Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 4 Human toxicology; risk evaluation human exposure
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Category: biocides

1. GENERAL INTRODUCTION

This chapter (NL exposure part) describes the methodology for estimation of the health risk resulting from primary and secondary exposure for the NL framework.

2. NL FRAMEWORK

The NL framework describes the evaluation and authorisation of biocides based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the Member States of the EU on 14 May 2000. The pesticide that contains such substances may be authorised if the testing criteria laid down in the Wgb (Plant Protection Products and Biocides Act 2007) [1] are met. The product is tested against the Plant Protection Products and Biocides Regulations (Rgb) [2]. The evaluation dossiers must meet Annex IIA, IIB, IIIA and IIIB of Directive 98/8/EC.

The NL framework describes the dossier requirements and evaluation methodologies for which specific rules apply in the national testing framework or when the national testing framework has been elaborated in more detail than the EU framework.

The NL procedure described in this chapter is used for evaluation of a substance for inclusion in Annex I in case no European procedure has been described.

2.1. Introduction

In general the data requirements for active substance and product, and the evaluation methodology do for the aspect risk evaluation human exposure not deviate from the EU framework. The NL procedure is only described where no EU procedure has been described. For the aspect Human toxicology, human exposure, the evaluation methodology in the RGB differ for some points from the EU framework (see paragraph 2.3). The NL procedure is only described where no EU procedure has been described.

2.2. Data requirements

There is no difference with data requirements in EU framework. The EU data requirements for human exposure are described in Chapter 4 human exposure, EU part.

2.3. Risk assessment

For the evaluation methodology used in the national authorisation reference is made to the Plant Protection Products and Biocides Regulations (Rgb). Article 3.5 (new and existing substances) and Article 10.3 (existing substances not including in Annex I) describes the authorisation criteria. The texts specifically referring to the risk for professional operators is given below in the grey frame (in Dutch) :

Artikel 3.5. Berekening humaan-toxicologisch risico als gevolg van professioneel gebruik

1. Een biocide heeft geen onaanvaardbare effecten op de gezondheid van de mens, bedoeld in artikel 49, eerste lid, onderdeel b, onder 3°, van de wet, indien bij de toepassing van bijlage VI, punten 55 tot en met 74, bij richtlijn 98/8/EG blijkt dat voor alle omstandigheden waarbij als gevolg van professioneel gebruik blootstelling aan de biocide kan optreden, een risico-index is berekend die ten hoogste gelijk is aan 1.

2. De risico-index wordt voor elke voor de toelating relevante blootstelling berekend door de blootstelling als gevolg van professioneel gebruik aan de biocide te delen door de gezondheidskundige norm als bedoeld in de punten 20 tot en met 30 en 34 van de gemeenschappelijke beginselen van bijlage VI bij richtlijn 98/8/EG.

3. Indien het mengen van een biocide met andere stoffen, middelen of preparaten wordt voorgeschreven zijn het eerste en tweede lid van overeenkomstige toepassing op het mengsel.

Artikel 10.3. Beoordeling van een aanvraag als bedoeld in artikel 121 van de wet

Het college geeft in de beoordeling van een aanvraag omtrent toelating van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet, ongeacht voor welke vorm van toelating als bedoeld in hoofdstuk 9 van de wet een aanvraag is ingediend, een oordeel over elk onderdeel van bijlage VI bij richtlijn 91/414/EEG onderscheidenlijk bijlage VI bij richtlijn 98/8/EG met inachtneming van de specifieke bepalingen die voor elke vorm van toelating bij wet of bij besluit zijn gegeven.

The EU evaluation methodology is also applied in the Netherlands for comparable uses. This means that at the national level exposure calculations as well as risk assessments, including the tiered approach, follow EU guidances. The Netherlands, however, has further elaborated/supplemented the guidances for some aspects on the basis of experience and expert judgement.
These further elaborations/supplements are presented in the text below.

2.3.1 Exposure calculations

Experience shows that as regards the choice of an AEL or MOE approach, the AEL approach can best be used The MOE approach is a dated approach and not very useful for route-to-route extrapolation.

In addition, the Netherlands drawn up exposure estimates for antifouling products on the basis of literature data. This NL model antifouling is added in appendix 2 (including the differences between NL model AF and the EU approach based on the HEEG opinion antifouling painting model (non)-professional brushing and rolling (TMII 2008) and the model for professional airless spraying and the model for (non)-professional manual spraying described in the TNsGs on human exposure 2002 and 2007. In the EU there are already Competent Authority reports for PT21 discussed at technical meetings. A harmonised approach is still not available.

