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Environmental risk assessment for veterinary medicinal products

Part 4. Exposure assessment scenarios

MHMM Montforts, JV Tarazona Lafarga[1]

[1] INIA, Laboratorio de Ecotoxicologica, Madrid, Spain

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RIVM, P.O. Box 1, 3720 BA Bilthoven, telephone: 31 - 30 - 274 91 11; telefax: 31 - 30 - 274 29 71

Abstract

Residues of veterinary medicinal products reach the environment through spreading of slurry on agricultural soil. In this report animal husbandry, slurry handling and environmental conditions throughout Europe are considered in order to define realistic worst case scenarios, in conjunction with environmental distribution models. Given the variability in manure management a straightforward approach for the manure model was selected. Realistic worst case conditions are proposed in a simple scenario assuming single treatment per place, standard European nitrogen production values, application of the a manure application rate of 170 kg N/ha/year in one time, with a manure production volume of one month containing the full residue, no dissipation during storage, and incorporation into 5 cm soil. Risk reduction measures related to manure management and manure treatment cannot be assessed using the proposed methodology. Scenarios and models for distribution to surface and groundwater provided by FOCUS are considered suitable for veterinary drugs. Additionally, for run-off and erosion in Mediterranean regions a river-catchment model is designed.

Preface

The objective of this research was to develop scenarios for the risk assessment of residues from veterinary medicinal products in slurry, under different European conditions, incorporating information on realistic agricultural and veterinarian practice, land use, geomorphology and climate. The research was performed in the 5th EU Framework Program Project ERAVMIS, Contract No. EVK1-CT-1999-00003.

The support and contributions of Martha van Eerdt (RIVM-LAE) and our co-workers Alistair Boxall (ERAVMIS), Johannes Tolls (ERAVMIS), Anja Verschoor (ERAVMIS), Flemming Ingerslev (ERAVMIS), and Johann Moltmann (POSEIDON), are gratefully acknowledged.

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Samenvatting

Residuen van diergeneesmiddelen bereiken het milieu met de mest die op landbouwgronden wordt aangewend. In dit rapport worden veehouderij, mestbehandeling en milieuomstandigheden in Europa gekarakteriseerd en worden realistische scenarios voor deze parameters voorgesteld, in samenhang met geschikte verspreidingsmodellen.

Uit de gegevens blijkt dat runder- en varkensmest de voornaamste mesttypen zijn waarmee in Europa het land bemest wordt. Regionaal of lokaal kunnen schapen- en kippenmest een belangrijke rol spelen. Verdere onderverdelingen in bijvoorbeeld melkkoeien en vleeskalveren kunnen van belang zijn voor specifieke gebieden.

De kwaliteit van de mest hangt af van diersoort, ras, leeftijd, sexe en voeding. Mestproductie en –kwaliteit worden meer of minder intensief geregistreerd door EU-landen als gevolg van beperkingen in het gebruik van dierlijke meststoffen. Omdat de scenarios van toepassing moeten zijn op de centrale registratie op Europees niveau, worden de normen voor goed landbouwkundig gebruik en mestkwaliteit ontwikkeld onder de Nitraatrichtlijn voorgesteld. Lichaamsgewichten bij toepassing zijn gebaseerd op eindgewichten voor ouderdieren en gemiddelden voor productiedieren.

In algemene zin zijn zowel dosering als excretie modelprocessen die een zekere tijdsspanne duren, afhankelijk van de wijze van toediening en de aard van de stof. Representatieve mimimale tijdsspannes bedragen 3 tot 21 dagen.

De hoeveelheid mest die vervuild zal worden is beperkt door de opslagcapaciteit van het opslagsysteem en de mogelijkheden voor het afvoeren van de mest. In systemen waarbij de mest afgevoerd wordt op transportbanden is verdunning van vervuilde mest met schone mest beperkt. In systemen waarin de mest verzameld wordt totdat de mest opgeruimd kan worden, zullen de residuen altijd verdund worden met schone mest. Opslagtijden zijn waargenomen in Engeland, variërend van 0 weken tot 4 jaar, en in Nederland van 2 tot 12 maanden.

De wijze van mestopslag en van bemesten kunnen de uiteindelijke concentraties in het milieu sterk bepalen. Binnen en tussen mestsystemen is de variatie in temperatuur, zuurstof, zuurgraad en nutriënten groot. Deze onzekerheden in parameters, relaties, en resultaten zijn aanmerkelijk.

De diepte waarop de mest ingewerkt wordt hangt af van de wijze van toedienen. In het veld is waargenomen dat niet-inwerken een veelvoorkomende praktijk is. De mest wordt in één of in meerdere keren uitgereden, afhankelijk van bodem- en gewastype.

In verband met de variabiliteit in mestbehandeling is gekozen voor een eenvoudige benadering. Een scenario onder realistische ‘worst-case’ omstandigheden wordt voorgesteld, uitgaande van een enkele behandeling per dierverblijfplaats, een vastgestelde stikstofproductie, toediening van een stikstofgift van 170 kg N/ha/jaar met een hoeveelheid mest gelijk aan de productie in 1 maand, geen verdwijning van het residue tijdens de opslag, geen nabehandeling van de mest, en een inwerkdiepte van 5 cm in de bodem. Risicoreductiemaatregelen die betrekking hebben op mestbehandeling en mestgebruik kunnen met deze benadering niet worden geverifieerd.

Scenario’s en modellen voor distributie in het milieu zijn vastgesteld door FOCUS (Forum for the Co-ordination of pesticide fate models and their Use) voor de Europese registratie van gewasbeschermingsmiddelen, en worden geschikt geacht voor diergeneesmiddelen.

In aanvulling op het FOCUS instrumentarium, wordt voor oppervlakkige afstroming en bodemerosie in mediterrane gebieden een toegespitst stroomgebiedenscenario en –model aangedragen.

Summary

Residues of veterinary medicinal products reach the environment through spreading of slurry on agricultural soil. In this report animal husbandry, slurry handling and environmental conditions throughout Europe are considered in order to define realistic worst case scenarios, in conjunction with environmental distribution models.

The data indicate that bovine and pig manure are the main slurry types used to fertilise land in Europe. However, sheep and chicken manure are regionally and locally important. The use of further subdivisions (e.g. dairy cows and veal) may also be relevant for targeted areas.

Manure quality depends on species, race, age, sex, and feeding. Slurry production and quality is monitored more or less intensively in EU countries due to the restrictions in the use of fertilisers. Targeting the marketing Authorisation at a European level, the agricultural practice and standards developed under the Nitrate directive should be used where manure quality at application are concerned. Body weights at treatment are based on adult weights for parent animals and the mean of slaughter weight and starting weight for production animals.

In general, both dosing and excretion are model processes that last a certain time span, depending on method of administration and substance. Representative minimal time spans are in the range of 3-21 days.

The amount of contaminated manure is delimited by the storage capacity of the system and the opportunities to take the slurry out. In animal breeding systems where manure is removed on conveyer belts, dilution of residues with clean manure is avoidable. In systems where the manure is collected until it can be removed (e.g. by moving out all animals) the residues will always be diluted due to production of uncontaminated manure. Manure storage times ranging from zero weeks to 4 years have been established in the UK, and in the Netherlands ranging from 2 to 12 months.

The methods employed in slurry storage and application could significantly effect concentrations. There is a great variation in temperature, redox potential, pH, and storage time within systems and between systems. The uncertainty in the slurry exposure parameters, model relations, and model results is considerable, also given the variation in the conditions and starting materials.

The depth of incorporation depends on the method of application. In the field, the worst case situation of no incorporation has been registered as general agricultural practice. Manure spreading events vary depending on a/o. soil and crop type, and range from one event to several spreading events per season.

