

Draft Assessment Report (DAR)

- public version -

**Initial risk assessment provided by the rapporteur Member State
The Netherlands for the existing active substance**

ETRIDIAZOLE

**of the third stage (part B) of the review programme
referred to in Article 8(2) of Council Directive 91/414/EEC**

Volume 3, Annex B, part 6, Appendices

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Appendix 1**Standard terms and abbreviations****Part 1 Technical Terms**

A	ampere
ACH	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD ₅₀	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathie
BSP	bromosulphophthalein
Bt	bacillus thuringiensis
Bti	bacillus thuringiensis israelensis
Btk	bacillus thuringiensis kurstaki
Btt	bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight
c	centi- ($\times 10^{-2}$)
°C	degree Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system

COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRES	dietary risk evaluation system
DT ₅₀	period required for 50 percent dissipation (define method of estimation)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC ₅₀	median effective concentration
ECD	electron capture detector
ECU	European currency unit
ED ₅₀	median effective dose
EDI	estimated daily intake
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F ₀	parental generation
F ₁	filial generation, first
F ₂	filial generation, second
FIA	fluorescence immunoassay
FID	flame ionisation detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice

GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high-energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H _s	Shannon-Weaver index
Ht	haematocrit
I	indoor
I ₅₀	inhibitory dose, 50%
IC ₅₀	median immobilisation concentration or median inhibitory concentration
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
iv	intravenous
IVF	<i>in vitro</i> fertilisation
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole, see also H)
K _{ads}	adsorption constant
K _{des}	apparent desorption coefficient
K _{oc}	organic carbon adsorption coefficient
K _{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC ₅₀	lethal concentration, median
LCA	life cycle analysis

LC _{Lo}	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LD _{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mo	month(s)
mol	Mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration) or number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend

NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter content
op	organophosphorous pesticide
Pa	Pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC _A	predicted environmental concentration in air
PEC _S	predicted environmental concentration in soil
PEC _{SW}	predicted environmental concentration in surface water
PEC _{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant
PNEC	predicted no effect concentration
po	by mouth
P _{OW}	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion (10 ⁻⁹)
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
ppq	parts per quadrillion (10 ⁻²⁴)
ppt	parts per trillion (10 ⁻¹²)
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r ²	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL ₅₀	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	rotations per minute

rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short-term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
$t_{1/2}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC_{Lo}	toxic concentration low
TID	thermionic detector, alkali flame detector
TD_{Lo}	toxic dose low
TDR	time domain reflectrometry
TER	toxicity exposure ration
TER_i	toxicity exposure ration for initial exposure
TER_{ST}	toxicity exposure ration following repeated exposure
TER_{LT}	toxicity exposure ration following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
T_{Im}	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tranccard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average

UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
=	less than or equal to
>	greater than
=	greater than or equal to

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Part 2 Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GRIN	Germplasm Resources Information Network
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer

IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organisation for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Programme (USA)
OECD	Organisation for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unités
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

Part 3**PREPARATION (FORMULATION) TYPES AND CODES***

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block baits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active ingredient into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic) spraying.
EO	Emulsion, water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion, oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 µm.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.

FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 µm.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glass-houses.
GR	Granule	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Grease	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.
MG	Microgranule	A granule in the particle size range from 100 to 600 µm.
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pesticide	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.

SB	Scrap bait	Special forms of bait.
SC	Suspension concentrate (= flowable concentrate)	A stable suspension of active substance(s) in a fluid intended for dilution with water before use.
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles and of fine globules in a continuous water phase.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but may contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active substance after dilution with water.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small, flat plates for dissolution in water.
TP	Tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

*based upon the catalogue of Pesticide Formulation types and International Coding Systems, developed by GIFAP in co-operation with the German working group on documentation questions. (Arbeitsgruppe EDV Pflanzenschutz Versuchswesen). GIFAP Technical Monograph No 2. 1989.

APPENDIX 2: SPECIFIC TERMS AND ABBREVIATIONS

a	absolute organ weight
AAP	Algal Assay Procedure medium
aerob	aerobic test conditions
a-GT	alpha-glutamyl-transferase
ALAT	alanine aminotransferase
ALP	alkaline phosphatase
amu	atomic mass units
anaer	anaerobic test conditions
AR	applied radioactivity in dermal studies, administered radioactivity in oral studies
ASAT	aspartate aminotransferase
ASTM	American Society for Testing and Materials
B	bacteria
biodeg	biodegradation
Chr. ab.	chromosome aberrations
CMC	carboxymethylcellulose
CoE	Council of Europe
crit.	criterion
d	decreased, but not statistically significantly
dc	statistically significantly decreased
DFI	Daily Food Intake
DMF	dimethylformamide
DO	Dissolved Oxygen
dr	dose-related
DWI	Daily Water Intake
E	total effect of mortality and fecundity/parasitic capacity, used in arthropod toxicity tests
E. coli	<i>Escherichia coli</i>
equal	used when the values given by the notifier are expressed in mg/kg bw/day.
equivalent	used when values given by the notifier are only expressed in mg/kg food, not in mg/kg bw/day, as species-dependent factor is used to translate these data to mg/kg bw/day.
ETE	Estimated Theoretical Exposure
GCP	good clinical practice
GIDH	glutamic-acid dehydrogenase
GOT	glutamic-oxalacetic transaminase
GPT	glutamic-pyruvic transaminase
HDL	high density lipoproteins
HPRT	hypoxanthine- guanine phosphoribosyl transferase
i	increased, but not statistically significantly
ic	statistically significantly increased
MC	moisture content in soil (v/v)
Mc	mammalian cells
MWHC	maximum water holding capacity (soils)
n/a	not applicable
n.d.	not detected
n.r.	not reported
ns	not significant
o.m.	organic matter

