# Norway

**OECD Survey of National Pesticide Risk Indicators, 1999-2000**

| **COUNTRY, MINISTRY** |
|---|
| Norway<br><br>Norwegian Agricultural Inspection Service |

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| **INDICATOR NAME** |
|---|
| Environmental Risk Indicator |

| **WHEN AND WHY WAS THE INDICATOR DEVELOPED?** |
|---|
| Norway has implemented a national risk reduction action plan concerning the use of plant protection products spanning the years 1998 to 2002. The plan includes a series of different measures and recommendations to reduce the use of pesticides and the risk to human health and the environment. One such measure was the reorganisation of the tax system for plant protection products, by the Norwegian Agriculture Inspection Service (NAIS), to reflect these goals. This green tax is differentiated according to the potential risk to human health and the environment, and the products with the highest potential risk receive the highest tax. Indicators were developed as tools to monitor development in health and environmental risk, and to see if the measures of the action plan have the intended effect on risk reduction. |

| **HOW HAS THE INDICATOR BEEN USED?** |
|---|
| The indicator is used to produce a "Cumulative Environmental Index" for all active ingredients in all plant protection products by year, to show the change in risk over time. The environmental risk index, for monitoring the development of environmental risk over time) summarizes the risk from different areas of toxicity and exposure (e.g., different groups of organisms, persistence, bioaccumulation). |

**DESCRIPTION OF THE INDICATOR:**

**TYPES OF RISK**

Aquatic, Terrestrial, Fate
Acute (Long-term could be incorporated; to maintain simplicity in the indicator, chronic toxicity was not considered - a limitation of the indicator)

**ROUTES OF EXPOSURE**

Spray drift
Runoff
Leaching

**VARIABLES INCLUDED**

**Pesticide Active Ingredient:**
(i) Physicochemical and fate properties:

$DT50_{soil}$ (days)
purification $DT_{50}$ (depuration rate from bioaccumulation studies, stated as a DT50 value in days)
$K_{oc}$
solubility in water (mg/L)
bioconcentration factor (BCF)
$P_{ow}$ (octanol-water partition coefficient)

(ii) Toxicity:

14-day LC50 for earthworms
$LD50_{oral}$ for bees (☞g/bee)
$LD50_{contact}$ for bees (☞g/bee)
dietary LC50 for birds (mg/kg food)
acute oral LD50 for birds (mg/kg body weight) (alternative)
acute LC50 for fish (mg/L)
acute LC50/EC50 for aquatic invertebrates (*Daphnia*, mg/L)
EC50 for algae (mg/L)
acute EC50 for aquatic vascular plants (mg/L)

**Pesticide use:**

area treated (ha); if no use data are available, the SAD is used to calculate area treated

Standardised Area Dose (SAD; mL or g/decare); a SAD is determined for each approved plant protection product (decare = 1/10 hectare); see Appendix I for a discussion of the calculation of this parameter.

application rate (g/ha; AR); the SAD is used in all calculations

NOTE: A pesticide is usually used for a range of crops with different label rates. Each of these label rates can be used to calculate "E" (Environmental Risk Index) for that active ingredient, application rate, and crop. This "E" is later to be multiplied with the area of crop treated with that active ingredient at that label rate. Summarized with values for all crops and pesticide products, this would then be the optimal way of calculating the risk indicator. Unfortunately, only sales data are available in Norway, and there is no simple way of relating this to specific use in different crops (and label rates). As a simplification, SAD is, therefore, used as a standard application rate. SAD is defined, simply, as the maximum application rate in the dominating crop.

**Soil/site data:**
mixing depth in soil (cm)
dry soil bulk density ($g/cm^3$)

**Fate:**
drift tables (Ganzelmeier et al., 1995)

**Other:**
fraction of pesticide application intercepted by crop canopy ($f_{int}$) (default values are used for this variable: 0 for bare soil, 0.5 if a crop is present)

crop height (for calculation of spray drift; crop(s) that the SAD were based on were chosen)

**METHODS OR FORMULAE FOR COMBINING VARIABLES**:

$E = (T + A + L + 2P + B + 1)^2$ {can be calculated for most pesticide active ingredients}

where:
E = Environmental risk index
T = Score for undesirable terrestrial effects
A = Score for undesirable aquatic effects
L = Score for leaching potential
P = Score for persistence
B = Score for bio-accumulation

E is calculated for each active ingredient in each product. As a result, an active ingredient that is used in several products can have several environmental risk indices (E) according to the actual application rate and type of use.

Collective Environmental Index = $\sum(E_{ij} \times area_{ij})$

where:
i = a particular active ingredient in a pest control product

j = a particular year
area = area of land (in decares = 1/10 hectare) treated with an active ingredient (the area is calculated by combining the application rate, based on the SAD, with the quantity sold. The quantity sold refers to that sold by the importer to the retailer or distributor and are, therefore, an uncertain measure of the quantities actually used in a particular year)

## I. TERRESTRIAL EFFECTS (T)

The score, T, is set equal to the highest of the following values ($T_{ew}$, $T_{bee}$ or $T_{bird}$).

(i) Earthworms ($T_{ew}$)

Toxicity exposure ratio ($TER_{ew}$) = Toxicity / $PEC_{soil}$

where:
Toxicity = 14-day LC50 for earthworms
PIEC = Predicted Initial Environmental Concentration
$PIEC_{soil}$ = AR x (1 - $f_{int}$)/(100 x depth x bd); for a single application

and:
AR = application rate (g/ha)
$f_{int}$ = fraction intercepted by crop canopy (default = 0 for bare soil, up to 0.5 if crop present)
depth = mixing depth (cm; default = 5 cm for soil surface applications, 20 cm for incorporation)
bd = dry soil bulk density (g/cm$^3$; default = 1.5 g/cm$^3$)

Using the standard default values, for single applications,

$PIEC_{soil}$ (mg/kg) = AR/750 (assuming no incorporation or interception)
$PIEC_{soil}$ (mg/kg) = AR/1500 (assuming no incorporation and 50% interception)
$PiEC_{soil}$ (mg/kg) = AR/3000 (assuming incorporation and no interception)

The PIEC, as indicated above, is for one application only. A simplified worst-case $PIEC_{soil}$ (mg/kg), assuming additive soil residues, could be calculated for multiple applications.