Given the variability in manure management a straightforward approach for the manure model was selected. Realistic worst case conditions are hence proposed in a simple scenario assuming single treatment per place, standard European nitrogen production values, application of the maximum manure application rate of 170 kg N/ha/year in one time, with a manure production volume of 1 month (30 days) containing the full residue, no dissipation during storage, and no after-treatment of slurry, and incorporation into 5 cm soil. Risk reduction measures related to manure management and manure treatment cannot be assessed using the proposed methodology.

Exposure scenarios and models provided by FOCUS (Forum for the Co-ordination of pesticide fate models and their Use) who established standard leaching and surface water exposure scenarios for pesticide registration in Europe, are considered suitable for veterinary drugs. Additionally to the FOCUS models, for run-off and erosion in Mediterranean regions a designated river-catchment scenario and model is designed.

1. Introduction

1.1 Scope of the report

This report investigates the possibility of defining scenarios for exposure and distribution models for the environmental risk assessment (ERA) of veterinary medicinal products (VMPs) at registration.

A critical component of any modelling procedure is the identification of relevant scenarios to characterise the environmental conditions determining model input parameters. A scenario comprises a unique combination of agronomic and environmental conditions that realistically represent areas in which a substance is to be applied. Relevant means in this context that the selected parameters should be realistic and that the scale of the modelling is adequate.

For registration of veterinary medicines a realistic worst case scenario is needed in conjunction with a model to identify acceptable uses and measures that mitigate the risk when the product is used.

A number of realistic 'worst case' scenarios have been developed for use in the environmental risk assessment of plant protection products for use in leaching models, surface water models and runoff models. The current study investigates the usefulness of these scenarios for veterinary medicines.

1.2 Scenarios and exposure models

The scenario defines parameters (distributions) in the exposure models, all of which are related:

1) Emission
    a) pathology and remediation: occurrence of infections and diseases throughout the year(s)
    b) excretion of residues by animals
2) Storage
    a) Slurry production
    b) storage time
    c) storage conditions
    d) slurry removal
    e) slurry quality
3) Immission into soil
    a) load
    b) repetitions
    c) soil management
4) Environmental conditions
    a) climate
    b) soil
    c) weather/hydrology
    d) topography.

If a product is used or not depends on the pathology (occurrence of diseases). The presupposition is that treatment occurs, thus pathology is not a parameter. Dosage is a parameter, which is not variable, because the modelling is performed using a given prescribed dosage: dose rate (mg/kg body weight) and duration of treatment.

Several animals have more production cycles in one year, which may all need treatment. Depending on the model type (rate or capacity), this introduces the need to standardise body weights and treatment rates. Excretion of residues is also an input-parameter in the model. Excretion patterns and cumulative excretion may differ depending on species, race, mode of application and dosage. This will result in a selection of an excretion value (deterministic) or a range of values.

The input, storage and outflow of contaminated and uncontaminated slurry determine the loads that will reach the soil. Residues can be excreted during a time period in which the slurry basin is emptied. The time after excretion and before the basin is (partly) emptied differs for every situation. Slurry storage, production and removal should thus be defined in scenarios. A description of feedlot production systems is given in [7].

The most realistic period that degradation can take place in slurry and in soil cannot be determined with a rule of thumb. Given the number of cycles per year, and assuming that the time between the applications in the cycles is constant, one can search for the worst-case and best case combinations of slurry storage time and soil residence time. Storage time is a function of output (spreading intervals) and input (time of application or excretion). However, as these functions largely depend on the (unknown and individual) substance handling, either a complete subroutine with detailed inputs are needed, or a scenario for every livestock category of interest is to be defined. In this way dosing, excretion and manure handling are made part of the scenario rather than of the algorithms.

Climate and soils are important factors in the determination of chemical concentrations in the environment. In 1993, the European Commission and the European Crop Protection Association jointly established FOCUS (FOrum for the Co-ordination of pesticide fate models and their USe) who, as one of its tasks, established standard leaching and surface water exposure scenarios for pesticide registration in Europe. These scenarios are probably also appropriate for use in the environmental risk assessment of veterinary pharmaceuticals. In general, scenario analysis using calibrated distribution models for groundwater and surface water showed that:

- substance characteristics,
- lateral boundary conditions,
- time of application of the substance,
- soil characteristics, and
- weather conditions,

define the concentration of the pesticide in the drainpipes and thereby the fraction of the dosage leached to surface water and groundwater. Therefore we base the further descriptions on the FOCUS reports [17-20].

All exposure models operate within certain dimensions: time units, distances and areas, on which the parameter values depend, and the type of model is not necessarily related to the spatial scale of the simulation. The parameter value is considered representative for the range of values, or rates for the modelled process, encountered in the field, for both the selected area and interval in space and time. In general the accuracy of input values decrease with the size of the area or duration for which the prediction is made, because the variation in the parameter increases. There are two ways of increasing the applicability of the modelling result together with decreasing variability. Models can be applied to grid cells of a topographic GIS-chart, each cell with its own characteristics (parameter values). By downsizing the cell dimensions and time steps, the variability per cell decreases. Evidently, the efforts to parameterise and calibrate all cells will be huge, and one has to consider how to interpret the detailed outcomes. One may find the definition of representative vulnerable conditions (scenario) for a single calculation a suitable option. This has certain advantages: the outcome is fairly simple; this point simulation allows for validation of the model and the characteristics (scenario) can be assigned by means of spatial analysis of all information.

The exposure modelling can be split in three major submodules: on for the animal husbandry phase, one for the slurry handling and one for the environmental phase.

In this report animal husbandry, slurry handling and environmental conditions throughout Europe are considered in order to define realistic worst case scenarios, in conjunction with models to identify acceptable uses and measures that mitigate the risk when the product is used.

2. Agricultural practices in the EU

Agricultural practices will play a very important role in determining the concentrations of veterinary drugs in the environment. This chapter reviews available data on agricultural practices in the EU. The data obtained may be useful in the refinement of current environmental risk assessment approaches.

2.1 Distribution of livestock

Absolute numbers of individual animals kept on holdings in the member states (Table 2-1 and Table 2-2) mean that the greatest densities of livestock are found in the Netherlands, France, the UK and Italy (Figure 1).

Table 2-1 Number of holdings, average area per holding and total agricultural area by member state in EU-15 [13].

Member state	Number of holdings (1000 holdings)	Average area per holding (ha)	Total agricultural area (1000 ha)
EU-15	7370	17.4	128238
Belgium	71	19.1	1356.1
Denmark	69	39.6	2732.4
Germany	567	30.3	17180.1
Greece	802	4.5	3609.0
Spain	1278	19.7	25176.6
France	735	38.5	28297.5
Ireland	153	28.2	4314.6
Italy	2482	5.9	14643.8
Luxembourg	3	39.9	119.7
Netherlands	113	17.7	2000.1
Austria	222	15.4	3418.8
Portugal	451	8.7	3923.7
Finland	101	21.7	2191.7
Sweden	89	34.4	3061.6
United Kingdom	235	70.1	16473.5

Table 2-2 Livestock in EU member states (numbers times 1000) [13].