PEC	Predicted Environmental Concentration
PEG	polyethylene glycol
pF	moisture tension (soil) in [log cm _{water column}]
PIEC	Predicted Initial Environmental Concentration
pointmut.	pointmutations
r	relative organ weight
r.a.	radioactivity
res.	result
Ri	Reliability Index, referring to the intrinsic reliability of a test with respect to the quality of the study. 1=reliable (can be used for risk assessment), 2=less reliable (can be used if reliable data are not available), 3=not reliable (can be used if reliable or less reliable data are not available), 4= no original data (reliable (can be used if reliable, less reliable, or unreliable data are not available).
S. typh.	<i>Salmonella typhimurium</i>
SPE	Solid Phase Extraction
Sub.	Substance
T	temperature
TWA	time weighted average
TWAE	time weighted average environmental concentration
wat/sed	water/sediment system
w/w	weight per weight
-	negative
+	positive
-act.	without activation
+act.	with activation
%v/v	the percentage expressed by volume
%w/w	the percentage expressed by weight

APPENDIX 3: Exposure model calculations and risk assessment**1. BASIC APPLICATION INFORMATION***Product information*

Product	:	AATERRA ME
Purpose	:	Fungicide
Active substance (a.s.)	:	Etridiazole 700 g a.s./L
Product type	:	Micro-Emulsion (ME)
Package size	:	1 L bottle, HDPE/Polyamide Co-Extrude bottle with tamper-proof screw caps having an opening of 42 mm

1.1 OPERATOR EXPOSURE

Based on the intended use (GAP, document D-1) and a minimum volume of 1000 litres of irrigation water per ha, these are the maximum concentrations:

Application of AATERRA ME by drip irrigation

Crop	Max. dose rate (g a.s./ha)	Dose rate (L product/ha)	Volume of irrigation water/ha	Concentration of a.s. in irrigation water (mg a.s./L)	Concentration of product in irrigation water (ml product/L)
Cucumber	280	0.4	1000	280	0.4
			1250	224	0.32
			1500	187	0.27
Tomato and pepper	560	0.8	1000	560	0.8
			1250	448	0.64
			1500	373	0.54
ornamentals	7000	10.0	1000	7000	10.0
			1250	5600	8.0
			1500	4667	6.75

Application technique : through drip irrigation

Input data

Concentration a.s. in formulation	:	700 g a.s. /L
Spray volume	:	not applicable
Application rate cucumber	:	0.28 kg a.s./ha (0.4 L product/ha)
Application rate tomato and pepper	:	0.28 –0.56 kg a.s./ha (0.4-0.8 L product/ha)
Application rate ornamentals	:	7 kg a.s./ha (10 L product/ha)
Area treated tomatoes, pepper, Cucumber	:	3 ha ¹

¹ Based on data from CBS, the Netherlands. Landbouwtellingen Regionaal 2004. For manual applications in glasshouses, normally default 1 ha is used. However, application of AATERRA ME is performed by irrigation, and therefore, it is assumed that more than 1 ha can be treated in one day. Assumptions are based on the total amount of m² for crop and the amount of enterprises. Data from glasshouses in the Netherlands are considered representative for the EU.

Area treated ornamentals : 2 ha¹

1.2 BYSTANDER EXPOSURE

Input data

Not applicable.

1.3 WORKER EXPOSURE

Input data

Duration of activities : 6 hours (3 h cutting, 3 h sorting/bundling)

1.4 RISK ASSESSMENT

Input data

Dermal absorption : 18% (undiluted formulation)

Inhalation absorption : 100%

2. OPERATOR EXPOSURE

According to the notifier, exposure of the operator only occurs during mixing and loading since it is assumed that for application of AATERRA ME by drip-irrigation operators are not exposed. However, considering the volatility of etridiazole (as indicated by the vapour pressure of 1.43 Pa and Henry's law constant of 3.02 Pa.m³/mol), and the atmospheric DT₅₀ of 1.556 days, occurrence of etridiazole in air cannot be excluded *a priori*. Significant losses of etridiazole through volatilisation were also observed in soil and water/sediment studies (see Volume 3, Annex B, B.8.1.1 and B.8.4.3). Respiratory exposure of the operator to etridiazole during application (inspection during drip irrigation) cannot be excluded therefore.

