye protection / face protection

# Rovral® WG

A protectant fungicide for the control of a wide range of fungal diseases in agricultural and horticultural crops

A water dispersible granule containing 750 g/kg iprodione.

## Risk and Safety Information

### Warning:

Causes serious eye irritation.  
Very toxic to aquatic life with long lasting effects.  
Suspected of causing cancer.

Wear protective gloves/protective clothing/eye protection/face protection. Obtain special instructions before use. If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If exposed or concerned: get medical advice/attention. Collect spillage.

This material and its container must be disposed of in a safe way. Dispose of contents/container to a licensed waste disposal contractor or collection site except for triple rinsed empty containers which can be disposed of as non-hazardous waste.

### Conventional Sprayer:

To protect aquatic organisms respect an unsprayed buffer zone of 5m to surface water bodies.

### Air Assisted Sprayer:

To protect aquatic organisms respect an unsprayed buffer zone of 15m to surface water bodies.

**To avoid risks to human health and the environment, comply with the instructions for use.**

### Authorization holder:

BASF plc, P O Box 4,  
Earl Road, Cheadle Hulme,  
Cheshire, SK8 6QG, UK

Supplied by:  
BASF Ireland Limited  
P.O. Box 4, Earl Road  
Cheadle Hulme, CHEADLE  
Cheshire SK8 6QG, UK  
Tel: 01 825 5701  
Fax: 01 825 2038  
Emergency Information  
(24 hours freephone):  
0049 180 227 3112  
Technical Enquiries:  
0044 (0)845 602 2553  
(office hours)

**1** kg

PCS No.: 02729



European Commission

No Hazard Classification



This product is a soluble concentrate containing 360 g/l (30.77 % ww) glyphosate, present as 480 g/l (41.6 % ww) of the isopropylamine salt of glyphosate.

Degraded by micro-organisms / microbes in the soil.

A foliar applied translocated herbicide for the control of emerged annual and perennial grass and broad-leaved weeds in industrial and amenity situations, around the farm and non-crop areas.

IE, 0704, F - 1067 4343

PCS Number: 02314



5 411773 027319 >

e 1 Litre

VPEMB Monsanto B-2040  
© Monsanto Apz, 2007 (Mclb)  
Lot Number / Production Date:



PPE:

Wear suitable gloves

PEEL HERE FOR DIRECTIONS FOR USE



FOR USE ONLY AS A NON-SELECTIVE HERBICIDE IN NON-CROP AREAS.

**SAFETY INFORMATION**

KEEP OUT OF REACH OF CHILDREN.

WEAR SUITABLE GLOVES,

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS.

IF SWALLOWED, SEEK MEDICAL ADVICE IMMEDIATELY AND SHOW THIS CONTAINER OR LABEL.

THIS MATERIAL AND ITS CONTAINER MUST BE DISPOSED OF IN A SAFE WAY.

To avoid risks to man and the environment, comply with the instructions for use.

PCS Number: 02314

Marketed in Ireland by:

**MONSANTO IRELAND LIMITED**

Unit C2, Dunshaughlin Business Park  
Dunshaughlin, County Meath

Tel.: (01) 825 0555 / 825 0574, Fax: (01) 825 0570

Authorisation holder:

**MONSANTO UK LIMITED**

The Maris Centre, 45 Hauxton Road  
Trumpington, Cambridge, CB2 9LQ, UK

In case of emergency day or night, telephone Chemical Emergency Centre: 00 44 1865 407333

READ CAREFULLY THE RECOMMENDATIONS FOR USE ATTACHED TO THIS CONTAINER

All users must ensure that they have read this leaflet and follow its advice before using the product.

Protect from frost.

Imported

Roundup®, Biactive®, Monsanto® and the Vine symbol are registered trade marks of Monsanto Technology LLC. Not for reformulation or repackaging. No licence is granted under any patent.