Member state	Pig	Cattle	Table	Laying hens	Sheep	Goats
EU-15	118 650	83 243	4 231 026	356 959	96 150	12 047
Belgium	7 498	2 977	201 874	13 654	113	11
Denmark	11 494	2 026	141 610	3993	93	0
Germany	24 795	15 227	349 964	50 200	2 324	93
Greece	938	542	82 502	17 586	9 244	5 668
Spain	19 269	5 825	588 764	44 347	23 937	2 734
France	15 473	20 154	960 138	61 483	10 125	1 114
Ireland	1 717	6 992	64 296	2 903	5 391	0
Italy	8 155	7 345	400 803	56 627	10 920	1 390
Luxembourg	74	205			6	1
Netherlands	11 437	4 287	351 698	40 580	1 400	110
Austria	3 680	2 198	55 324	6 048	381	54
Portugal	2 365	1 285	205 510	7 490	3 380	781
Finland	1 444	1 125	41 121	4 984	111	6
Sweden	2 353	1 708		5 725	469	5
United Kingdom	7 959	11 347	787 422	41 340	28 256	81

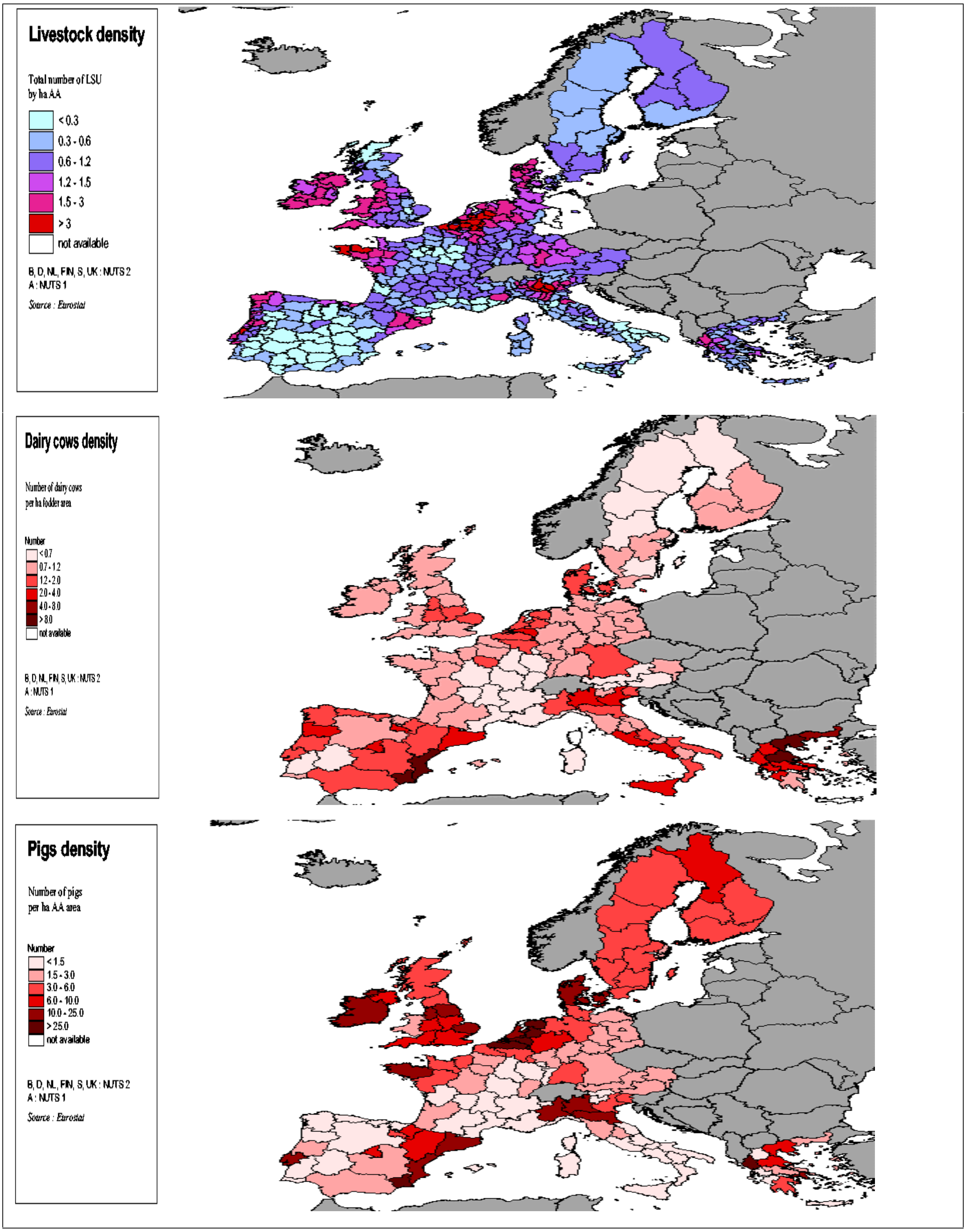

Figure 1 Density of total livestock, dairy cows and pigs in the EU [10].

Table 2-3 Animal places per farm in the Netherlands (1995) as presented in [32].

Animal type	animal places	farms	Average number of places per farm
dairy cows	1675000	36000	47
cattle	4550000	54400	84
pigs	14400000	21250	678
horses and ponies	107000	20000	5
sheep	1627000	21000	77
goats	100000	3700	27
chickens	91400000	4500	20311
broilers	44000000	1200	36667
hens	39500000	2700	14630
turkeys	1250000	140	8929
ducks	860000	120	7167
rabbits	250000	100	2500

2.2 Distribution of slurry

Livestock manure is the second most important source of nutrient inputs to agricultural land [40]. The nutrient content of manure varies from country to country and from one region to another within a country. It depends on the type of livestock, the grazing systems, and the nutrient content of the different fodder and foodstuffs used for livestock. The nitrogen input from manure is calculated by EUROSTAT multiplying the numbers of the different livestock types by a manure coefficient specific to that type and country. The same coefficients are used for all years. The relative contribution of the animal types to the manure-N input per country is depicted in Figure 2.

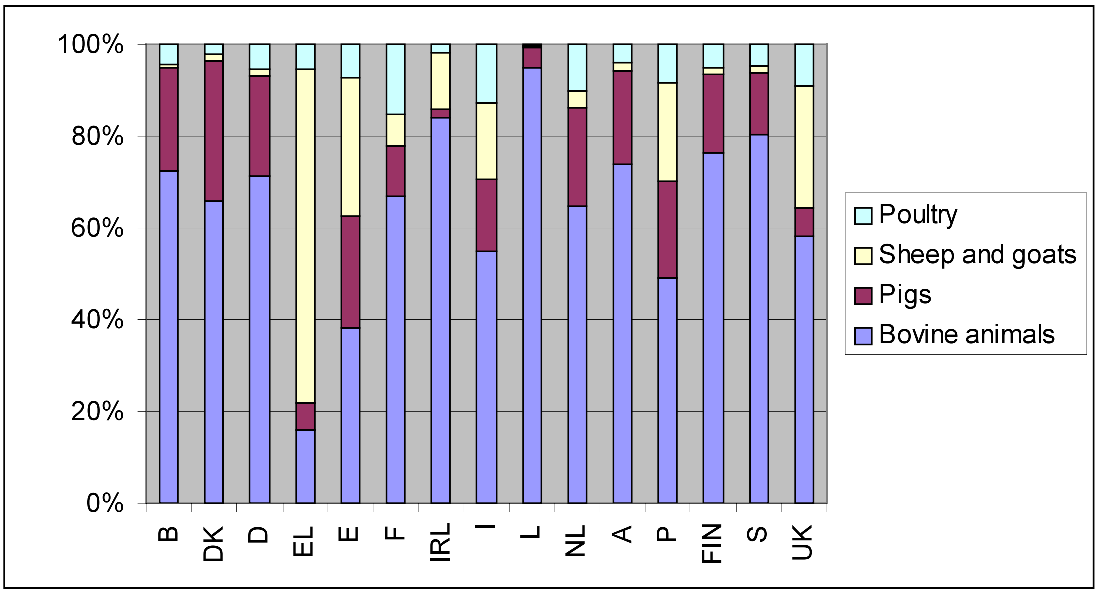

Figure 2 Nitrogen input from manure in EU member states in 1995.

This gives a different picture compared to the relative number of animals per country (Figure 3).