For the present purpose the original UK-POEM and DE (GM) spreadsheets are used to estimate operator exposure during mixing/loading. The models differ from each other. The DE (GM) spreadsheet calculates with different reduction factors for PPE while the UK sheet only calculates with gloves as reduction factor.

2.1 Exposure estimates with the UK model

The model is largely based on unpublished studies, carried out in the UK by industry and MAFF. 75th percentiles are calculated.

For making the exposure estimate with the UK model, an application method should be chosen. In case of AATERRA ME, the specific application by irrigation is not available. Therefore, for mixing and loading one of the automatic application methods is chosen (however, since it only concerns the module for mixing/loading, the results for all automatic applications methods are the same).

2.1.1 Mixing and loading AATERRA ME for application on cucumber, without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	AATERRA ME	Active substance	etridiazole
Formulation type	water-based	a.s. concentration	700 mg/ml
Dermal absorption from product	18 %	Dermal absorption from spray	%
Container	1 litre any closure		
PPE during mix/loading	None	PPE during application	None
Dose	0.4 l/ha	Work rate/day	3 ha
Application volume	1000 l/ha	Duration of spraying	n.a. h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	0.4 litres product/ha
Work rate	3 ha/day
Number of operations	2 /day
Hand contamination	0.02 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	0.02 ml/day

ABSORBED DERMAL DOSE

	Mix/load
Dermal exposure	0.02 ml/day
Concen. of a.s. product or spray	700 mg/ml
Dermal exposure to a.s.	14 mg/day
Percent absorbed	18 %
Absorbed dose	2.52 mg/day

PREDICTED EXPOSURE

Total absorbed dose	2.52 mg/day
Operator body weight	60 kg
Operator exposure	0.042 mg/kg bw/day

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be based on the basis of this document.

2.1.2 Mixing and loading AATTERRA ME for application on cucumber, with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	AATTERRA ME	Active substance	etridiazole
Formulation type	water-based	a.s. concentration	700 mg/ml
Dermal absorption from product	18 %	Dermal absorption from spray	%
Container	1 litre any closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	0.4 l/ha	Work rate/day	3 ha
Application volume	1000 l/ha	Duration of spraying	n.a. h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	0.4 litres product/ha
Work rate	3 ha/day
Number of operations	2 /day
Hand contamination	0.02 ml/day
Protective clothing	Gloves
Transmission to skin	5 %
Dermal exposure to formulation	0.001 ml/day

ABSORBED DERMAL DOSE

	Mix/load
Dermal exposure	0.001 ml/day
Concen. of a.s. product or spray	700 mg/ml
Dermal exposure to a.s.	0.7 mg/day
Percent absorbed	18 %
Absorbed dose	0.126 mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.126 mg/day
Operator body weight	60 kg
Operator exposure	0.0021 mg/kg bw/day

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2.1.3 Mixing and loading AATERRA ME for application on tomato and pepper, without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	AATERRA ME	Active substance	etridiazole
Formulation type	water-based	a.s. concentration	700 mg/ml
Dermal absorption from product	18 %	Dermal absorption from spray	%
Container	1 litre any closure		
PPE during mix/loading	None	PPE during application	None
Dose	0.8 l/ha	Work rate/day	3 ha
Application volume	1000 l/ha	Duration of spraying	n.a. h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	0.8 litres product/ha
Work rate	3 ha/day
Number of operations	3 /day
Hand contamination	0.03 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	0.03 ml/day

ABSORBED DERMAL DOSE

	Mix/load
Dermal exposure	0.03 ml/day
Concen. of a.s. product or spray	700 mg/ml
Dermal exposure to a.s.	21 mg/day
Percent absorbed	18 %
Absorbed dose	3.78 mg/day

PREDICTED EXPOSURE

Total absorbed dose	3.78 mg/day
Operator body weight	60 kg
Operator exposure	0.063 mg/kg bw/day

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must be based on the basis of this document.

2.1.4 Mixing and loading AATERRA ME for application on tomato and pepper, with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	AATERRA ME	Active substance	etridiazole
Formulation type	water-based	a.s. concentration	700 mg/ml
Dermal absorption from product	18 %	Dermal absorption from spray	%
Container	1 litre any closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	0.8 l/ha	Work rate/day	3 ha
Application volume	1000 l/ha	Duration of spraying	n.a. h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	0.8 litres product/ha
Work rate	3 ha/day
Number of operations	3 /day
Hand contamination	0.03 ml/day
Protective clothing	Gloves
Transmission to skin	5 %
Dermal exposure to formulation	0.0015 ml/day

ABSORBED DERMAL DOSE

	Mix/load
Dermal exposure	0.0015 ml/day
Concen. of a.s. product or spray	700 mg/ml
Dermal exposure to a.s.	1.05 mg/day
Percent absorbed	18 %
Absorbed dose	0.189 mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.189 mg/day
Operator body weight	60 kg
Operator exposure	0.00315 mg/kg bw/day

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be based on the basis of this document.