For the exposure assessment methology used in the national authorisation reference is made to the Plant Protection Products and Biocides Regulations (Rgb). Article 3.6, 3.12 and bijlage III (new and existing substances) of the RGB describes the authorisation criteria. The text from the Rgb specifically referring to the exposure of the professional operators is given below in the grey frame (in Dutch):

Artikel 3.6. Blootstelling als gevolg van professioneel gebruik

1. Het college schat de kwantitatieve blootstelling aan de biocide, bedoeld in de punten 31 tot en met 33 van Bijlage VI bij richtlijn 98/8/EG, zonder rekening te houden met het effect van persoonlijke beschermingsmaatregelen en met gebruikmaking van een model uit een daartoe aangewezen richtsnoer of in het geval de biocide een aangroeiwerende verf is, het NL-model aangroeiwerende verf.

2. Bij toepassing van punt 24 van bijlage VI bij richtlijn 98/8/EG wordt als goede reden tot bezorgdheid aangemerkt een risico-index die groter is dan 1 bij enige vorm van blootstelling zonder rekening te houden met risicobeheersmaatregelen, bijzondere voorwaarden of beperkingen.

3. Het college gaat bij de toepassing van bijlage VI bij richtlijn 98/8/EG voor wat betreft persoonlijke beschermingsmaatregelen, uit van bijlage III (II BGB).

4. In aanvulling op het derde lid hanteert het college voor wat betreft persoonlijke beschermingsmaatregelen, de beschermingsfactor zoals die is gemeten, wanneer blijkt dat de gemeten blootstelling met toepassing van de voorgestelde beschermende kleding en apparatuur onder de geldende gebruiksomstandigheden en bij het juiste gebruik, anders is dan bij bepaling van de blootstelling overeenkomstig het eerste lid.

5. De minister stelt de modellen, genoemd in het eerste lid, in een bijlage bij deze regeling vast.

As described under EU framework, exposure is initially estimated for the unprotected operator in normal working clothes (Tier I). The effect of protective measures will, where necessary, be included in a later stage of the assessment. Surrogate exposure values with PPE are available in most models. Potential hand exposure can be calculated from actual measured exposure data (see agreement TM I 2008 in MOTA). Default values for PPE can be used in other cases. For secondary exposure it is investigated whether protective measures can be prescribed. In principle, if there is no safe use for the non-professional user without PPE the product cannot be authorised.
The proper use of suitable protective clothing for non-professional use is the personal responsibility of the non-professional operator.
NL uses the default values described in Appendix III of the Rgb for the effectiveness of protective measures.
The text from the Rgb specifically referring to protection measurements and protection factors of personal protective equipment for is given below (in Dutch):

Artikel 3.12. Voorschriften inzake bescherming voortvloeiend uit de richtlijn tot opneming van de werkzame stof

Het college neemt een beschermingsmaatregel die is vermeld bij de richtlijn tot opneming van een werkzame stof in bijlage I bij richtlijn 98/8/EG in de gebruiksvoorschriften op voor zover deze beschermingsmaatregel voortvloeit uit de beoordeling van de desbetreffende biocide en dit in overeenstemming is met de beoordeling als bedoeld in artikel 12 van het besluit.

Bijlage III. Beschermingsfactoren van persoonlijke beschermingsmiddelen (bijlage II BGB geworden)

Persoonlijke beschermingsmaatregel	*Toegekende beschermingsfactor*
Halfgelaatsmasker en volgelaatsmasker met filtertype 2	*10*
Aangedreven volgelaatsmasker met filtertype 2	*20*
Aangedreven volgelaatsmasker met filtertype 3	*40*
Lichaamsbedekking toepasser materiaaltype CEN 3 of 4 (niet voor handen, hoofd en nek)	*10*
Lichaamsbedekking werkenden in / aan gewas / behandelde ruimte (niet voor handen, hoofd en nek)	*5*
Handschoenen, niet-vaste middelen	*10*
Handschoenen, vaste middelen	*20*
Laarzen (chemisch resistent)	*10*
Gesloten spuitcabines	*10*

For those PPE with a protection factor greater 10, Article 3.13 van de Plant Protection Products and Biocides Regulations (Rgb) describes in which cases the use of a protection factor greater than 10 is allowed. The text from the Rgb is given below (in Dutch):

Artikel 3.13. Beschermingsfactor meer dan tien

1. Het college neemt alleen bij de toelating van biociden als bedoeld in de artikelen 30 en 31 van het besluit alsmede bij biociden van productsoort 21 als bedoeld in bijlage V bij richtlijn 98/8/EG een voorschrift op dat leidt tot een persoonlijke bescherming met een beschermingsfactor van meer dan tien als bedoeld in bijlage III (II BGB).