The score for $T_{ew}$ is assigned according to the following table based on the calculated TER:

| **TER based on 14-day LC50** | **$T_{ew}$** |
|---|---|
| > 100 | 0 |
| 10-100 | 2 |
| < 10 | 4 |

The EPPO (European and Mediterranean Plant Protection Organisation) has defined a threshold value of 100, and EU (Uniform Principles) a value of 10. With these values as a basis, this table was constructed.

(ii) Bees (Tbee)

Hazard quotient for oral exposure (*Qho*) = AR / $LD50_{oral}$
Hazard quotient for contact exposure (*Qhc*) = AR / $LD50_{contact}$

where:
AR = application rate (g/ha)
$LD50_{oral\ and\ contact}$ = ☞g/bee

The highest of the hazard quotients is assigned a score, $T_{bee}$, based on the following table:

| ***Qho / Qhc*** | ***$T_{bee}$*** |
|---|---|
| *< 50* | *0* |
| *50-100* | *0.5* |
| *100-1000* | *1* |
| *1000-10000* | *1.5* |
| *> 10000* | *2* |

*Scores for Tbee can only reach 2 points. This is because products which are toxic for bees will be labeled accordingly and may not be used on or over flowering vegetation. This will reduce the exposure. Additionally, these data can also be used as an indicator for other arthropods which are not exclusively related to flowering vegetation.*

*(iii) Birds ($T_{bird}$)*

*To simplify the indicator for birds, only dietary exposure was considered (i.e., exposure via water, drifting spray, other prey, inhalation, etc. were not included).*

*Toxicity exposure ratio ($TER_{bird}$) = Toxicity / PIEC*

*where:*
*Toxicity = dietary LC50 (mg/kg food)*
*(or Toxicity = acute oral LD50 (mg/kg body weight); alternative if dietary data are not available)*
*Predicted Initial Environmental Concentration, PIEC (mg/kg) = application rate (kg/ha) x K and:*
*K = constant, based on measurements made by Hoerger & Kenaga (1972) to estimate the concentration of pesticide residues in foodstuffs which comprise a bird's diet (see below).*

*A worst case was chosen for this indicator, using a diet of leaves and small insects according to the formula:*

*$PIEC_{leaves\ and\ small\ insects}$ (mg/kg) = application rate (kg/ha) x 30* *(Equation 1)*

*The value of K = 30 is based on information from research reports which shows that spraying at the rate of 1 kg/ha results in residues on leaves corresponding to 30 mg/kg. Other diets consisting of different types of food stuff can be determined using the following constants:*

$PIEC_{leaves}$ *(mg/kg) = application rate (kg/ha) x 31.3*
$PIEC_{corn\ seed}$ *(mg/kg) = application rate (kg/ha) x 2.7*
$PIEC_{small\ insects/weed\ seeds}$ *(mg/kg) = application rate (kg/ha) x 29.5*
$PIEC_{large\ insects}$ *(mg/kg) = application rate (kg/ha) x 3.0*

*If dietary toxicity data are not available, and acute oral LD50 values are used, the calculation of the TER must take account of the quantity of contaminated food the bird ingests. ECPA (1995) proposes a method in which one assumes that small birds (10 g) have a daily food intake of approximately 30% of their body weight while large birds (100 g or more) consume approximately 10% of their body weight. The constant, K, from equation 1 above, is adjusted for the food intake per kg of body weight. Using acute oral toxicity data in this manner is considered to be a very crude estimate of exposures. The exposure values (PIEC) are now calculated as daily intake as follows:*

*Small birds: Daily intake (mg/kg body weight) = application rate (kg/ha) x 9*
*Large birds: Daily intake (mg/kg body weight) = application rate (kg/ha) x 3*

*For treated seeds and granules, the amount of active ingredient per kg of seed or granule are stated. TER values can, therefore, be calculated directly by dividing the dietary toxicity values by this concentration. If no relevant diet (consumption) data are available, an equivalent intake of the active ingredient can be calculated assuming the bird eats only treated seeds or grains. If the seed treatment agent of the granules have been shown to have a repellent effect on birds, a TER would not be calculated as it is then assumed that the active ingredient (product) would not pose a problem.*

*The lowest TER value calculated for the most sensitive species is used to assign a score, Tbird, according to the following table:*

| ***TER*** | $T_{bird}$ |
|---|---|
| > 10 | 0 |
| 1-10 | 2 |
| < 1 | 4 |

*The EU (Uniform Principles) has defined the threshold value as 10 for this TER. With this value as a basis, this table was constructed. The EU has no recommendations of other threshold values for acute studies with birds.*

***II. AQUATIC EFFECTS** (A)*

*Exposure of aquatic organisms to runoff from drainage systems is not considered as there are no simple methods to calculate these concentrations.*

*Toxicity Exposure Ratio ($TER_{aquatic}$) = Toxicity / ($PEC_{surface\ runoff}$ or $PEC_{spray\ drift}$)*

*(The TER using $PEC_{spraydrift}$ and the TER using $PEC_{surface\ runoff}$ are calculated separately and the one that gives the lowest TER value is used in further calculations.)*

*where:*
*Toxicity = acute toxicity (LC50/EC50) for algae/water plants, pelagic invertebrates (Daphnia*), and fish

$PEC_{spray\ drift}$ = loading to 30 cm depth of water for a 10 meter no-spray zone, based on Ganzelmeier et al. (1995)