2.1.5 Mixing and loading AATERRA ME for application on ornamentals, without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	AATERRA ME	Active substance	etridiazole
Formulation type	water-based	a.s. concentration	700 mg/ml
Dermal absorption from product	18 %	Dermal absorption from spray	%
Container	1 litre any closure		
PPE during mix/loading	None	PPE during application	None
Dose	10 l/ha	Work rate/day	2 ha
Application volume	l/ha	Duration of spraying	n.a. h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	10 litres product/ha
Work rate	2 ha/day
Number of operations	20 /day
Hand contamination	0.2 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	0.2 ml/day

ABSORBED DERMAL DOSE

	Mix/load
Dermal exposure	0.2 ml/day
Concen. of a.s. product or spray	700 mg/ml
Dermal exposure to a.s.	140 mg/day
Percent absorbed	18 %
Absorbed dose	25.2 mg/day

PREDICTED EXPOSURE

Total absorbed dose	25.2 mg/day
Operator body weight	60 kg
Operator exposure	0.42 mg/kg bw/day

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be based on the basis of this document.

2.1.6 Mixing and loading AATTERRA ME for application on ornamentals, with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	AATTERRA ME	Active substance	etridiazole
Formulation type	water-based	a.s. concentration	700 mg/ml
Dermal absorption from product	18 %	Dermal absorption from spray	%
Container	1 litre any closure		
PPE during mix/loading	Gloves	PPE during application	None
Dose	10 l/ha	Work rate/day	2 ha
Application volume	l/ha	Duration of spraying	n.a. h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	10 litres product/ha
Work rate	2 ha/day
Number of operations	20 /day
Hand contamination	0.2 ml/day
Protective clothing	Gloves
Transmission to skin	5 %
Dermal exposure to formulation	0.01 ml/day

ABSORBED DERMAL DOSE

	Mix/load
Dermal exposure	0.01 ml/day
Concen. of a.s. product or spray	700 mg/ml
Dermal exposure to a.s.	7 mg/day
Percent absorbed	18 %
Absorbed dose	1.26 mg/day

PREDICTED EXPOSURE

Total absorbed dose	1.26 mg/day
Operator body weight	60 kg
Operator exposure	0.021 mg/kg bw/day

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be the basis of this document.

2.2 Exposure estimates with the German model

The German model is based on unpublished studies performed by industry and all carried out in Germany. For mixing/loading the nature of the formulation is an important variable. The format of exposure is mg/kg and the chosen statistic is the geometric mean (GM).

For making the exposure estimate with the German model, an application method should be chosen. In case of AATERRA ME, the specific application by irrigation is not available, therefore, for mixing and loading the model for tractor mounted application method is chosen. Etridiazole is volatile (1.43 Pa). The inhalation exposure estimates for AATERRA ME might be an underestimation of real exposure, because exposure to vapours is not considered in the German model.

2.2.1 Mixing and loading AATTERRA ME for application on cucumber

= FIELD CROP TRACTOR MOUNTED =

Treated area per day		A =	3	ha/d	at BBA = 20
Use rate		R =	0.28	kg a.i./ha	
Mixing/loading of the product [mg/person per kg a.i.]					Appl. of the spray [mg/pers. per kg a.i.]
	liquid	solid: WP	solid: WG	I*a = 0,001	D*a/c = 0,06
I*m	0.0006	0.07	0.008	D*a/h = 0,38	D*a/b = 1,6
D*m/h	2.4	6	2		

Estimated inhalation exposure:

Im = I*m x R x A	0.0006	0.28	3	0.000504 mg/pers. x d
I, in total =				0.000504 mg/pers. x d

Estimated dermal exposure:

Dm/h = D*m/h x R x A	2.4	0.28	3	2.016 mg/pers. x d
D, in total =				2.016 mg/pers. x d

Estimated inh. exp. PPE factor

Im =	0.000504	-	1	0.000504 mg/pers. x d
				0.000504 mg/pers. x d

Estimated derm. exp.