2. In afwijking van het eerste lid kan het college bij het mengen, vullen en toepassen van vaste biociden een persoonlijke bescherming voorschrijven met behulp van handschoenen, als bedoeld in bijlage III (II BGB) met een beschermingsfactor 20.

This means that specifically for antifoulings, use of suitable respiration protection (compressed mask; air supplied respirator with full face visor), gloves, protective clothing (double coveralls with hood) and boots results in a dermal exposure reduction of 99%. This extent of reduction is taken into account in the risk assessment for national authorisations, see appendix 1 [3, 4].

The Common Principles distinguish between exposure of non-professional users and professional users (primary exposure); it is stated that where for non-professional users wearing PPE would be the only way to restrict exposure, the product should not normally be authorised.

This means that in the Netherlands, for non-professional uses, as indicated in the TNsG on human exposure (Part 2.2.3), the effect of PPE in the risk assessment is not taken into account.
For professional users, however, different forms of PPE can be prescribed to reduce dermal and respiratory exposure. Monitoring of the use of PPE by this group has been provided for (supervision employer/authorities (AI)).

At the TMIII 2009 an HEEG proposal is presented on default protection factors for protective clothing and gloves. It can be concluded that the default values are approximately the same as in the Rgb.

2.4. Approval

The assessment of the risk has been laid down in regulations. The Wgb (Plant protection products and biocides Act) 2007 [1] stipulates in Art. 49 (1) (b3 and b4): “a biocide may only be authorised where this has no unacceptable effect on men and animal, directly or via residues”.

The evaluation of products on the basis of existing active substances already included in Annex I or new substances has been laid down in the Plant Protection Products and Biocides Regulations (Rgb) [2] where it is elaborated that these products are evaluated according to the national specific criteria.

Another provision is that a biocide will only be authorised or registered where the following is adequately taken into account:
a. all conditions under which the biocide is normally used,
b. the manner in which the biocide-treated material can be used, and
c. the consequences of the use and removal of the biocide.

The evaluation of products based on old substances already included in Annex I, or new substances, has been laid down in the Decision Common Principles Evaluation Biocides (Bgbbbio) which elaborates the evaluation of such products in accordance with the Common Principles (UP).

2.4.1 Criteria and trigger values

The starting points (testing framework with criteria and trigger values) for evaluation as regards the effects on humans in NL framework are approximately the same as in EU framework (see for differences paragraph 2.4 Derivation endpoints and limit values (NL specific procedures) in Chapter 4, human exposure, NL part.

2.4.2 Testing

According to Principle 15 of the Common Principles, in support of Directive 98/8/EG, a risk assessment is always carried out for a biocide, also where a biocide has not been classified.

Testing is based on the fact that primary and secondary exposure are sufficiently safe for humans on the basis of a risk assessment where the most critical effect is taken into account. The assessment is based on the fact that the potential exposure may not exceed the health based reference value, usually the AEL, for which a so-called tiered approach is applied as presented in artikel 3.7 Gezondheidskundige norm lid. 6 and 7 (see NL tox part). For simplified extension request, authorisations at het request of the ministry and for existing substances not yet included in Annex I 3.7, zevende lid will not be applied (see the text from the relevant articles 10.9, 3.11 and 10.1 from the Rgb given below (in Dutch)):

Artikel 3.7. Gezondheidskundige norm

6. Wanneer uit de risicobeoordeling bedoeld in bijlage VI bij richtlijn 98/8/EG blijkt dat de risico-index zonder gebruik van persoonlijke beschermingsmiddelen groter is dan 1, wordt de gezondheidskundige norm met uitzondering van die voor kankerverwekkende effecten zonder toxicologische drempelwaarde, opnieuw berekend met behulp van de methode allometrische extrapolatie en wordt de risico-index opnieuw bepaald.

7. Wanneer na toepassing van het zesde lid de risico-index bij de dermale blootstellingsroute groter is dan 1, wordt bijlage IIB, puntl 6.4, bij richtlijn 98/8/EG toegepast. Het college bepaalt de risico-index bij de dermale blootstellingsroute met behulp van de experimenteel verkregen nieuwe informatie opnieuw.