## PPE recommendations on a Pesticide Label

| Code | Prevention precautionary statement   | Hazard class                                       | Hazard category |
|------|--|--|-----------------|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. | Acute toxicity - dermal                            | 1, 2, 3, 4      |
|      |  | Skin corrosion                                     | 1A, 1B, 1C      |
|      |  | Skin / eye irritation                              | 2               |
|      |  | Skin sensitization / serious eye damage/irritation | 1               |
| P284 | Wear respiratory protection  | Acute toxicity — inhalation                        | 1, 2            |
| P285 | In case of inadequate ventilation wear respiratory protection.             | Respiratory sensitisation                          | 1               |

# The importance of pesticide label -Application rate & PPE

*Recommended application rate: 7.5 L product/ha (1.125 kg a.i./ha), Spray volume: 500 L/ha,  
Treated area: 5 ha/day - field crop; tractor mounted*

## Estimation of operator exposure (acc. to the German model)

|                            |                                     |                            |
|----------------------------|-------------------------------------|----------------------------|
| Active substance (a.s.)    | glufosinate ammonium                |                            |
| Product                    | BASTA 15 SL                         |                            |
| Intended use(s)            | olive trees                         |                            |
| Type of preparation        | Field Crops, Tractor Mounted (FCTM) |                            |
|                            | Liquid                              |                            |
| Application rate (AR)      | 1.125                               | kg a.s./ha                 |
| Treated area per day (A)   | 5                                   | ha/d                       |
| Systemic AOEL              | 0.0021                              | mg/kg bw/d                 |
| Dermal absorption (DA)     | 16                                  | % for mixing/loading (m/l) |
|                            | 14                                  | % for application (appl.)  |
| Inhalation absorption (IA) | 100                                 | %                          |
| Body weight (BW)           | 70                                  | kg                         |

No PPE: exposure levels,  
exceeded AOEL  
by **2600%**

With PPE: **98%** AOEL

Application rate + 10%  
No PPE: exposure levels  
exceeded AOEL  
by **2825%**

With PPE: **108%** AOEL

## **c.3**

# **Interpretation of label and SDS in relation to first aid measures**

# 1<sup>st</sup> aid measures & precautionary statements

- Annex IV to Regulation (EC) 1272/2008: list of precautionary statements
  - P101 – P103: precautionary statements – general
  - P201 – P285: precautionary statements – prevention
  - P301 – P391: precautionary statements – response *{considered under first aid measures due to their purpose}*
  - P401 – P422: precautionary statements – storage
  - P501: precautionary statements – disposal



European  
Commission

# First-aid measures: Regulation (EC) 1272/2008

## (Table 6.2 - Precautionary statements – Response)

| Code               | <u>Response</u> precautionary statement   | Hazard class                   | Hazard category |
|--------------------|---|--------------------------------|-----------------|
| P301 + P310        | IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.   | Acute toxicity – oral          | 1, 2, 3         |
|                    |   | Aspiration hazard              | 1               |
| P301 + P312        | IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.                                  | Acute toxicity – oral          | 4               |
| P301 + P330 + P331 | IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  | Skin corrosion                 | 1A, 1B, 1C      |
| P302 + P334        | IF ON SKIN: Immerse in cool water/wrap in wet bandages.   | Pyrophoric liquids             | 1               |
| P302 + P350        | IF ON SKIN: Gently wash with plenty of soap and water.  | Acute toxicity – dermal        | 1, 2            |
| P302 + P352        | IF ON SKIN: Wash with plenty of soap and water.   | <b>Acute toxicity – dermal</b> | 3, 4            |
|                    |   | <b>Skin irritation</b>         | 2               |
|                    |   | <b>Skin sensitisation</b>      | 1, 1A, 1B       |
| P303 + P361 + P353 | IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/ shower. | Flammable liquids              | 1, 2, 3         |
|                    |   | Skin corrosion                 | 1A, 1B, 1C      |

## First-aid measures (2)

| Code               | Response precautionary statement   | Hazard class   | Hazard category |
|--------------------|--|--|-----------------|
| P304 + P340        | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.                                 | Acute toxicity — inhalation  | 1, 2, 3, 4      |
|                    |  | Skin corrosion   | 1A, 1B, 1C      |
|                    |  | Specific target organ toxicity — single exposure; respiratory tract irritation | 3               |
|                    |  | Specific target organ toxicity — single exposure; narcosis                     | 3               |
| P304 + P341        | IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.      | <b>Respiratory sensitisation</b>   |                 |
| P305 + P351 + P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. | Skin corrosion   | 1A, 1B, 1C      |
|                    |  | Serious eye damage/eye irritation  | 1               |
|                    |  | Eye irritation   | 2               |
| P306 + P360        | IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.                   | Oxidising liquids  | 1               |
|                    |  | Oxidising solids   | 1               |