(A simplified version of the equation for calculating spray drift, using 30 cm depth of water is:
PEC (µg/L) = application rate (g/ha) x percent spray drift (from Ganzelmeier et al. 1995) / 300)

$PEC_{surface\ runoff}$ = loading to water where 0.5% runoff* from a 1.0 ha field enters a 0.2 ha pond which is 1.0 m deep, based on ECPA (1995) and Wauchope (1978)

*It is proposed that the runoff percentage should be modified (using a multiplication factor) based on the properties of the active ingredient as follows:

Pesticides with *high* potential for particle-bound transport: 0.5%
Pesticides with *medium* potential for particle-bound transport: 0.3%
Pesticides with *low* potential for particle-bound transport: 0.1%

Particle-bound transport is assessed based on Goss and Wauchope (1990):

| **Potential** | **Criteria** |
|---|---|
| High | $DT50_{soil}$ ≥ 40 days and $K_{oc}$ ≥ 1000 |
| | $DT50_{soil}$ ≥ 40 days, $K_{oc}$ ≥ 500 and solubility ≤ 0.5 mg/L |
| Low | $DT50_{soil}$ ≤ 1 day |
| | $DT50_{soil}$ ≤ 2 days and $K_{oc}$ ≤ 500 |
| | $DT50_{soil}$ ≤ 4 days, $K_{oc}$ ≤ 900 and solubility ≥ 0.5 mg/L |
| | $DT50_{soil}$ ≤ 40 days, $K_{oc}$ ≤ 500 and solubility ≥ 0.5 mg/L |
| | $DT50_{soil}$ ≤ 40 days, $K_{oc}$ ≤ 900 and solubility ≥ 2 mg/L |
| Medium | All other instances |

The TER should be calculated for the most sensitive endpoint of studies with algae and water plants, and similarly for the most sensitive of *Daphnia* and fish. These TER values are scored

("A") based on the following table. The highest score is used as the indicator value for the total risk of undesirable effects in the aquatic environment.

| TER based on acute studies with fish or invertebrates | TER based on studies with algae or aquatic vascular plants | A |
|---|---|---|
| > 100 | > 10 | 0 |
| 10-100 | 1-10 | 1 |
| 1-10 | 0.1-1 | 2 |
| 0.1-1 | 0.01-0.1 | 3 |
| < 0.1 | < 0.01 | 4 |

The EU (Uniform Principles) has defined threshold TER values of 100 (based on acute studies with fish and *Daphnia*) and 10 (based on studies with algae). With these values as the basis, this table was constructed.

## **<u>III. LEACHING POTENTIAL</u> (L)**

The GUS index (Gustavson, 1989) is used to calculate the potential for groundwater pollution and for leaching of pesticides into surface water via the drainage systems. This index is based on the chemical's adsorption ($K_{oc}$) and persistence (DT50) in soil. Mean values of $K_{oc}$ and $DT50_{soil}$ are used for this parameter as follows:

$$GUS = \log(DT50_{soil}) \times (4-\log(K_{oc}))$$

GUS is usually interpreted as follows:

| | |
|---|---|
| GUS > 2.8 | high leaching potential |
| GUS 1.8-2.8 | medium leaching potential |
| GUS < 1.8 | low leaching potential |

The application rate is also taken into account as it has great significance for the quantity of pesticide which could be leached. Pesticides are assigned a score for leaching potential (L), based on the GUS value and the application rate, using the following table:

| **GUS** | **Pesticide Application Rate (g ai/ha)** | | | |
|---|---|---|---|---|
| | **< 100** | **100-1000** | **1000-2000** | **> 2000** |
| < 1.8 | 0 | 0 | 0 | 0 |
| 1.8-2.8 | 1.25 | 1.5 | 1.75 | 2 |
| > 2.8 | 2.5 | 3 | 3.5 | 4 |

## **<u>IV. PERSISTENCE IN SOIL</u> (P)**

Each pesticide active ingredient is assigned a persistence factor, P, based on the $DT50_{soil}$ and application rate. The mean value from relevant degradation studies is used for this parameter, and according to the following table:

| DT50 (days) | Pesticide Application Rate (g ai/ha) | | | |
|---|---|---|---|---|
| | **< 100** | **100-1000** | **1000-2000** | **> 2000** |
| <10 | 0 | 0 | 0 | 0 |
| 10-30 | 0 | 0 | 0.5 | 1 |
| 30-60 | 0.5 | 1 | 1.5 | 2 |
| 60-200 | 1.5 | 2 | 2.5 | 3 |
| 200-365 | 2.5 | 3 | 3.5 | 4 |
| > 365 | 4 | | | |

## V. BIO-ACCUMULATION (B)

The bio-concentration factor (BCF) cannot be used as a criterion on its own but must be related to the pesticide's persistence and purification half-life (i.e., depuration rate determined in bio-concentration studies, reported as a DT50 value in days). For consistency among all pesticide active ingredients, we have chosen to use persistence data from soil studies because many pesticides lack degradation studies in water/sediment systems. The BCF for whole fish is used as a standard. The score (B) for bio-accumulation is obtained according to the table below. Figures in brackets give the weighting factor for the individual property and the total score for each cell of the table is obtained by multiplying these factors together. If the BCF is not available, $\log P_{ow}$ can be used, but in that case the column for the slower rate of purification is used. A low bio-concentration factor (BCF < 100 or $\log P_{ow} < 3$), very rapid purification (DT50 <1 day) or very rapid degradation in soil (DT50 < 1 day) give a nil score for bio-accumulation, but are omitted from the table for clarity. The highest available value is used for bioaccumulation. (Paired values of BCF and purification DT50 should be used, i.e., the pair that gives the highest score is used. For $DT50_{soil}$, the mean value used in scoring for persistence should be used.)