- For simplified extension requests:

Artikel 10.9. Vereenvoudigde uitbreidingstoelating biociden

1. Artikel 3.7, zevende lid, is niet van toepassing bij een beoordeling van een aanvraag tot uitbreiding van de toepassing als bedoeld in artikel 126, eerste lid, van de wet

- For authorisation at het request of the ministry:

Artikel 3.11. Beoordeling toelating op aanvraag van de minister

Artikel 3.7, zevende lid, is niet van toepassing bij een beoordeling van een aanvraag tot toelating van de minister als bedoeld in artikel 55 van de wet.

- For existing substances not yet included in Annex I:

Artikel 10.1. Werkingsgebied

De hoofdstukken 2 en 3 van deze regeling zijn van toepassing bij besluiten op grond van hoofdstuk 9 van de wet met uitzondering van de artikel 2.7, derde en zevende lid, en 3.7, zevende lid

In the EU the tiered approach is described in Ch 4.1.TNsG on Annex I inclusion (see chapter human exposure EU part). In the EU refinement of the risk assessment can be based on several refinement situations as allometric scaling, new dermal absorption data, route specific mitigation measures (as PPE) with no evident preference for one refinement method.

In the Netherlands the tiered approach has an evident purpose to diminish the use of PPE by professional users. Therefore, the Netherlands prefer to use the allometric extrapolation in the first step to refine the risk assessment. New dermal absorption data will be used in the second step. PPE will be used as no further refinement is possible. To diminish the use of PPE available exposure data based on use in practice could be used. The tiered approach can also be used for non-professionals taken into account that the product cannot be authorised as only by using PPE safe use is identified.

Where the exposure would still exceed the AEL, the product cannot be authorised.

2.5 Developments

The developments in EU framework will also affect exposure calculations and risk evaluations in NL framework in view of the aim of the greatest possible harmonisation. The Netherlands will be involved in the preparation of new (User) Guidance documents.

3. APPENDICES

Appendix 1 Method for exposure estimation for antifouling agents

In the NL the NL model for antifouling as described below is used. PT21 is not discussed in the TM until now. The different approaches NL model AF and the EU approach are compared.

NL model antifouling
Exposure may occur when using biocides. The most important exposure moment is the application of the product. During this activity the product can be taken up in the body by respiration, dermal absorption and ingestion. Oral exposure is not taken into account on the assumption that oral exposure does not need to occur if adequate personal hygiene is observed. Exposure estimation of an unprotected worker/consumer by means of models is elaborated below. The starting points for the exposure estimation are presented first, followed by further information about the surrogate exposure values.

STARTING POINTS EXPOSURE ESTIMATION:

Specific data for the formulation
Concentration active substance (in %)
Appearance of the product
Pack size
Application
Recommended layer thickness in µm
Spreading rate in m^2/L
Relative density formulation (basis) in kg/l

Assumptions and normalised values:
For the evaluation calculations, assumptions are made which justify adjustment on the basis of representative information. It is assumed that for rolling, brushing and spraying two paint layers are always applied with a recommended drying period as interval. A dry layer thickness of X µm is recommended for applying one paint layer, for which a spreading rate of Y m^2/L is indicated. The default value is that 1000/Y ml paint per square metre is required to apply a recommended paint layer thickness of X µm in one pass.

The following assumptions are made as regards treated surface and application rate:

<u>Brushing and rollling (professional/non-professional)</u>
Application: manual brushing.
Per working day: 1 - 6 hours application
60 - 180 m^2 treated.

<u>Airless spraying (professional)</u>
Application: airless spraying.
Per working day: 6 hours application

<u>Manual spraying (professional)</u>
Application: manual spraying.
Per working day: 1 - 6 hours application
200 - 1200 m^2 treated.

Data calculated with the values above

Dose formulation per m^2:	…g/m^2
Dose active substance per m^2:	… g a.s./m^2
1 L formulation = g formulation: in which % a.s. =	… g a.s./L
Number of handlings mixing/loading:	… (or n.a. (not applicable): formulation is supplied ready for use)

SURROGATE EXPOSURE VALUES USED

Brushing and rolling

Based on the available data about exposure to paints, no further distinction needs to be made between mixing and application of paint. Exposure during mixing is considered negligible.

No common models are available to estimate exposure during brushing of the formulation. A surrogate exposure value for dermal exposure of 5 ml paint/hour is derived on the basis of a published study (Roff [5]) into the exposure during brushing of a wood preservative.