## First-aid measures (3)

| Code        | Response precautionary statement   | Hazard class   | Hazard category     |
|-------------|--|--|---------------------|
| P307 + P311 | IF exposed: Call a POISON CENTER or doctor/physician.                            | Specific target organ toxicity – single exposure                           | 1                   |
| P308 + P313 | IF exposed or concerned: Get medical advice/attention.                           | Germ cell mutagenicity   | 1A, 1B, 2           |
|             |  | Carcinogenicity  | 1A, 1B, 2           |
|             |  | Reproductive toxicity  | 1A, 1B, 2           |
|             |  | Reproductive toxicity – effects on or via lactation                        | Additional category |
| P309 + P311 | IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.      | <b>Specific target organ toxicity – single exposure</b>                    | 2                   |
| P332 + P313 | If skin irritation occurs: Get medical advice/attention.                         | Skin irritation  | 2                   |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention.                 | Skin sensitisation   | 1, 1A, 1B           |
| P335 + P334 | Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages. | Pyrophoric solids  | 1                   |
|             |  | Substances and mixtures which, in contact with water, emit flammable gases | 1, 2                |



European  
Commission

## First-aid measures (4)

| Code        | Response precautionary statement  | Hazard class   | Hazard category  |
|-------------|---|--|------------------|
| P337 + P313 | If eye irritation persists: Get medical advice/attention.   | <b>Eye irritation</b>  | 2                |
| P342 + P311 | If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/ physician.  | Respiratory sensitisation  | 1, 1A, 1B        |
| P370 + P376 | In case of fire: Stop leak if safe to do so.  | Oxidizing gases  | 1                |
| P370 + P378 | In case of fire: Use ... for extinction.<br><br><i>[... Manufacturer/supplier to specify appropriate media. — if water increases risk.]</i> | Flammable liquids  | 1, 2, 3          |
|             |   | Flammable solids   | 1, 2             |
|             |   | Self-reactive substances and mixtures                                      | A, B, C, D, E, F |
|             |   | Pyrophoric liquids   | 1                |
|             |   | Pyrophoric solids  | 1                |
|             |   | Substances and mixtures which, in contact with water, emit flammable gases | 1, 2, 3          |
|             |   | Oxidising liquids  | 1, 2, 3          |
|             |   | Oxidising solids   | 1, 2, 3          |



# First-aid measures (5)

| Code               | Response precautionary statement   | Hazard class                          | Hazard category                   |
|--------------------|--|---------------------------------------|-----------------------------------|
| P370 + P380        | In case of fire: Evacuate area.  | <b>Explosives</b>                     | Divisions 1.1, 1.2, 1.3, 1.4, 1.5 |
| P370 + P380 + P375 | In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.                            | Self-reactive substances and mixtures | Types A, B                        |
| P371 + P380 + P375 | In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion. | Oxidising liquids                     | 1                                 |
|                    |  | Oxidising solids                      | 1                                 |

# Further reading: The EU Legislation

**DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides**

**Reg. (EC) 283/2013:** COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

**Reg. (EC) 284/2013 :** COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

**Dir. 1999/45/EC** DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

**Dir. 67/548/EEC:** COUNCIL DIRECTIVE of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC) This Directive has been amended several times. Regulation (EC) No 1272/2008 has made remarkable modifications, and it shall repeal directive 67/548/EEC from 1 June 2015 by introducing the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

# Further reading: The EU Legislation

**Reg. (EC) 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

**Reg. (EC) 547/2011** COMMISSION REGULATION (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

**Reg. (EC) 1272/2008** REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

**DIRECTIVE 2009/128/EC** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

## Calculation models

- [http://www.bvl.bund.de/EN/04\\_PlantProtectionProducts/11\\_Applicants/02\\_AuthorisationProcedure/06\\_Toxicology/PlantProtectionProducts\\_toxicol\\_node.html](http://www.bvl.bund.de/EN/04_PlantProtectionProducts/11_Applicants/02_AuthorisationProcedure/06_Toxicology/PlantProtectionProducts_toxicol_node.html)
- <http://www.efsa.europa.eu/en/efsajournal/pub/3874.htm>

\***Reference:** Carol Ramsay, Pesticide Education Specialist, Washington State University



# Thank you for your attention!

**Kyriaki Machera, MSc, PhD, ERT**

Regulatory Toxicologist

Head, Laboratory of Toxicological Control of  
Pesticides

Director, Benaki Phytopathological Institute  
8, St.Delta str., 145 61 Kifissia, Attica, Greece  
k.[machera@bpi.gr](mailto:machera@bpi.gr), machera@otenet.gr

**Better Training for Safer Food  
BTSF**

• *European Commission  
Consumers, Health and Food Executive Agency  
DRB A3/042  
L-2920 Luxembourg*