| Persistence in soil, DT50 | BCF: 100-1000 or log $P_{ow}$ 3-4 (1) | | BCF > 1000 or log Pow > 4 (2) | |
|---|---|---|---|---|
| | Purification DT50 | | Purification DT50 | |
| | 1-10 days (0.5) | > 10 days (1) | 1-10 days (0.5) | > 10 days (1) |
| 1-10 days (0.5) | 0.25 | 0.5 | 0.5 | 1 |
| 10-60 days (1) | 0.5 | 1 | 1 | 2 |
| 60-200 days(1.5) | 0.75 | 1.5 | 1.5 | 3 |
| > 200 days (2) | 1 | 2 | 2 | 4 |

**VI. SPECIAL CASES**

Seed treatment agents:

$E = (2T_{bird} + L/2 + 2P + B + 1)^2$

The exposure for earthworms, bees and aquatic organisms is seen as insignificant because of the application method and the scores for these groups are, therefore, set at nil. The risk of exposure for birds is increased and the score, $T_{bird}$, is therefore multiplied by 2. The significance of mobility is halved because the danger of leaching is less when the chemical is bound to seed rather than free in the soil.

Greenhouse pesticides:

E = 1

Greenhouse pesticides are seen as a minor problem so far as environmental exposure is concerned, given correct use. Environmental exposure can, in all probability, be limited to runoff to the environment following spillage or careless use so that the pesticides enter the drainage system or drain through the floor. They are therefore given an environmental index of 1 to take account of the quantity used (related to area).

Micro-biological agents:

E = 1

Micro-biological agents have also been assigned an environmental risk index of 1 so that account can be taken of the quantity used. There are few approved micro-biological agents in Norway at present and they are sold on a limited sale.

**TOXICITY**

The most sensitive organism or toxicity value (LC50/LD50/EC50) from standard laboratory toxicity testing is used for each toxicity variable. If these data are not available, results from other submitted studies may be used.

**EXPOSURE VARIABLES**

Mechanistic models are used to calculate exposure variables in TER's; TER scores are added to fate scores.

When choosing the value for variables of $K_{oc}$ and $DT50_{soil}$, the average of all results from standard laboratory tests is used.

**TOXICITY AND EXPOSURE**

Toxicity/exposure ratios are used and scored., and added to scores for fate processes (e.g., leaching potential and persistence in soil).

**RISK AND USE**

Use is multiplied by the risk index.

**AGGREGATION OF PESTICIDES AND CROPS**

Summed over pesticides.

**USE OF SCORING**

Toxicity and fate are given scores from 1-4 based on a geometric scale.

**TREATMENT OF MISSING DATA**

For toxicity values, you can use alternative endpoints.

**HOW ARE THE RESULTS OF THE INDICATOR PRESENTED?** (give examples)

By calculating the "collective environmental risk index for monitoring over time" for each year, one has an indicator for the change of risk over time.

In Norway, we have chosen to use the mean of the indicator values for the years 1996 and 1997 as a starting point, and have set this to be 100%. Percent is chosen, since the actual indicator values have no intrinsic meaning, but only gives a relative value. A simple graph can be made showing the development from 1996/1997 (100%) to subsequent years.

**LESSONS LEARNED FROM WORKING WITH INDICATORS:**
**obstacles to overcome, successful approaches, benefits and limitations of indicators**

The most difficult obstacle has been the lack of good, simple models to quantify parameters such as operator exposure, runoff, and leaching through drainage systems. In general, it is important not to be too ambitious when developing risk indicator systems, as the systems otherwise will become too complicated. Simplifications of calculations and acceptance of data of inferior quality may be necessary.

It has been difficult to assign weights to reflect the relative importance of different parameters that are not normally considered comparable. Another main problem related to use of the environmental risk indicators is deciding relevant input data when there are large variations, as with degradation times, adsorption coefficients and other parameters that vary with different soil types. We decided to use a mean of standardised laboratory data, but field data may often give a better picture of what really happens when the substance is used.

It is important not to attach too much significance to the final outcome for a single year, but to look at successive years together. It is important to be aware of some of the factors which may be exerting an influence on the results of the index for a particular year, and view this in context with other years (e.g., an announcement of increases in pesticide taxes which causes increased sales in a particular year).

It is important to bear in mind the overall objective of the risk indicators, and to be aware that the systems should not be used in other contexts without considering the need for modifications. For example, our systems are designed to describe the development in health and environmental risk with time on a national level for all our pesticides collectively, and thus may not always describe the characteristics of a single substance well.

The use of risk indicator models must always be followed up by a scientific evaluation, and must only be regarded as a tool for a rough estimation of risk.

Sales data are used to estimate areas treated with an active ingredient. The quantity sold refers to that sold by the importer to the retailer or distributor and are, therefore, an uncertain measure of the quantities actually used in a particular year. Some of the variations from year to year can be due to commercial arrangements of the importers as well as to changes made by the users. The statistics nevertheless give a good picture of consumption in a slightly longer time perspective. In interpreting the movements of the environmental risk index, it is therefore very important not to attach too much importance to the single year, but to look at several successive years together.

**IMPORTANT REFERENCES:**


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**APPENDIX I. Guidelines for calculation of standardised area dose (SAD) of plant protection products.**

Prepared by the Norwegian Crop Research Institute
Approved by the Norwegian Agricultural Inspection Service
Version 1.0

**1. Scope:**

The guidelines apply to all pesticides governed by the Act regarding plant protection products, etc.

**2. Calculation object:**

An SAD (Standardised Area Dose) is set for each approved product. The Norwegian Agriculture inspection Service can choose to look at several products with the same active ingredient as a whole, if these products do not have a corresponding area of application.