Dm/h =	2.016	SS 110	0.01	0.02016 mg/pers. x d
				0.02016 mg/pers. x d

	abs. rate	Estimated exposure		Systemic exposure	
		without PPE	with PPE	without PPE	with PPE
Inhalation: m/l	100%	0.000504	0.000504	0.000504	0.000504
Dermal: m/l	18%	2.016	0.02016	0.362880	0.0036288
		mg/pers./d:		0.363384	0.0041328

Possible PPE: specific instructions	Abbr.	Red.-factor	to lower:
Particle filtering half mask (m/l)	ST 110	0.08	Im
Half mask with comb. filter (m/l)	ST 210	0.02	
Particle filtering half mask (appl.)	ST 120	0.08	Ia
Half mask with comb. filter (appl.)	ST 220	0.02	
Protective gloves (m/l)	SS 110	0.01	Dm/h
Protective gloves (appl.)	SS 120	0.01	Da/h
Half mask (appl.)	ST 120 / 220	0.8	Da/c
Broad-brimmed headgear (appl.: high crops)	SS 420	0.5	
Hood and visor (appl.: high crops)	SS 520	0.05	Da/b
Protective garment + sturdy footwear (appl.)	SS 220	0.05	

2.2.2 Mixing and loading AATTERRA ME for application on tomato and pepper

= FIELD CROP TRACTOR MOUNTED =

Treated area per day		A =	3	ha/d	at BBA = 20
Use rate		R =	0.56	kg a.i./ha	
Mixing/loading of the product [mg/person per kg a.i.]					Appl. of the spray [mg/pers. per kg a.i.]
	liquid	solid: WP	solid: WG	I*a = 0,001	D*a/c = 0,06
I*m	0.0006	0.07	0.008	D*a/h = 0,38	D*a/b = 1,6
D*m/h	2.4	6	2		

Estimated inhalation exposure:

Im = I*m x R x A	0.0006	0.56	3	0.001008 mg/pers. x d
I, in total =				0.001008 mg/pers. x d

Estimated dermal exposure:

Dm/h = D*m/h x R x A	2.4	0.56	3	4.032 mg/pers. x d
D, in total =				4.032 mg/pers. x d

Estimated inh. exp. PPE factor

Im =	0.001008	-	1	0.001008 mg/pers. x d
				0.001008 mg/pers. x d

Estimated derm. exp.

Dm/h =	4.032	SS 110	0.01	0.04032 mg/pers. x d
				0.04032 mg/pers. x d

		Estimated exposure		Systemic exposure	
	abs. rate	without PPE	with PPE	without PPE	with PPE
Inhalation: m/l	100%	0.001008	0.001008	0.001008	0.001008
Dermal: m/l	18%	4.032	0.04032	0.725760	0.0072576
			mg/pers./d:	0.726768	0.0082656

Possible PPE: specific instructions	Abbr.	Red.-factor	to lower:
Particle filtering half mask (m/l)	ST 110	0.08	Im
Half mask with comb. filter (m/l)	ST 210	0.02	
Particle filtering half mask (appl.)	ST 120	0.08	Ia
Half mask with comb. filter (appl.)	ST 220	0.02	
Protective gloves (m/l)	SS 110	0.01	Dm/h
Protective gloves (appl.)	SS 120	0.01	Da/h
Half mask (appl.)	ST 120 / 220	0.8	Da/c
Broad-brimmed headgear (appl.: high crops)	SS 420	0.5	
Hood and visor (appl.: high crops)	SS 520	0.05	
Protective garment + sturdy footwear (appl.)	SS 220	0.05	Da/b

2.2.3 Mixing and loading AATTERRA ME for application on ornamentals

= FIELD CROP TRACTOR MOUNTED =

Treated area per day		A =	2	ha/d	at BBA = 20
Use rate		R =	7	kg a.i./ha	
Mixing/loading of the product [mg/person per kg a.i.]					Appl. of the spray [mg/pers. per kg a.i.]
	liquid	solid: WP	solid: WG	I*a = 0,001	D*a/c = 0,06
I*m	0.0006	0.07	0.008	D*a/h = 0,38	D*a/b = 1,6
D*m/h	2.4	6	2		

Estimated inhalation exposure:

Im = I*m x R x A	0.0006	7	2	0.0084 mg/pers. x d
I, in total =				0.0084 mg/pers. x d

Estimated dermal exposure:

Dm/h = D*m/h x R x A	2.4	7	2	33.6 mg/pers. x d
D, in total =				33.6 mg/pers. x d

Estimated inh. exp. PPE factor

Im =	0.0084	-	1	0.0084 mg/pers. x d
				0.0084 mg/pers. x d

Estimated derm. exp.

Dm/h =	33.6	SS 110	0.01	0.336 mg/pers. x d
				0.336 mg/pers. x d

		Estimated exposure		Systemic exposure	
	abs. rate	without PPE	with PPE	without PPE	with PPE
Inhalation: m/l	100%	0.0084	0.0084	0.0084	0.0084
Dermal: m/l	18%	33.6	0.336	6.048000	0.06048
			mg/pers./d:	6.0564	0.06888