This approach may possibly overestimate the professional dermal exposure because the study concerns non-professional users.

Respiratory exposure may be negligible, depending on the vapour pressure of the active substance.

AIRLESS SPRAYING [3,4]

Surrogate exposure values have been derived for airless spraying of paint by a professional worker. These values enable drawing up exposure estimates for other paints (taken into account the need of a letter of access to the study from which the surrogate exposure values are derived) with comparable use scenario and protection regime, where the following (round) values can be applied for a 6-hour (working day). Here, only the painter is relevant.

- Potential respiratory exposure17 mg paint/m3 ≈	1.63 mg paint/hour
- Potential body exposure excluding hands	175 g paint
- Potential hand exposure	no data
- Actual body exposure (1 clothing layer)	7 g paint (use of coveralls)
- Actual body exposure (2 clothing layers)	1 g paint (use of clothing underneath coveralls)
- Actual hand exposure	2 g paint

As regards the partition of the paint over the body it is assumed that 50% of the total exposure lands on the body and 50% on the hands. Because potential data for hands are not available, a dermal exposure including hands of 350 g paint is assumed. Furthermore, a respiration rate of 1.6 L/min is assumed.

No further distinction needs to be made between application and loading of the paint.

Calculations based on the above are given below.

Without use of exposure reducing measures

Estimated exposure (mg a.s.)= surrogate exposure value (mg/hour) x percentage a.s. x task duration per day (hours)

Dermal exposure:	58333 mg/hour x …% x 6 = …mg a.s./day
Respiratory exposure:	1.63 mg paint/hour x …% x 6 = …mg a.s./day

With use of exposure reducing measures

one clothing layer

Estimated exposure (mg a.s.)= surrogate exposure value (mg/hour) x percentage a.s.x task duration per day (hours)

Dermal exposure: 1500 mg/hour x …% x 6 = … mg a.s./day
Respiratory exposure: unknown

two clothing layers
Estimated exposure (mg a.s.)= surrogate exposure value (mg/hour) x percentage a.s.x task duration per day (hours)
Dermal exposure: 500 mg/hour x …% x 6 = … mg a.s./day
Respiratory exposure: unknown

MANUAL SPRAYING
The Biocides Steering Group (BSG) derived a model for the professional operator from data on manual spraying of liquid biocides, for activities such as wood preservation.
Assuming that this study is a representative estimate of the actual situation, the following values are derived for exposure. These are 984 mg/kg active substance and 6.23 mg/m^3/kg active substance for dermal and respiratory exposure, respectively.

Estimated exposure (mg a.s.)= surrogate exposure value (mg/kg) x dose (kg a.s./m^2) x treated surface (m^2)
Dermal exposure: 984 mg/kg x (…) x (200–1200) m^2 = … mg a.s./day
Respiratory exposure: 6.23 mg /m^3 /kg x (…) x (200–1200) m^2 = ...mg a.s./day

Appendix 2 Differences between NL model AF and the EU approach based on the HEEG opinion antifouling painting model (non)-professional brushing and rolling (TMII 2008) and the model for professional airless spraying and the models for (non)-professional manual spraying described in the TNsGs on human exposure 2002 and 2007. For only one substance PT21 "Tralopyril RMS UK" the CAR is presented on CIRCA. The EU approach is not harmonised until now.

For the **non-professional brushing and rolling** the NL-model AF used the 5 ml fluid/hour as surrogate exposure values for dermal exposure based on Roff 1997 (90th percentile). For the non-professional use of brushing and rolling several models are described in the TNsG on human exposure 2002/2007: consumer painting model 2, 3 and 4. Model 2 is based on Roff 1997 with 50th and 75th percentiles with 3 g/hour (worst case 75th%) (for in-use product at norminal density of 1 g/ml). The 75th percentiles from model 3 gives a surrogate value of 1.4 g/hour (for in-use product at norminal density of 1 g/ml).The 75th percentiles from model 4 gives a surrogate value of 6.4 g/hour (densities ranging from 1.25 to 2 g/ml) resulting in 3 to 5 ml/hour.

Based on the different surrogate values for dermal exposure in the different model the surrogate value of 5 ml/hour used in the NL seems reasonable.