**3. Dose basis for each area of application or control purpose:**

Many products can be used in several cultures and for several control purposes and it is therefore necessary to define the decare dosage for each area of application or control purpose. This will then form the basis for calculation of SAD in an evaluation that includes the importance of each area of application. The dosage per decare for each area of application, etc., is stipulated in the following way:

3.1 The highest permitted dosage is used as a basis for calculation of SAD for areas of applicaiton or control purposes where the dosage has been specified as a quantity of the product per area unit.
3.2 In the case of areas of application or control purposes where spraying disperses the product and the dosage has been specified as a utility concentration, and the utility volume per decare has not been specified, this is converted to decare dosage according to the following principles:

Highest permitted quantity of product per 100 litres water x [(no. of litres fluid/decare) / 100] = highest permitted decare dosage

When the label gives no specification of the fluid consumption, this is stipulated on the basis of the normal fluid volume for the relevant area of control.

3.3 In the case of areas of application or control purposes where the dosage has been specified as a quantity per meter row and the utility volume per decare has not been specified, this is converted to decare dosage according to the following principles:

Highest permitted quantity of the product per 1,000 metres row = highest permitted decare dosage.

3.4 In the case of areas of application or control purposes where the dosage has been specified as the quantity per unit of weight of seeds, and the utility volume per decare has not been given, this is converted to decare dosage according to the following principles:

Highest permitted volume product per unit of weight of seeds x number of units of weight of seeds per decare = highest permitted decare dosage

The “number of units of weight of seeds per decare” factor is stipulated on the basis of the mean recommended sow volume and the same volume is used in all products used on the species in question.

3.5 A decare dosage according to the following principles is used for treatment of plants in forest nurseries, if the utility volume per decare has not been specified:

Highest permitted volume of product for 25- plants = highest permitted decare dosage

3.6 In the case of areas of application or control purposes where the dosage has been specified as the quantity of product per pot, this is converted to the decare dosage according to the following principles, if the utility volume per decare has not been given:

Highest permitted volume of product per pot x 50,000 = highest permitted decare dosage

3.7 In the case of areas of application or control purposes where the dosage has been specified as the quantity of product per room volume (air), this is converted to a decare dosage according to the following principles, if the utility volume per decare has not been specified:

Highest permitted volume for 5,000 $m^3$ = highest permitted decare dosage

3.8 In case of split treatment, i.e., a combating strategy where the product volume is divided into two or more part-treatments, the highest permitted total dosage the strategy shall use is the basis for further calculation of SAD.

3.9 In the case of repeated treatment, i.e., a situation where treatment no. 2, 3, etc., depends on the development in the pest’s situation since the previous treatment, and where an assessment of whether treatment shall be repeated or not is made for each treatment, the highest permitted dosage for each treatment shall be used as a basis for further calculation of SAD.

3.10 SAD for “ready-to-use” products is stipulated on the basis of the SAD stipulated for other products wit the same active ingredient approved for occupational use if the “ready-to-use” product in question does not have any area dosage specified on the label.

3.11 In the case of products that cannot be implemented in any of the above-mentioned calculation principles, the Norwegian Agriculture Inspection Service stipulates and SAD based on an estimate.

**4.  Calculation of SAD for a product approved for several areas of application and/or control purposes:**

4.1 In the case of a product approved for seed treatment and spraying purposes, SAD is stipulated on the basis of the areas of applicaiton that involve spraying the product, unless the product in question is mainly used for seed treatment purposes.  Products used for dipping, mixing or watering are placed on an equal footing with seed treatment products here, unless a specific decare dosage has been given on the label.

4.2 In the case of products approved for use on open ground and in greenhouses, SAD is stipulated on the basis of the areas of applicaiton that are on open ground, unless the product in question is mainly used in a greenhouse.

4.3 In the case of a product approved for use for several control purposes in one and the same culture, the highest permitted dosage for the control purpose(s) that are expected to represent most of the consumption in the culture as a whole shall be used as a basis for further calculation of SAD.  The control purpose that represents a minor percentage of the consumption of the product in the culture in question shall not be included in the basis for stipulation of SAD.

4.4 In the case of products approved in several cultures, SAD is stipulated on the basis of the dosage in the largest cultures from a point of view of area, which alone or together are at least 50% of the area in which, according to the label, the product may be used.  Choice of dosage in each culture is made according to the principles mentioned in the item above.  Where product consumption is expected to have a different distribution between cultures than the area distribution between the cultures given in the approved area of application, the main cultures that are expected to represent at least 50% of the consumption of the product shall be used as a basis for calculation of SAD.

**5.  Calculation of SAD for products that have specified special dosages on the label for use in integrated control.**

The dosages recommended used in accordance with the label in integrated control of pests shall not be used as a basis for assessment of SAD, as long as other higher dosages have been specified on the label.

**OECD Survey of National Pesticide Risk Indicators, 1999-2000**

**COUNTRY, MINISTRY**

Norway

Norwegian Agricultural Inspection Service

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**INDICATOR NAME**

Human Health Risk Indicator

**WHEN AND WHY WAS THE INDICATOR DEVELOPED?**

Norway has implemented a national risk reduction action plan concerning the use of plant protection products spanning the years 1998 to 2002. The plan includes a series of different measures and recommendations to reduce the use of pesticides and the risk to human health and the environment. One such measure was the reorganisation of the tax system for plant protection products, by the Norwegian Agriculture Inspection Service (NAIS), to reflect these goals. This green tax is differentiated according to the potential risk to human health and the environment, and the products with the highest potential risk receive the highest tax. Indicators were developed as tools to monitor development in health and environmental risk, and to see if the measures of the action plan have the intended effect on risk reduction.

**HOW HAS THE INDICATOR BEEN USED?**

The indicator is used to produce a “Collective Health Risk Index” for all active ingredients in all plant protection products by year, to show the change in risk over time. This risk indicator is based on potential hazard (inherent properties) as standardised national or international guidelines for the assessment of risks to the users of pesticides have not yet been developed. A simplified estimation of exposure is used, in which the degree of exposure is assessed according to the type of formulation and the method of application (distribution). This information is taken from approved product labels.