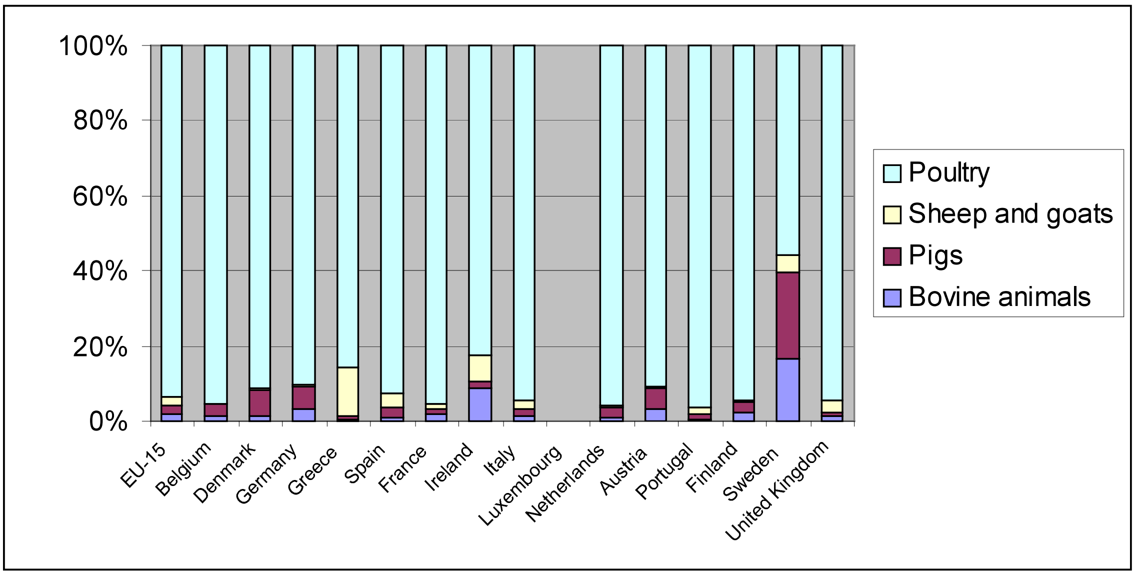

Figure 3 Livestock in EU member states 1997-1998 [13].

These data indicate that bovine and pig manure is the main slurry types used to fertilise land (if organic fertilisers are used). However, sheep and chicken manure are regionally and locally important. The use of further subdivisions (e.g. dairy cows, veal, fattening pigs, and broilers) may also be relevant for targeted areas.
It can be discussed whether it is relevant to discern further animal categories such as horses and donkeys, rabbits, ducks, turkeys, geese, fur-breeding animals (foxes, minks), ostriches, emoes and nandoes, guinea-fowls and quails. On field scale they may be relevant for exposure. Sludge from (wastewater treatment plants processing wastewater from) fisheries may also be used as fertiliser.

In 1995 the Netherlands and Belgium, both of which have high livestock density, had the largest input of nitrogen from livestock manure per ha, followed by Denmark, Ireland and Luxembourg. However, if low national figures are interpreted to mean that no manure problem exists, then this is misleading, especially for large countries, such as France, Spain, Italy and the UK, where the pattern of agriculture can vary widely from one region to another (Figure 4).

The environmental risk assessment at registration is mandatory for new substances only. Therefore, the scenarios are considered to target the central Marketing Authorisation Decision at the community level for the specific use of the product. Depending of the goal of the modelling this information on manure spreading has to be used differently. If one is concerned with finding the worst case situation or the complete distribution of risks over Europe, detailed information on land use and slurry immission is needed.
However, if the identification of a safe use is required, the definition of a realistic situation is sufficient. Under the Nitrate Directive (91/676/EC) vulnerable areas are discerned and member states have to enforce nitrogen immission standards. This Directive sets a uniform standard of 170 kg N/ha per year. Hence, this immission standard can be used as a parameter value that will define realistic situations at the EU level.

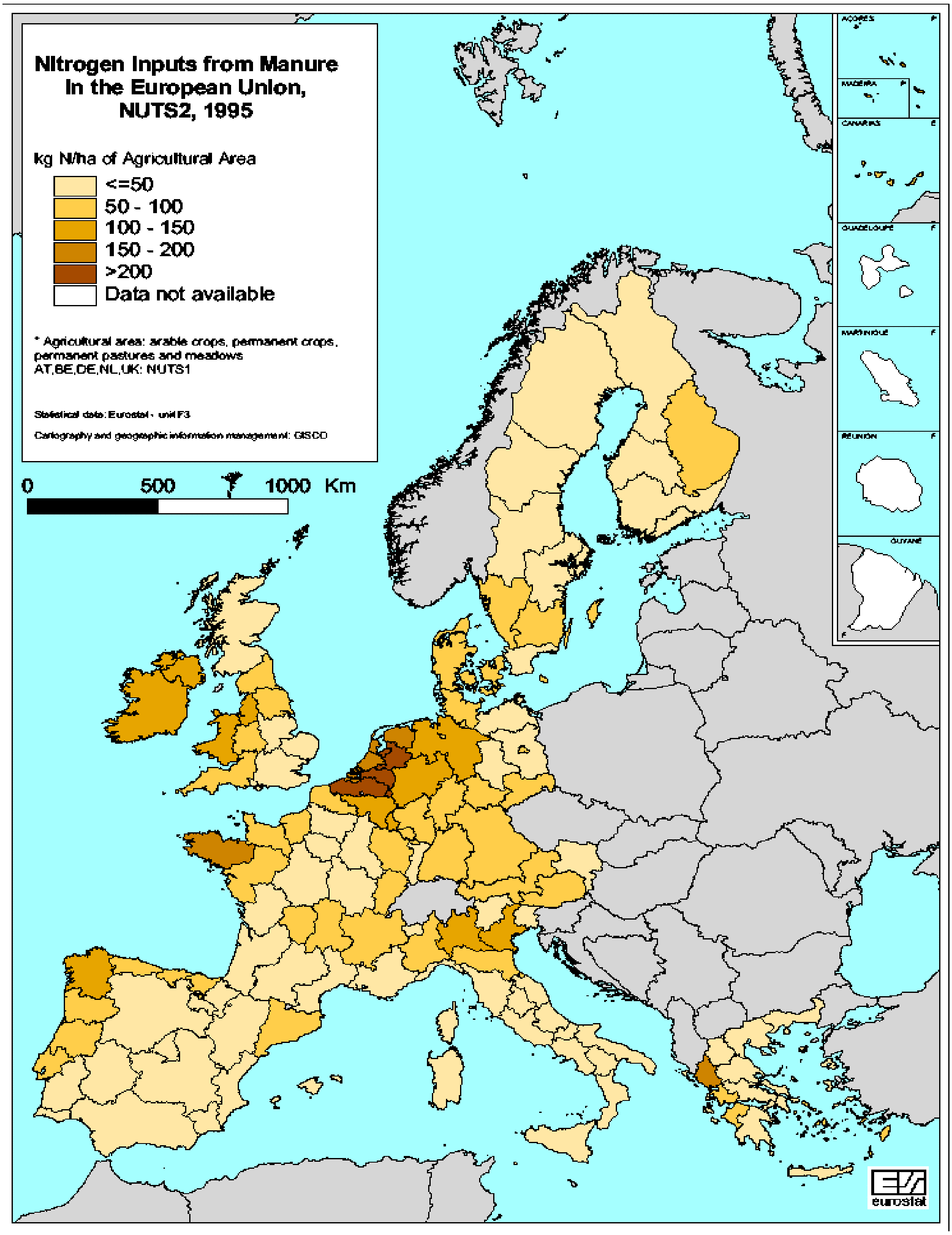

Figure 4 Nitrogen load from manure in the European Union 1995 [40].

2.3 Animal husbandry and manure production

The quantity of manure/slurry produced by livestock and methods of animal husbandry will potentially have an impact on concentrations of veterinary medicines in the environment. Manure quality depends on species, race, age, sex, and feeding. Slurry production and quality is monitored more or less intensively in EU countries due to the restrictions in the use of fertilisers. The figures in the publications are not always comparable, as they may refer to some (adult) individuals or to the total husbandry system (including young) and are not always identical (due to differences in feed, race and housing conditions) [1-4,8,9,22,28,56]. The worst case situation is described with manure low in nitrogen. We propose to use the lower nitrogen production standards presented to the European Resource Management of the European Commission DG XI by Ketelaars and Van der Meer (1999) [28] (Table 2-4). Body weights at treatment are proposed based on adult weights for parent animals and the mean of slaughter weight and starting weight for production animals.