Possible PPE: specific instructions	Abbr.	Red.-factor	to lower:
Particle filtering half mask (m/l)	ST 110	0.08	Im
Half mask with comb. filter (m/l)	ST 210	0.02	
Particle filtering half mask (appl.)	ST 120	0.08	Ia
Half mask with comb. filter (appl.)	ST 220	0.02	
Protective gloves (m/l)	SS 110	0.01	Dm/h
Protective gloves (appl.)	SS 120	0.01	Da/h
Half mask (appl.)	ST 120 / 220	0.8	Da/c
Broad-brimmed headgear (appl.: high crops)	SS 420	0.5	
Hood and visor (appl.: high crops)	SS 520	0.05	
Protective garment + sturdy footwear (appl.)	SS 220	0.05	Da/b

2.3 Risk assessment for operators

Appendix table 2.3.1 Operator internal exposure and risk assessment

Model	Route	Estimated internal exposure (mg a.s./day)		AOEL Systemic * (mg a.s./day)	% AOEL	
		without PPE	with PPE		without PPE	with PPE
Mixing/loading AATERRA ME for application on cucumber via drip irrigation						
UK- 75 th	Respiratory	-	-	1.8	-	-
	Dermal	2.52	0.13	1.8	140	7
	Total	2.52	0.13	1.8	140	7
DE- GM	Respiratory	0.0005**	0.0005**	2.1	0.02	0.02
	Dermal	0.3629	0.0036	2.1	17	0.2
	Total	0.36	0.004	2.1	17	0.2
Mixing/loading AATERRA ME for application on tomato and pepper via drip irrigation						
UK- 75 th	Respiratory	-	-	1.8	-	-
	Dermal	3.78	0.19	1.8	210	11
	Total	3.78	0.19	1.8	210	11
DE- GM	Respiratory	0.001**	0.001**	2.1	0.05	0.05
	Dermal	0.7258	0.007	2.1	35	0.3
	Total	0.73	0.008	2.1	35	0.4
Mixing/loading AATERRA ME for application on ornamentals via drip irrigation						
UK- 75 th	Respiratory	-	-	1.8	-	-
	Dermal	25.2	1.26	1.8	1400	70
	Total	25.2	1.26	1.8	1400	70
DE- GM	Respiratory	0.0084**	0.0084**	2.1	0.4	0.4
	Dermal	6.048	0.0605	2.1	288	3
	Total	6.06	0.07	2.1	288	3

* Assuming a body weight of 60 kg for UK-POEM and 70 kg for German model

- No data available

** exposure might be an underestimation, because exposure to vapours is not considered in the German model, see also below for further calculations

Calculated data for respiratory exposure of the operators during mixing and loading might be underestimations, because exposure to vapours is not considered in the German model.

No data were available on the exposure of operators during application.

The notifier submitted estimations of concentrations of etridiazole and dichloro-etridiazole in air due to volatilisation (Klein, 2006). See paragraph 4.1 for further information.

Based on the estimated air concentrations (0 – 4 hours after application; see paragraph 4.1), an operator exposure of 1 hour (as worst-case for mixing/loading and possible inspection during drip

irrigation) and a respiration rate of 1.25 m³/h, the respiratory exposure of the operator to etridiazole and dichloro-etridiazole can be calculated (see appendix Table 2.3.2).

Respiratory operator exposure = 1 x 1.25 m³/h x air concentration during 0 – 4 hours

Appendix Table 2.3.2 Estimated respiratory exposure of the operator

	Estimated respiratory exposure of the operator to etridiazole (mg/day)	Estimated respiratory exposure of the operator to dichloro-etridiazole (mg/day)
Vegetable crops	0.013 (= 0.6% of the AOEL)	0.0015 (= 0.07% of the AOEL)
Ornamentals	0.168 (= 8% of the AOEL)	0.019 (= 0.9% of the AOEL)

The calculations in appendix Table 2.3.2 illustrate that the respiratory exposure of the operator was indeed underestimated by the German model. However, the additional calculations of the respiratory exposure based on estimated air concentrations, do not change the conclusions drawn based on calculations with UK-POEM and the German model.

3. Bystander exposure

The presence of bystanders should be kept to a minimum. This can easily be achieved in a greenhouse, where no person should be allowed in who is not involved in the application process. Therefore, no estimation of bystander exposure for application of AATERRA ME in greenhouses will be performed.

3.1 Risk assessment for bystanders

Not applicable.

4. Worker exposure

According to the notifier, AATERRA ME is applied to substrates (as a root and substrate fungicide) and therefore no dislodgeable residues are anticipated and no exposure of workers when handling treated plants. This is acceptable and it is indeed assumed that dermal exposure of the workers is negligible. However, during and after treatment via the irrigation system, workers can be present in the glasshouses for re-entry activities. Given the volatility of etridiazole and the soil/water metabolite dichloro-etridiazole occurrence of etridiazole and dichloro-etridiazole in air cannot be excluded *a priori*.