**DESCRIPTION OF THE INDICATOR:**

**TYPES OF RISK**

Human Health

**ROUTES OF EXPOSURE**

Exposure to users during mixing/loading and application (not explicit).

**VARIABLES INCLUDED**

**Pesticide Active Ingredient:**
(i) Physicochemical and fate properties:

not used

(ii) Toxicity:

risk phrases, label statements (determined from regulatory risk assessments)

**Pesticide use:**

formulation type
method of application (distribution, dispersion)
area of application (decares; 1/10 of a hectare)
SAD (Standardised area dose; L or kg/ha)

**Soil/site data:**

not used

**Fate:**

not used

**METHODS OR FORMULAE FOR COMBINING VARIABLES**:
**I. Classification of health risk**

The inherent properties of pesticide products are classified according to the risk phrases that appear on the product labels. It is important to note that it is the whole product that is labeled and that the concentrations of the active ingredients have been taken into account. The concentration of active ingredients is, therefore, irrelevant in the following assessment of health risk.

| **Symbol** | **Very Toxic**<br>**T+** | **Toxic/Corrosive**<br>**T/C** | **Harmful**<br>**Xn** | **Irritant**<br>**Xi** |
|---|---|---|---|---|
| Points | 60 | 20 | 10 | 5 |
| Risk phrases indicating acute toxicity | R 26 (+3)<br>R 27 (+5)<br>R 28 | R 23 (+3) R 34<br>R 25 (+5) R35 (+5)<br>R 25 | R 20 (+3)<br>R 21 (+5)<br>R 22<br>R 65 | R 36<br>R 37<br>R 38 |
| Risk phrases indicating chronic | R 39 | R 39<br>R 45 | R 33<br>R 40 | R 41 (+5)<br>R 43 |

| | | | | |
|---|---|---|---|---|
| toxicity (x 5) | (Equals 300 points) | R 49<br>R 46<br>R 48/23 (+3)<br>R 48/24 (+5)<br>R 48/25<br>R 60<br>R 61<br><br>(Equals 100 points) | R 42<br>R 215<br>R 48/20 (+3)<br>R 48/21 (+5)<br>R 48/22<br>R 62 (+5)<br>R 63 (+5)<br>R 64 (+5)<br><br>(Equals 50 points) | (Equals 25 points) |

The risk phrases are grouped according to the symbol of danger that they represent - Irritant (Xi), Harmful (Xn), Toxic (T) or Very Toxic (T+). Corrosive (C) is placed in the same group as the toxic symbol. Each group is then designated a certain amount of points, 5, 10, 20 or 60, respectively, for the above-mentioned symbols of danger. These specific numbers are used to insure that the final risk indices are well scattered along a large scale, and that they give a somewhat realistic image of the increase in relative danger from one group to another. In other words, we consider risk phrases classified as harmful to imply a doubling of the risk compared to risk phrases classified as irritants, and risk phrases classified as toxic imply that they represent twice the risk compared to risk phrases in the harmful group. Risk phrases in the very toxic-group are considered to represent such a great danger of serious effects that we have chosen to give them three times the points as the ones classified as toxic.

The risk phrases in each group are categorized again according to whether they represent acute or chronic effects (or in some cases, effects that can become chronic even if the exposure was of a short duration, such as allergies, serious eye damage, or damage to the unborn child). We consider chronic effects to be more serious than acute effects and the risk phrases representing these effects are thus weighted more heavily by multiplying the points in each group by 5 (in other words, “chronic risk phrases” are given 25, 50, 100 and 300 points for the groups corresponding to Irritant, Harmful, Toxic and Very toxic symbols, respectively).

For the users of plant protection products, dermal toxicity is considered more dangerous (the risk of exposure is higher) than oral toxicity and is thus also weighted more heavily by adding 5 points to the point total they already have. This is the case for the risk phrases R21, R24, R27, R48/21 and R48/24. Inhalation toxicity is also considered more dangerous and is weighted by adding an extra three points to the risk phrases R20, R23, R26, R48/20 and R48/23.

Other risk phrases are also weighted with 5 additional points because of the seriousness of the effects they describe, such as “causes severe burns” (R35), “risk of serious eye damage” (R41) and effects on reproduction categorized as harmful (R62, R63 and R64).

The total index for the health risk for a particular product is calculated by adding the points for all the risk phrases that appear on the product label.

Products having no labelling are given 0.1 points.

**II. Exposure**

Typical situations in which the user can be exposed to pesticides are while mixing/loading (diluting) the product, during application (often spraying) of the diluted product, and when handling treated plant material. An assessment is made for each product of whether exposure is low or high during mixing/loading and during application. Greater emphasis is placed on exposure when mixing/loading than to exposure during application, as in the former, one works with the concentrated product and it is easy to spill product. Weighting factors for low and high exposure when mixing/loading are 1 and 3, respectively, while those for application are 1 and 2, respectively.

- Mixing/loading:

During mixing, exposure is dependent on the concentration of the active ingredients in the product, the number of times the product is handled during mixing and diluting, and the type of formulation. The type of formulation has great significance in this regard, and is weighted accordingly.

Examples of formulations which can entail low exposure while mixing are ready-to-use products, gels, granules, water soluble tablets, and formulations in water soluble bags. Seed treatment agents also have a low factor because practically all treatment is undertaken in closed systems where the workers' risk of exposure is low.

Examples of formulations which can entail high exposure while mixing are emulsions, powders, suspensions, and other soluble concentrates.