Table 2-4 Standardised nitrogen production standards, rounds, and treatment body weights, for different livestock categories.

Type of Livestock	Nitrogen production standard [kg N/ place/year]	Rounds per year	Proposed body weight at treatment
Cattle			
Dairy cows	60		425 adult, 25 kg per calf (0.6 calves per place per year)
Other cows	44		425 adult, 25 kg per calf (0.6 calves per place per year)
Veal[#]	10	1.8	140
0-1 year	18		200
1-2 year	31		400
>2 year	35		450
Pigs			
Sows with piglets till 25 kg	32		240 adult; 9 kg per piglet (20 piglets per place)
Slaughter pigs 25-105 kg	7.5	3	65
Poultry			
Laying Hens	0.35		1.6
Broilers, 1.8 kg	0.23	9	1
Ducks, 3.3 kg	0.41	7	1.6
Turkeys, 13 kg	0.90	2.7	6.5
Sheep			
Ewes with lambs till 40 kg	13		75 adult; 20 kg per lamb (1.6 lambs per place)
Goat			
Females with kids till 7 kg	13		65 adult; 3.5 kg per kid (1.8 kids per place)
Rabbit			
Females with kittens	3.9	6.75 births	2 kg adult; 1 kg per kitten (50 kittens per place)
Horses	35		400

[#] veal data based on [54] and [32]

2.4 Slurry management

Slurry management may be an important factor in the release of veterinary pharmaceuticals to the environment. The methods employed in its storage and application could significantly effect concentrations, particularly due to their influence on chemical degradation and exposure to different hydrological pathways. There may be a great variation in temperature, redox potential, pH, and storage time. The input, storage and outflow of contaminated and uncontaminated slurry determine the loads that will reach the soil. Residues can be excreted during a time period in which the slurry basin is emptied. The time after excretion and before the basin is emptied differs for every situation. Slurry storage, production and removal should thus be defined in scenarios.

2.4.1 Slurry storage conditions

The excreta obtained indoors, referred to as manure, are collected and stored for some time. Slurry is the mixture of manure and materials from the housing of animals (e.g. spilled feed, straw, litter, sand, water, down, carcasses). Different animal types may contribute to the same slurry storage system and the treated animals do not exclusively determine final concentrations. Depending on the manure structure (solid or liquid), the manure is kept in bedding, piled, or stored in tanks or lagoons. Storage can be above ground and underground. Depending on structure and handling, the manure can be aerobic or anaerobic. The influence of storage conditions and manure quality is further discussed by Bouwman and Reus (1994) [11]. They recommend defining standard conditions for every manure type. Different manure types and storage systems will influence storage conditions and manure composition in different ways [12]. Conditions like oxygen levels, manure age, microbial activity and temperature will determine the fate of organic contaminants to a large extent, but are highly diverse within and between storage systems.

In the period June to September, the pit temperature for cattle in the Netherlands is considered to be 15°C; in the remaining months this is 10°C. The temperature in liquid pig and poultry manure is considered to be 15°C year-round. This is based on measurements and theoretical consideration that the temperature will be between the soil temperature and stable temperature. In out-door silos the temperature is defined at an average soil temperature 10°C [51].

The actual temperature in the slurry pit of a Dutch pig finishing facility with 1000 places ranged from 15 to 19°C during the year, mean 16.8, sd 1.4°C [24], cited in [38]. Pig manure temperatures under rearing facilities in Canada were reported to range from 16°C-23°C over the year [42]. Typical values of air temperature (15-35°C), air velocity (0.1-0.5 m/s), and liquid manure temperature (15-35°C) found in under-floor swine manure storage pits were recorded in Illinois, USA [6]. Temperatures in manure/bedding packs used in hoop structures for finishing pigs ranged from –1°C to 47°C, 15-45 cm below the surface during February (Iowa, USA) [46]. Manure collected from Wisconsin USA cattle stables (floor) in February ranged from 6-8°C in a free-stall and 14.5-14.9°C in a tie-stall. In all samples the pH was around 8 [35]. In a calf manure pile erected outdoors in winter (New York, USA) the temperature rose from an initial 10°C to 29°C in the first five days, fell to 15°C after thirty days, was at its lowest, 4°C, after 80 days and then steadily increased until termination of the study [27]. In biogas production cells in Texas, during summer and winter, the temperature in the beef cattle manure pile was initially about 25°C, but temperature dropped rapidly during the first month as the manure became anaerobic. Temperature began rising during summer months, a result of warmer ambient temperatures, and peaked around the first of August at 22°C. The temperature dropped below 15°C in the middle of October and has remained there until May 2000. The pH at the start was 7 [39].

Average soil temperatures for Europe are summarised in the FOCUS scenario document on groundwater leaching (Table 3-2; Figure 7) [18] and range from 4 to 18°C.

In poultry manure row piles stored in a high-rise poultry house (25°C air temperature) the temperature at 15 cm below the surface was found to be in the range 34-43°C. In the piles amended with cardboard, hay or saw dust, temperatures were higher: 52-63°C [41].
The following data refer to Dutch good agricultural for poultry (Table 2-5). Poultry manure is used in arable land and compost for mushrooms [15].

Table 2-5 Manure types, storage and treatment in poultry housing in the Netherlands.

Animal category	**Manure**	**Removal from stable**	**Storage/ treatment**	**Dry matter content (%)**		**Temperature (°C)**	
				Stable	**Storage/ treatment**	**Stable**	**Storage/ treatment**
Hen, caged	Wet	1x per year or less	Pit or silo		±15		20-25
	Dry		Removal in container	40-60		20-25	?
			Shed	40-60	40-80	20-25	20-60
			Drying by aeration	40-60	60-80	20-25	20-25
			Drying by composting	40-60	60-80	20-25	50-70
Free-ranging hens	Dry	1x per cycle (±15 months)	-	±60		20-60	
			Aeration in pit	60-80		20-25	
		1x or more per week	Aeration on conveyor belts in pit, removal in container	40-60		20-25	20-60
Broilers	Dry	1x per cycle (±8 weeks)	-	50-70		25-40	

In conclusion, depending on climate, season, storage systems and manure structure, temperatures can range from ambient (freezing) to 65°C (composting) [14]. For underground slurry storage systems this range is narrowed down to 4-18°C. For storage of solid manure (piles, containers) temperatures can be quite higher and varying due to composting processes (until anaerobicity is reached).
Manure can be treated during storage in order to optimise composting and reduce odour and methane emissions. An overview is of possibilities is given by [5]:

Biofiltration

Biofiltration is a recent waste treatment process where aerobic bacteria growth and activity is promoted by fixing them on a very porous and solid media (clay beads, straw stalks, plastic discs, etc.). Once colonies of aerobic bacteria are established on the media, the liquid waste stream is trickled on the bacteria-media matrix, along with a flow of air. Alternatively, the waste stream could be pre-aerated.

Biofilters require backwashing to remove excess bacteria, which would otherwise eventually plug the matrix. This sludge has to be managed either as a waste to recirculate into the treatment system, to dispose of, or to process. There is no reduction in the volume of liquid to store or apply. Installation and maintenance costs are much higher that the equivalent cost of application.

Sequential Batch Reactors

Sequential batch reactors are also relatively compact waste treatment systems where the growth of aerobic bacteria is controlled for efficient biodegradation of organic matter and denitrification of nitrogen in the liquid.