4.1 Exposure estimates for re-entry activities

During the degradation of etridiazole in soil under aerobic conditions, one metabolite with similar volatilisation properties as the parent substance was detected and identified as dichloro-etridiazole, occurring at levels of up to 13% of applied etridiazole. The notifier submitted estimations of concentrations of etridiazole and dichloro-etridiazole in air due to volatilisation (Klein, 2006). At present, there is no guidance for determination of concentrations in air and successive atmospheric deposition available within the EC evaluation process. Therefore, the notifier calculated the concentrations resulting from volatilisation of etridiazole and dichloro-etridiazole in the different compartments based on the models EVA 1.1 and EVA 2.0 (Exposure Via Air), that have been developed by the German Federal Environmental Agency (UBA) for registration purposes in Germany.

As a worst-case for etridiazole, calculations were conducted for maximum application rates for ornamental crops (7 kg a.s./ha) and the group of vegetable crops (0.56 kg a.s./ha). The metabolite dichloro-etridiazole was found in soil at maximum rate of 10-13% of applied radioactivity 4-30 days after application. It can be reasonably assumed that only part of the amount formed would be available for volatilisation due to adsorption processes in soil. However, as the extent of this limitation cannot be assessed and due to the rather low K_{ow} values of both etridiazole (195-349) and dichloro-etridiazole (50-129), it was assumed that the maximum amount of dichloro-etridiazole formed is available for volatilisation. Besides the maximum formation rate of dichloro-etridiazole, the ratio between the molar masses of dichloro-etridiazole and etridiazole was taken into account (213 / 247.5

= 0.861). Therefore, the following theoretical application rates of dichloro-etridiazole were derived for calculation purposes:

- ornamental crops: $7 \text{ kg a.s./ha} \times 13\% \times 0.861 = 0.784 \text{ kg dichloro-etridiazole/ha}$
- vegetable crops: $0.56 \text{ kg a.s./ha} \times 13\% \times 0.861 = 0.063 \text{ kg dichloro-etridiazole/ha}$

Emission rates were estimated according to EVA 1.1, due to the fact that the more recent version of the model, EVA 2.0, is based on empirical results on deposition of pesticides and accordingly, volatilisation data is not determined. However, indoor application scenarios are not implemented in EVA 1.1. Parameters referring to greenhouses were thus derived from EVA 2.0.

The calculation of the emission rate with EVA 1.1 is based on the assumption that the main factor influencing the emission of a compound is its vapour pressure. Default values for greenhouse dimensions from the model EVA 2.0 were used for the calculation of concentrations in air:

- floor space of buildings = 300 m^2
- volume of building = 1000 m^3

For a reasonable worst-case assessment, air exchange must be considered. The default air exchange rate in EVA 2.0 is 24.5 V/h (referring to air shutters being opened to an angle of 45°), corresponding to an exchange rate of 0.41 V/min. Calculations with these default values resulted in the following estimated air concentrations:

Appendix Table 4.1.1 Estimation of maximum concentrations in air for etridiazole and dichloro-etridiazole

Time after application (hours)	Air concentration etridiazole ($\mu\text{g a.s./m}^3$) after application in ornamentals (app. rate 7 kg a.s./ha)	Air concentration etridiazole ($\mu\text{g a.s./m}^3$) after application in vegetables (app. rate 0.56 kg a.s./ha)	Air concentration dichloro-etridiazole ($\mu\text{g a.s./m}^3$) after application in ornamentals (app. rate 0.784 kg a.s./ha)	Air concentration dichloro-etridiazole ($\mu\text{g a.s./m}^3$) after application in vegetables (app. rate 0.063 kg a.s./ha)
0 - 4	134.48	10.76	15.06	1.21
4 - 12	66.99	5.36	7.50	0.60
12 - 24	33.75	2.70	3.78	0.30
>24	0	0	0	0

It should be noted that these are very worst-case estimates, since it is assumed that the applied dose of etridiazole and the formed amount of dichloro-etridiazole is completely available for volatilisation. However, part of the applied dose will not be available for volatilisation due to adsorption processes in soil/substrate, but the amount cannot be quantified.

Based on the estimated air concentrations (0 – 4 hours and 4 – 12 hours after application), a worker exposure of 6 hours (see paragraph 1.3) and a respiration rate of $1.25 \text{ m}^3/\text{h}$, the respiratory exposure of the worker can be calculated (see appendix Table 4.1.2):

Respiratory worker exposure = $(4 \times 1.25 \text{ m}^3/\text{h} \times \text{air concentration during 0 – 4 hours}) + (2 \times 1.25 \text{ m}^3/\text{h} \times \text{air concentration during 4 - 12 hours})$

Appendix Table 4.1.2 Estimated respiratory exposure of the worker

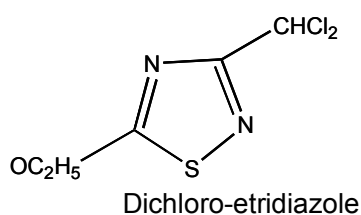
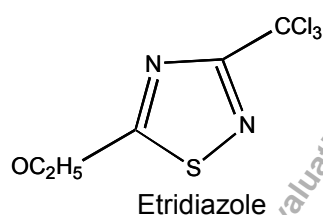
	Estimated respiratory exposure of the worker to etridiazole (mg/day)	Estimated respiratory exposure of the worker to dichloro-etridiazole (mg/day)
Vegetable crops	0.067	0.0076
Ornamentals	0.840	0.094

4.2 Risk assessment for worker exposure

AATERRA ME is applied to substrates (as a soil and root fungicide) and therefore no dislodgeable residues are anticipated and no exposure of workers when handling treated plants.