- Application:

During application, the degree of exposure will be dependent on conditions such as the concentration of the active ingredients in the diluted product, the application rate, the size of the area to be sprayed area, and, particularly, the method of application. The application is also dependent on the crop in which the pesticide is used, and for products approved for use on several crops the same rule is used as for the calculation of standardised area dose (SAD). That is to say, one uses the crop or crops which together make up 50% or more of the area of application. SAD is the standardised area dose which is set for all pesticides by The Norwegian Crop Research Institute. The area of application is the number of decares (1/10 hectare) of the crop which is to be treated. Guidelines for calculation of the SAD are given in Appendix I. In cases where there are several large crops, the one that entails the highest potential degree of exposure is used.

Examples of application methods which can entail low exposure are:

- open ground: granulate spreader; tunnel spraying in forest nurseries; field spraying with a spreader, assess in relation to working pressure (high working pressure produces small droplets and increases the workers' degree of exposure)
- greenhouse: cold mist generator, smoking

Examples of application methods which can entail high exposure are:

- open ground: tractor-mounted mist spraying, dressed seed
- open ground/greenhouse: back-pack mist spraying and manual pressure spraying
- greenhouse: hot mist generator

**III. Health Risk Index for each Pesticide Product (Product Risk Index)**

The factor for mixing/loading is multiplied by the factor for the method of application which, together, give a crude measure of the relative exposure to the user for a particular spraying operation under standard conditions (e.g., wind speed, consumption, etc.). An overall risk index is obtained by multiplying the exposure factors by the factor for the health hazard class. This risk index does not take into account the total amount of a pesticide active ingredient used by a particular farmer during each treatment (i.e., consumption), but measures the health risk per kilogram or per litre of the product. Seed treatment agents and adhesives are given an overall risk index of 1. As of April 2000, the approved plant protection products in Norway range from 0.1 for the products representing the lowest risk to health, to 888 for a product that is very toxic and has a high risk or exposure.

**IV. Index for Monitoring Changes Over Time**

First, a relative index is developed to reflect the risk of pesticide products to human health for the users during the course of a year. This can be achieved by calculating the indicator for the risks involved during a single use and mltiplying this by the number of uses during the year.The Product Risk Index for each pesticide product includes an exposure class which crudely expresses the risk of exposure compared with any other use of pesticides. One can come closer to quantifying the exposure to a pesticide by multiplying the "exposure class" by the consumption of pesticide in a single application. Consumption can be estimated by using the expression (SAD x Area of application). The following expression is, therefore, taken to be an appropriate indicator for the risk associated with a single application:

(Product Risk Index) x (SAD x Area of application)

By multiplying this expression by the number of times the product is used in the course of the year, we find a risk indicator for the total of the year's usage. The number of applications in the course of a year can be determined by the following expression:

(Annual consumption of product in kilos (or litres)) / (SAD x Area of application).

After multiplication and simplification, the equation becomes:

**Health Risk Indicator$_i$** = (Product Risk Index) x (Annual consumption of product, in kg or litres)

where i = a particular pesticide product

This expression is an indicator which crudely expresses the health risk involved in the use of the product, taking into account exposure, extent of use and inherent properties. This indicator lacks a reliable correlation with the number of users who are exposed over the AOEL (Acceptable Operator Exposure Level) and, perhaps, says little about the risk associated with the product apart from when it is actually in use.

The "health risk indicators" for each individual product are then added together for each year to obtain a collective health risk index which can be used to monitor changes over time:

**Collective health risk index** = Health risk indicator$_1$ + Health risk indicator$_2$ + ..... Health risk indicator$_i$

As the collective health risk index is intended to include all approved pesticides, the phasing out of small products will have little effect on it while for products which are widely used even a small alteration of the formulation may have a significant effect on the index. Dilution or redesign of the formulation can lower the "product's health risk index". A change of the application rate will affect the quantity used.

**TOXICITY**

A single factor is determined for each product depending on risk phrases on labels and, therefore, the Health Hazard Class.**EXPOSURE VARIABLES**

Factors for exposure during mixing/loading and exposure during application are multiplied.

**TOXICITY AND EXPOSURE**

Factors for each are multiplied.

**RISK AND USE**

Use (consumption, i.e., SAD x area of application) is multiplied by the risk index.

**AGGREGATION OF PESTICIDES AND CROPS**

Summed over all pesticides.

**USE OF SCORING**

Variables are assigned factors depending on low or high risk, i.e., health hazard (ranging from 0.1 to 888), exposure during mixing/loading (1 or 3), and exposure during application (1 or 2).

**TREATMENT OF MISSING DATA**

When there is inadequate documentation on toxicity, the product is placed in a class which would assign it a moderate degree of toxicity.

**HOW ARE THE RESULTS OF THE INDICATOR PRESENTED?**

By calculating the "collective health risk index for monitoring over time" for each year, one has an indicator for the change of risk over time. This can be shown using a simple (x, y) graph.

**LESSONS LEARNED FROM WORKING WITH INDICATORS:**
**obstacles to overcome, successful approaches, benefits and limitations of indicators**

The most difficult obstacle has been the lack of good, simple models to quantify parameters such as operator exposure. In general, it is important not to be too ambitious when developing risk indicator systems, as the systems otherwise will become too complicated. Simplifications of calculations and acceptance of data of inferior quality may be necessary.

It has been difficult to assign weights to reflect the relative importance of different parameters that are not normally considered comparable.
It is important not to attach too much significance to the final outcome for a single year, but to look at successive years together. It is important to be aware of some of the factors which may be exerting an influence on the results of the index for a particular year, and view this in context with other years (e.g., an announcement of increases in pesticide taxes which causes increased sales in a particular year).

It is important to bear in mind the overall objective of the risk indicators, and to be aware that the systems should not be used in other contexts without considering the need for modifications. For example, our systems are designed to describe the development in health and environmental risk with time on a national level for all our pesticides collectively, and thus may not always describe the characteristics of a single substance well.

The use of risk indicator models must always be followed up by a scientific evaluation, and must only be regarded as a tool for a rough estimation of risk.