A series of tanks are typically used. In the first one where a mixture of bacteria is entered (or reintroduced by recirculation) into the aerated and agitated waste stream. The liquid waste is either held in this tank for sufficient time to allow maximum bacterial activity, or else transferred to a holding tank for this purpose. Most systems are designed to allow strong nitrification (conversion of organic nitrogen and ammonia into nitrates). The liquid stream is then allowed to settle in an idle tank, where denitrifying bacteria convert nitrates into, ideally, elemental nitrogen and where solids (small clumps of bacteria) can settle. The treated liquids are then disposed of separately from the settled solids (sludge).

Storage Aeration

Storage aeration is used to maintain the manure in an aerobic state. When manure has sufficient amounts of oxygen present, very little odour is produced, and a significant amount of nitrogen can be removed from the manure by micro-organisms. Where the land base available for spreading is limited, it may be necessary to try to reduce the nitrogen content of the manure before it is spread on the land.

During the summer, liquid manure can be treated aerobically by using mechanical aeration equipment. Mechanical aerators operate by either pumping air bubbles into the manure, or by spraying the manure into the air. A high energy input is required to supply enough oxygen to the manure and keep the manure well mixed, and as with all mechanical equipment, a certain amount of maintenance is required to keep the system functional. The energy costs and labour requirements needed to keep a large volume of manure aerobic are high. Generally, total aeration is only used when the manure is to be spread in an area where odour control is important and soil incorporation is not possible. It is not practical to aerate manure that has been collected and stored under anaerobic conditions during the winter. Aeration is only feasible when the storage is emptied in the spring and fall, and aeration is used as a method of odour control during the summer.

Another alternative is the partially aerated storage. In this system, a mechanical aerator supplies enough oxygen to keep the upper layer of the manure aerobic. When the system is functioning properly, the manure at the bottom of the storage is decomposed anaerobically and the gases released from the decomposing manure at the bottom are absorbed and further decomposed as they rise toward the top, preventing odorous gases from being released. If the mechanical aerator fails to supply enough oxygen, or if the manure is not properly mixed, then offensive odours will be released.

Pre-Storage Aeration

An alternative method of controlling odours from stored liquid manure is pre-storage aeration. A treatment tank is used to hold seven days of manure production. The manure is partially decomposed under warm, aerobic conditions, and then transferred to the long-term storage. Although the manure is held anaerobically in the long-term storage, the odour level is reduced because the manure is partially decomposed.

Composting

Composting is a biological process in which micro-organisms aerobically convert organic materials into a soil-like material called compost. During composting, the micro-organisms consume oxygen while feeding on the organic matter and generate heat and large quantities of carbon dioxide and water vapour. The rate at which manure will compost depends upon the moisture content, the temperature, the level of oxygen available, the size of the manure particles and the relative quantities of carbon and nitrogen available to the micro-organisms for use as food. The optimum solids content for composting is between 40 and 50 percent. In the case of swine production, it is necessary to increase the solids content of hog manure from its normal 10 percent solids to at least 35 percent before it can be composted. The fresh manure can be screened and the resulting solids, which are about 35 percent moisture, composted directly. The liquids are collected and sent to storage. It is also possible to add some form of bulking agent such as straw or sawdust to adjust the moisture content before beginning composting. During the composting process, the volume of manure will be reduced by up to 50 percent. Considerable losses of nitrogen also occur during the process.

In order to provide the conditions for composting, it is necessary to ensure an adequate supply of oxygen throughout the pile, maintain the pile at 40 - 50 percent solids and mix the material on a regular basis. This process can be carried out using a windrow system, aerated static piles, or an in-vessel system. The windrow method consists of placing the mixture of raw materials in long narrow rows (typically 1.0 to 1.2 m high and 2.6 to 3 m wide). The windrows are then turned on a fixed schedule to increase aeration and rebuild the bed porosity. Aerated static piles are aerated directly with forced air systems to speed up the process. The in-vessel system confines the composting material within a building or container and uses forced aeration and mechanical turning to speed up the composting process.

Anaerobic Processes

With controlled anaerobic treatment processes, such as anaerobic lagoons and anaerobic digesters, the temperature and the nutrient levels of the manure are regulated so that only desirable gases and end products are produced. Whenever manure is stored in a pit or a pile, the manure decomposes anaerobically, but because the process is not controlled, many different gases can be formed.

The type of gases and end products formed by the anaerobic decomposition will depend upon the temperature and characteristics of the manure. The most common anaerobic process is carried out at mesophilic temperatures (30-35°C), which allows rapid growth of methane-forming bacteria. Alternatively, thermophilic digestion is also used for biogas production, where temperatures are kept between 60 to 65°C. Thermophilic digestion tends to be less stable than digester operation at mesophilic temperatures. More recently, bacteria strains were selected for a strong activity at psychrophilic temperatures (10 - 20°C) with liquid hog manure.

Anaerobic Lagoons

Anaerobic lagoons are often confused with earthen manure storages. Lagoons are carefully designed and managed to maintain optimum loading rates, retention time and temperature of the manure to maintain a balance between the acid-forming and methane-forming bacteria. Earthen manure storage structures are simply basins designed to store the manure between periods of land application.

Anaerobic Digesters

Anaerobic digesters are used to produce and recover methane gas from the decomposition of manure. Digesters consist of a large, airtight tank with devices for controlling the input of fresh manure into the tank, mixing the manure, maintaining the correct temperature, and drawing off methane gas and components of the digested manure. Methane production is affected by the temperature, loading rate, mixing, digestion time, and characteristics of the manure. To optimise the amount of methane produced by a digester, all the factors mentioned above must be carefully controlled. The control of these factors can be accomplished by a lot of labour or by mechanisation.

Considerable research and development is still underway on anaerobic digestion. The main agronomic advantage of this process is that the organic nitrogen in liquid manure is mineralised, which reduces subsequent odour production during storage.

In the past there has been a great deal of interest in methane gas production. The same volume of liquid manure remains to be stored and field applied after treatment. Anaerobic digestion results in a very slight reduction in total nutrient content, even if more stable and less odorous. The high capital costs for equipment combined with the high management requirement makes this system impractical. At present, other energy forms such as electricity are less expensive and much more versatile, when only considering biogas energy production as a justification.

Refeeding

There have been attempts made to recover some of the nutrients and energy contained in hog manure by feeding them back to livestock. Some form of treatment is required to improve animal acceptability, destroy pathogens and reduce odours. These forms of treatment include dehydration, treatment with formaldehyde and formalin, fermentation and aerobic treatment. While there have been situations on experimental farms where liquid wastes have been re-fed to swine, there is considerable debate regarding the value of this practice on commercial hog farms. Generally, refeeding is most successful when the manure from monogastric species such as swine, is re-fed to a ruminant species such as cattle. The handling of recycled manure presents problems, since most feeding systems are designed for dry rations.

Dehydration

Dehydration is a process that can be used for odour control. Dry manure does not support the growth of either micro-organisms or insects such as flies. As well, dry manure can be used as a soil conditioner, in much the same way as composted manure. The problem with dehydration is that the costs associated with moisture removal are high and can not be fully recovered from the sale of the final product.

Solids Separation

There are several benefits for separating the solid and the liquid portions of hog manure. In some manure handling systems, it is sometimes desirable to recycle the liquids for flushing. Another reason for separation of the solids from the liquid manure is to allow the use of different treatment processes. Since most of the phosphorus is associated with the solids in liquid manure, separation is also considered as an alternative approach to phosphorus management. Removing the solids can serve a similar function to pre-storage aeration. The remaining liquid is less concentrated and therefore will produce fewer odours when it decomposes. Depending upon the degree of separation, the solids may be dry enough to be composted, and the remaining liquid will be easier to handle when spreading on the land or aerating. The disadvantage of solids separation is the need for two separate manure-handling systems.