Comparing the surrogate exposure values for inhalatory exposure the 75th% in model 3 is 4.15 mg/m3, in model 4 0.05 mg/m3 and model 2 has no values as NL model AF because the exposure seems negligible. The surrogate exposure values for inhalatory exposure in the NL model AF is not worst case and reasonable because model 3 based on data from brush painting shed and fences seems less usefull then model 4 based on data from brush and roller painting antifoulant on the underside of small boats.

For the **professional airless spraying** the NL-model AF used the 58333 mg paint /hour as surrogate exposure values for dermal exposure and 1.63 mg paint/hour as surrogate exposure values for inhalatory exposure based on MC Cutcheon (90th percentile). For the professional use of airless painting spraying model 3 is described in the TNsG on human exposure 2002/2007. Model 3 is based on HSE Surveys 1993, 1996, IOM study on PPE, 1996 with 75th percentile of 250 mg/min for the body (95th% 745 mg/min) and 2.04 inside gloves (95th % 3.95). The uncertainty is moderate 90% C.I. for 75th%: 0.86-4.97 (hands), 152-410 (body), 7.5-40 (inhalation). As regards the partition of the paint over the body it is assumed that 50% of the total exposure lands on the body and 50% on the hands. Because potential data for hands are not available, a dermal exposure including hands of 250 mg/min is assumed (also approximately 204mg/min assuming that 2.04 mg/min corresponds to 1% of the actual dermal exposure inside gloves). This results in 500 mg/min (75th%) and 745 (95th%) as surrogate exposure value (30000 mg/hour and *89400 mg/hour* resp)). The 17.3 mg/m3 (75th %) surrogate exposure value for inhalatory exposure in model 3 (95th% 64.6 mg/m3) corresponds with the surrogate value of 1.63 mg paint per hour (= 17 mg paint per m3).

The 90th% surrogate exposure value of *58333 mg/hour* without the use of exposure reducing measures based on the MC Cutcheon study seems a reasonable value; taken into account the 90% C.I. for 75% be around 820x60 mg/min = *49200 mg/hour*. The MC Cutcheon study has also surrogate exposure values for the use of one clothing layer (1500 mg/hour) and two clothing layers (500 mg/hour). Therefore, the NL model AF based on this study gives extra possibilities to calculate the dermal exposure with risk mitigations measures as PPE.

Use of suitable respiration protection (compressed mask; air supplied respirator with full face visor), gloves, protective clothing (double coveralls with hood) and boots results in a dermal exposure reduction of 99%

For the **professional manual spraying** the NL-model AF used the 984 mg a.s./kg a.s. (= 748 mg/min) as surrogate exposure values for dermal exposure and 65,3 mg/m3 (=6.23 mg/m3 per kg a.s.) for inhalatory exposure based on a model from the Biocides Steering Group (BSG) (95th percentile). For the non-professional use of manual spraying consumer spraying and dusting model 3 (overhead task) is described in the TNsG on human exposure 2002/2007 with 75th percentiles of 176 mg/min for hand and forearm, 120 mg/min for legs, feet & face and 115 mg/m3 (for in-use product at norminal density of 1 g/ml). No values are available for the body. Assuming that 50% of the total exposure lands on the body and 50% on the hands the exposure of 176 + 120 will be round *400 mg/min (as 75th)*. The uncertainty is moderate 90% C.I. for 75% are 117-265 (hands), 85-170 (legs), 79-168 (inhalation).

Based on the surrogate values in the consumer spraying and dusting model 3 (overhead task) the surrogate value of *748 mg/min* for dermal exposure seems a reasonable (worst case) value: also taken into account the 90% C.I. for 75% be around *550 mg/min.* The surrogate value of 65,3 mg/m3 (95th %) is not worst case.

All applications: In the Netherlands 1-6 hours application is assumed for the professional user and 0.5-2 hours for the non-professional user to protect all users. In the TNsG 1-2 hours (62-135 min (90)) is used for the professional as non-professional user for brushing and rolling (also in the UK CAR for Tralopyril). For the professional user 40 – 360 min. (184). The default values has to be harmonisered in the future.

Conclusion: It can be concluded that the approach for calculating the exposure for brushing and rolling for the non-professional is comparable. For the professional the NL approach is worst case (6 in stead of 2 hours) application.

The NL approach seems comparable with the EU approach for airless spraying for the professional user.

The NL approach for manual spraying professional user seems a worst case approach because for professional use 1200 m2 (6 hours treatment) is used and a high surrogate value of *748 mg/min* for dermal exposure.

4 REFERENCES

[1] Wgb: Plant Protection Products and Biocides Act 2007.
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