Sales data are used to estimate areas treated with an active ingredient. The quantity sold refers to that sold by the importer to the retailer or distributor and are, therefore, an uncertain measure of the quantities actually used in a particular year. Some of the variations from year to year can be due to commercial arrangements of the importers as well as to changes made by the users. The statistics nevertheless give a good picture of consumption in a slightly longer time perspective. In interpreting the movements of the environmental risk index, it is therefore very important not to attach too much importance to the single year, but to look at several successive years together.

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## APPENDIX I. Guidelines for calculation of standardised area dose (SAD) of plant protection products.

Prepared by the Norwegian Crop Research Institute
Approved by the Norwegian Agricultural Inspection Service
Version 1.0

### 1. Scope:

The guidelines apply to all pesticides governed by the Act regarding plant protection products, etc.

### 2. Calculation object:

An SAD (Standardised Area Dose) is set for each approved product. The Norwegian Agriculture inspection Service can choose to look at several products with the same active ingredient as a whole, if these products do not have a corresponding area of application.

### 3. Dose basis for each area of application or control purpose:

Many products can be used in several cultures and for several control purposes and it is therefore necessary to define the decare dosage for each area of application or control purpose. This will then form the basis for calculation of SAD in an evaluation that includes the importance of each area of application. The dosage per decare for each area of application, etc., is stipulated in the following way:

3.1 The highest permitted dosage is used as a basis for calculation of SAD for areas of applicaiton or control purposes where the dosage has been specified as a quantity of the product per area unit.

3.2 In the case of areas of application or control purposes where spraying disperses the product and the dosage has been specified as a utility concentration, and the utility volume per decare has not been specified, this is converted to decare dosage according to the following principles:
Highest permitted quantity of product per 100 litres water x [(no. of litres fluid/decare) / 100] = highest permitted

decare dosage

When the label gives no specification of the fluid consumption, this is stipulated on the basis of the normal fluid volume for the relevant area of control.

3.3 In the case of areas of application or control purposes where the dosage has been specified as a quantity per meter row and the utility volume per decare has not been specified, this is converted to decare dosage according to the following principles:

Highest permitted quantity of the product per 1,000 metres row = highest permitted decare dosage.

3.4 In the case of areas of application or control purposes where the dosage has been specified as the quantity per unit of weight of seeds, and the utility volume per decare has not been given, this is converted to decare dosage according to the following principles:

Highest permitted volume product per unit of weight of seeds x number of units of weight of seeds per decare = highest permitted decare dosage

The “number of units of weight of seeds per decare” factor is stipulated on the basis of the mean recommended sow volume and the same volume is used in all products used on the species in question.

3.5 A decare dosage according to the following principles is used for treatment of plants in forest nurseries, if the utility volume per decare has not been specified:

Highest permitted volume of product for 25- plants = highest permitted decare dosage

3.6 In the case of areas of application or control purposes where the dosage has been specified as the quantity of product per pot, this is converted to the decare dosage according to the following principles, if the utility volume per decare has not been given:

Highest permitted volume of product per pot x 50,000 = highest permitted decare dosage

3.7 In the case of areas of application or control purposes where the dosage has been specified as the quantity of product per room volume (air), this is converted to a decare dosage according to the following principles, if the utility volume per decare has not been specified:

Highest permitted volume for 5,000 $m^3$ = highest permitted decare dosage

3.8 In case of split treatment, i.e., a combating strategy where the product volume is divided into two or more part-treatments, the highest permitted total dosage the strategy shall use is the basis for further calculation of SAD.
3.9 In the case of repeated treatment, i.e., a situation where treatment no. 2, 3, etc., depends on the development in the pest’s situation since the previous treatment, and where an assessment of whether treatment shall be repeated or not is made for each treatment, the highest permitted dosage for each treatment shall be used as a basis for further calculation of SAD.

3.10 SAD for “ready-to-use” products is stipulated on the basis of the SAD stipulated for other products wit the same active ingredient approved for occupational use if the “ready-to-use” product in question does not have any area dosage specified on the label.

3.11 In the case of products that cannot be implemented in any of the above-mentioned calculation principles, the Norwegian Agriculture Inspection Service stipulates and SAD based on an estimate.

**4. Calculation of SAD for a product approved for several areas of application and/or control purposes:**

4.1 In the case of a product approved for seed treatment and spraying purposes, SAD is stipulated on the basis of the areas of applicaiton that involve spraying the product, unless the product in question is mainly used for seed treatment purposes. Products used for dipping, mixing or watering are placed on an equal footing with seed treatment products here, unless a specific decare dosage has been given on the label.

4.2 In the case of products approved for use on open ground and in greenhouses, SAD is stipulated on the basis of the areas of applicaiton that are on open ground, unless the product in question is mainly used in a greenhouse.

4.3 In the case of a product approved for use for several control purposes in one and the same culture, the highest permitted dosage for the control purpose(s) that are expected to represent most of the consumption in the culture as a whole shall be used as a basis for further calculation of SAD. The control purpose that represents a minor percentage of the consumption of the product in the culture in question shall not be included in the basis for stipulation of SAD.

4.4 In the case of products approved in several cultures, SAD is stipulated on the basis of the dosage in the largest cultures from a point of view of area, which alone or together are at least 50% of the area in which, according to the label, the product may be used. Choice of dosage in each culture is made according to the principles mentioned in the item above. Where product consumption is expected to have a different distribution between cultures than the area distribution between the cultures given in the approved area of application, the main cultures that are expected to represent at least 50% of the consumption of the product shall be used as a basis for calculation of SAD.

**5. Calculation of SAD for products that have specified special dosages on the label for use in integrated control.**

The dosages recommended used in accordance with the label in integrated control of pests shall not be used as a basis for assessment of SAD, as long as other higher dosages have been specified on the label.