Most long-term storage structures for liquid manure allow natural separation of the solids, as they effectively settle at the bottom of the structure after 200 or more days of storage. Separation can be done using filters or screens, or by allowing the solids to settle in a large tank or basin while removing the liquids from the top. Mechanical equipment is available, including centrifuges, cyclone separators, and stationary and vibrating screens, in a variety of sizes. Depending upon the flow rate and the type of mechanical equipment used, up to 50 percent of the solids can be removed. Settling basins can remove up to 95 percent of the solids, depending upon the design. Solids separation is applied in the Netherlands and solid and liquid fractions are spread in different seasons due to different fractions of mineral and organic nitrogen [54].

2.4.2 Slurry application

Slurry is collected in various containment systems and either applied directly to fields or stored. Slurry will be applied (injected) on grassland generally as soon as the field is accessible and possibly again after the first cutting. On arable land slurry will be applied before (and after) cropping in the period autumn-winter-spring [29], in one or two runs, and depending on the land use and waste strategy manure it may be applied once a week [57,59]. Spreading events are monitored as well at regional levels [1-4,8,9,53,54,56]. In the Netherlands and in Belgium, over 95% of the agricultural (arable) land is manured one to three times per year. In the Netherlands there is a strong preference to restrict manuring before the growing season, although at heavy soils a substantial number of farmers prefers to spread the liquid fractions before the growing season, and the solid fractions before the winter. In the Netherlands, chicken and pig manure is usually spread on arable land in one event, and cattle manure on grassland in up to four events (personal communication E. van Well, Centre for Agriculture and Environment (CLM), Utrecht, the Netherlands). In the Belgium province of Limburg, 20-60% of the farmers manures once per year, and 30-45% twice, and 2-30% three times [54], [49].

In the UK, a significant proportion is applied directly to land (Table 2-6). Different storage methods exist for slurry. In the UK cattle industry, one quarter of all farmers have one or more slurry stores on a farm (ADAS, 1998a; 1998b). The most common type of store is a tank or structure below ground; other types of stores comprise above ground circular tanks, earth bank lagoons and weeping wall stores. Most farms only have the capacity to store slurry for less than one month (51% in the dairy industry and 70% in the beef industry). Only 6% and 4% of dairy and beef farmers respectively have the capacity to store slurry for more than six months. Many farms with stores have slurry in them all of the time (58% of dairy farms and 38% of beef farms). On dairy farms, few slurry stores were empty for more than four months whilst on beef farms one quarter of respondents had empty stores for 5-6 months a year. Around half of cattle farmers stirred their slurry occasionally and less than 10% once a week, the remainder never stirred slurry lagoons. A small amount of cattle manure and slurry is transported off the farm area, the remainder being spread on fields on farm.

Over half of pig farmers that 57% have on farm stores (ADAS, 1997a), the majority being below ground tanks and the rest comprising earth bank lagoons or circular tanks above ground. Slurry from pig houses is ether collected monthly, daily or weekly. The capacity of stores varies with pig farmers storing slurry for less than one month to more than nine months. The majority of pig farmers (87%) have slurry in their stores all of the time.

Generally, the lagoons are unstirred although a small proportion (6%) is stirred weekly. Only 8% of pig farms transported any of their slurry off the farm.
In the poultry industry 37% (broilers) and 46% (layers) of holdings did not store any manure after its removal from poultry houses (ADAS, 1997b). If manure was stored, the majority of it was placed in the yard or field, where it may be covered. The manure was stored for 1-6. Generally, manure was removed from the cages weekly, although on some holdings it was removed at the end of the production cycle or daily. A relatively large proportion of poultry manure is transported off site.

Table 2-6 Percentage of farmyard manure spread directly to land in the UK (ADAS, 1997a; 1998a; 1998b).

Proportion of total manure	% of dairy farms	% of beef farms	% of pig farms
Less than 25%	36	26	41
25 - <50%	10	10	9
50% - <75%	16	22	13
75% or more	38	42	37

Another source reports the following data on slurry storage and application rates (Table 2-7). It is not specified to what animals the data apply [60].

Table 2-7 Amounts of slurry stored and applied, time of application and length of storage (WRc-NSF, 2000).

	% applied	quantity stored (gallon)	storage time (months)	application rate (kg/ha/y)	plough depth (cm)	waste content (kg P/m3)	waste content (kg N/m3)
slurry							
average	100	1042571	9.1	21212.88	16.49	0.68	2.69
SD	0	1462894	9.84	23015.33	7.56	0.55	2.41
min	100	0	0	80	0	0.12	0.99
max	100	5000000	50	100000	28	1.5	7
manure		(tonne)				(tonne)	(tonne)
average	98.44	2358.5	8.06	12636.89	16.53	1.07	2.11
SD	10.83	14150.5	6.1	14252	7.92	na	na
min	25	0	0	3	0	107	2.11
max	100	110000	48	55000	28	1.07	2.11

For the Netherlands the storage capacity of slurry basins depend on the slurry surplus and are expressed in terms of storage time: this varies between 2 and 12 months depending on the fate of the slurry (e.g. use on own farmland; export) [25]. In the Netherlands, 90% of the manure storage capacity is provided by pits (50%), silos (14%) and combination systems (37%), most of which are covered [51].
The periods in which the spreading of manure (i.e. stable manure, slurry and sludge) is allowed are different for indicated and non-indicated areas. For indicated areas this period is February 1-August 31 for grassland and arable land. For non-indicated areas this period is February 1-September 15 for grassland and the whole year for arable land [56]. In Flanders, Belgium, it is not allowed (decree of May 11th 1999) to use slurry on grassland between September 21 and January 31, and on arable land between September 21 and February 21, regardless of the soil texture [29].
On grassland, and arable land on sandy soil, the growing season is the period in which slurry is spread the most in The Netherlands, compared to the autumn (75:25). Arable land on clay or peat soil is manured almost exclusively in autumn and winter. One or two spreading events

within a half-year are most common. Liquid manure is mostly injected into the soil (grassland) or spread and incorporated within 24 hours (arable land) [25].
The frequency at which slurry is taken out of the storage facilities can have a different timing. For cattle and pig slurry, seven respectively three moments are considered by [51], which gives the following picture for storage in pits or in silos (Figure 5 and Figure 6). During the grazing season, 60% of the cattle manure is excreted in the stable. At emptying the storage tanks, 10% is left behind.

The manure produced by livestock will be applied to land, the amount applied being dependent on immission limits for nitrogen and phosphorus, fertiliser recommendations, or crop tolerance for slurry. These limits which are designed to avoid the excessive input of nutrients in soils vary across member states. Limit values of 50 kg ha^{-1} yr^{-1} for phosphorus and 170 kg ha^{-1} yr^{-1} for nitrogen are proposed for the derivation of PECs for the EU as a whole by Spaepen et al. (1997) [48]. In general, the Nitrate Directive applies to vulnerable areas in all member states and the standard set here (170 kg N/ha) can be considered as a realistic (not worst) case for these areas.

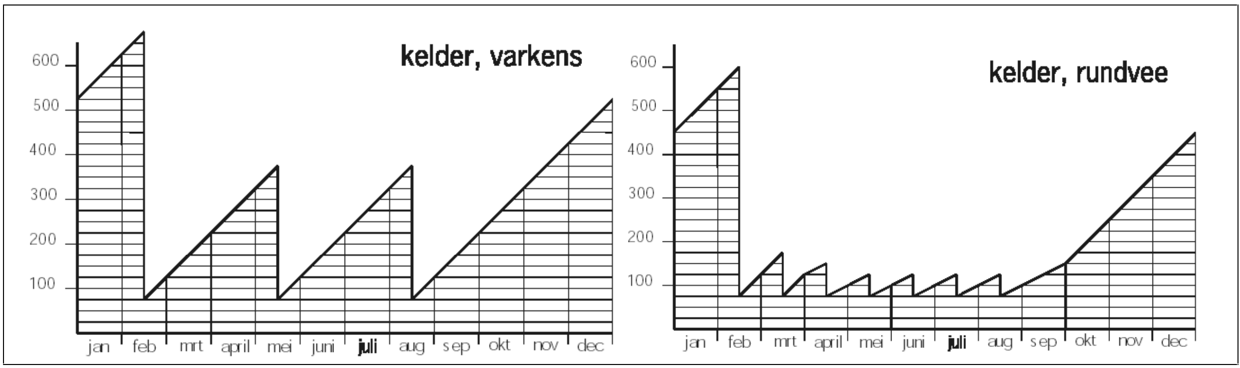

Figure 5 Utilisation of slurry storage capacity in farms with exclusively pits or silos, based on a capacity of 600 m^3, and a production of 100 m^3 per month. Varkens = pigs; rundvee = cattle; kelder = pit.