However, after and during treatment via the irrigation system, workers can be present in the glasshouses for re-entry activities. Given the volatility of etridiazole (as indicated by the vapour pressure of 1.43 Pa and Henry's law constant of $3.02 \text{ Pa} \cdot \text{m}^3/\text{mol}$), and the atmospheric DT_{50} of 1.556 days, respiratory exposure to etridiazole cannot be excluded. Air concentrations were estimated for etridiazole and the soil metabolite dichloro-etridiazole and the respiratory exposure of the worker was estimated.

The molecular structure of dichloro-etridiazole is highly comparable to that of etridiazole: the difference is one chlorine atom.



Based on the molecular structure and the Derek analysis (see B.6.8.1.3) it is assumed that the toxicity of dichloro-etridiazole is comparable to the toxicity of etridiazole. Therefore, the AOEL derived for etridiazole is also used for the risk assessment of dichloro-etridiazole.

Appendix Table 4.2.1 Worker internal exposure and risk assessment for etridiazole

Appendix Table 4.2.1 Worker internal exposure and risk assessment for ethirazole						
Model *	Route	Estimated internal exposure (mg a.s./day)		AOEL systemic ** (mg a.s./day)	% AOEL	
		without PPE	with PPE		without PPE	with PPE
Re-entry exposure during and after application of AATERRA ME via drip irrigation in vegetables						
	Respiratory	0.067	n.a.	2.1	3	n.a.

Model *	Route	Estimated internal exposure (mg a.s./day)		AOEL systemic ** (mg a.s./day)	% AOEL	
		without PPE	with PPE		without PPE	with PPE
	Dermal	-	-	-	-	-
	Total	0.067	n.a.	2.1	3	n.a.
<i>Re-entry exposure during and after application of AATERRA ME via drip irrigation in ornamentals</i>						
	Respiratory	0.840	n.a.	2.1	40	n.a.
	Dermal	-	-	-	-	-
	Total	0.840	n.a.	2.1	40	n.a.

* No model available. Respiratory exposure of the worker was calculated based on estimated air concentrations.

** Assuming a body weight of 70 kg

n.a. Not applicable

- The dermal exposure is not quantifiable.

It should be noted that local effects (minimal squamous/squamoid metaplasia of larynx mucosa) were observed in the 28-d inhalation study (see B.6.3.3, Study 1). For these effects, no NOAEL could be established: NOAEL <15 mg/m³ (equivalent to 4 mg/kg bw/d). These effects were however observed after repeated inhalatory exposure and the estimated air concentrations in Appendix Table 4.1.1 show that after 24 h, the air concentration of etridiazole is zero. It should also be taken into account that the LOAEL for the local effects is 280 mg a.s./d (assuming a body weight of 70 kg) and the maximum estimated respiratory exposure to etridiazole is 0.84 mg/d. It is therefore concluded that the risk of local effects is negligible.

Appendix Table 4.2.2 Worker internal exposure and risk assessment for dichloro-etridiazole

Appendix Table 4.2.2 Worker internal exposure and risk assessment for atramora ethanazole

Model *	Route	Estimated internal exposure (mg a.s./day)		AOEL systemic ** (mg a.s./day)	% AOEL	
		without PPE	with PPE		without PPE	with PPE
Re-entry exposure during and after application of AATERRA ME via drip irrigation in vegetables						
	Respiratory	0.0076	n.a.	2.1	0.4	n.a.
	Dermal	-	-	-	-	-
	Total	0.0076	n.a.	2.1	0.4	n.a.
Re-entry exposure during and after application of AATERRA ME via drip irrigation in ornamentals						
	Respiratory	0.094	n.a.	2.1	4.5	n.a.
	Dermal	-	-	-	-	-
	Total	0.094	n.a.	2.1	4.5	n.a.

* No model available. Respiratory exposure of the worker was calculated based on estimated air concentrations.

** Assuming a body weight of 70 kg

n.a. Not applicable

- The dermal exposure is not quantifiable.

It is possible that after volatilisation of etridiazole and dichloro-etridiazole, some deposition on the plants will subsequently occur. This might result in dermal exposure of the worker. However, the

amount of deposition cannot be quantified. Furthermore, it should be taken into account that the dermal absorption is 30% (for a low area dose, see list of endpoints). Given the relatively low respiratory exposure (see % AOEL), it is not expected that the potential dermal absorption will contribute significantly to the total exposure.

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