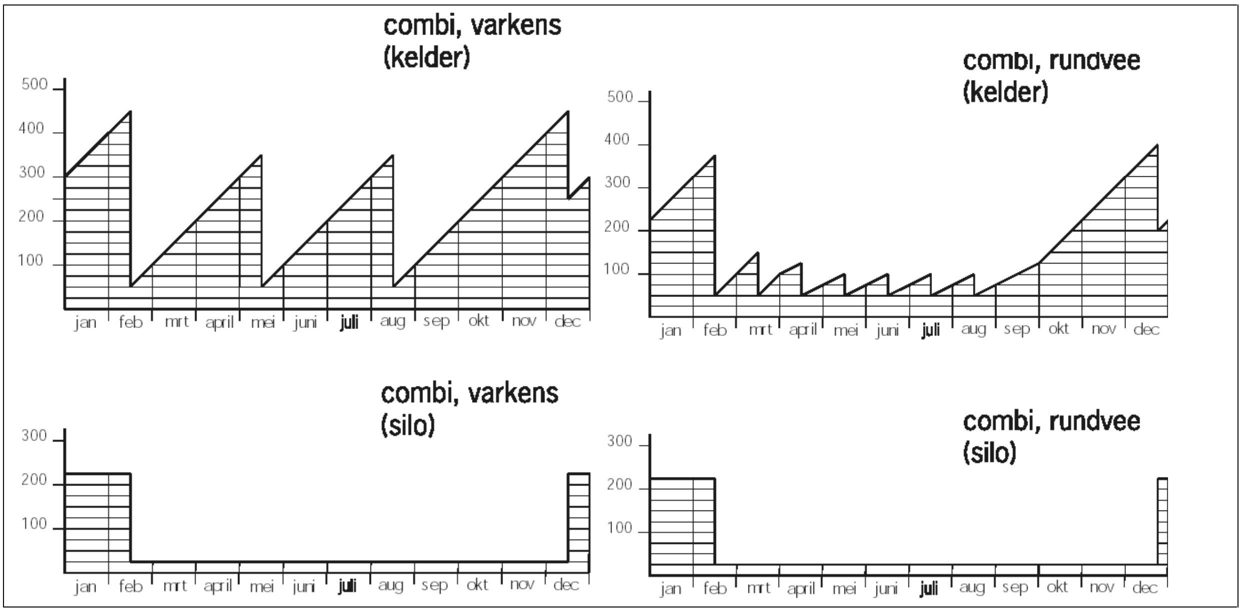

Figure 6 Utilisation of slurry storage capacity in farms with pits and silos, based on a capacity of 600 m^3, and a production of 100 m^3 per month. Varkens = pigs; rundvee = cattle; kelder = pit.

2.4.3 Slurry scenarios

Residue concentrations might be modelled provided the driving factors are quantified and standardised testing conditions are operational. Manure models that describe manure loading, quality change and fate of constituents (i.e. CO_2, NH_3) exist and could be adapted, but also have to be improved, a/o. on insufficiently developed manure production submodels, and the restriction to liquid manure facilities [23,36,37]. Some manure models operate at regional levels because the fate of omnipresent nutrients or oocytes is modelled [34] [58]. For the modelling of incidental contamination with medicinal products these models are not suitable.

Depending on the manure structure (solid or liquid), the manure is kept in bedding, piled, or stored in tanks or lagoons. Storage can be above ground (covered or not) and underground. Depending on structure and handling, the manure can be aerobic (transiently) or anaerobic. Acidity, oxygen levels, C:N-ratios, temperature and ammonia content determine microbial activity and hence manure quality and the concentration of the medicinal residues.

The uncertainty in the model parameters, relations, and results is considerable, also given the variation in the conditions and starting materials. Also, the effect of manure treatment might be considered. In theory, manure fractioning might concentrate residues in the solid or liquid fraction, and depending on the relative effective nitrogen concentration in these fractions; the load to soil might be different from the load when mixed manure is used. Manure treatment may decrease C and N content, hence increase drug residue concentrations and drug loads to soil. On the contrary, dilution with straw, degradation during storage, and slurry treatment, may lower drug residue concentrations.

The amount of slurry present in storage depends on the time of year; and depending on the number of cycles treated during this time, the concentration in the slurry is determined.
In general, both dosing and excretion are model processes that last a certain time span, depending on method of administration and substance [21,33,44,47,50]. Representative minimal time spans, based on the larger part of the dosage excreted, are in the range of 3-21 days.
The amount of manure that is spread containing the residue of the treatment is delimited by the storage capacity of the system and the opportunities to take the slurry out. In animal breeding systems where manure is removed on conveyer belts, dilution of residues with clean manure is avoidable. In systems where the manure is collected until it can be removed (e.g. by moving out all animals) the residues will always be diluted due to production of uncontaminated manure. Manure storage times ranging from zero weeks to 4 years have been established in the UK, and from 2 to 12 months in the Netherlands. Most UK farms only have the capacity to store slurry for less than one month (51% in the dairy industry and 70% in the beef industry). In Figure 5 a minimum storage time of 1 month for cattle and 3 months for pigs is proposed for the Netherlands. Figure 2 shows that cattle manure is the major source of animal N in Europe.

Targeting the marketing Authorisation at a European level, the agricultural practice and standards developed under the Nitrate directive should be used when emission of residues through manure is concerned [28]. The nitrogen immission standard of 170 kg N/ha/year describes a communautarian acceptable level.

The depth of incorporation depends on the method of application. In the field, no incorporation has been registered as general agricultural practice.

Realistic worst case conditions are hence proposed in a simple scenario (see Table 2-8 for details) assuming:

- single treatment per animal place,
- standard European nitrogen production values,
- application of the maximum manure application rate of 170 kg N/ha/year in one time,
- a manure production volume of 1 month (30 days) containing the full residue [P_N],
- no dissipation during storage, and no after-treatment of slurry,
- Incorporation into 5 cm soil with a bulk density of 1500 kg.m^{-3}.

$$PECsoil = \frac{D \cdot T \cdot m \cdot 170}{1500 \cdot 10000 \cdot 0.05 \cdot P_N}$$

Input		
D	Dosage used	[mg.kg$_{bw}^{-1}$.d^{-1}]
T	Duration of treatment	[d]
M	(Averaged) body weight	[kg$_{bw}$]
P_N	Nitrogen production animal in stable in 30 days	[kg$_N$]
Output		
PECsoil	Concentration in the soil	[mg$_c$.kg$_{soil}^{-1}$]

Table 2-8 European slurry scenarios for different livestock categories: fixed nitrogen production quota and body weights.

Type of Livestock	Nitrogen production (P_N) [kg N]	Proposed body weight (m) at treatment
Cattle		
Dairy cows	4.9	425 adult, 25 kg per calf (0.6 calf)
Other cows	3.6	425 adult, 25 kg per calf (0.6 calf)
Veal calves#	0.8	140
0-1 year	1.5	200
1-2 year	2.5	400
>2 year	2.9	450
Pigs		
Sows with piglets till 25 kg	2.6	240 adult; 9 kg per piglet (20 piglets)
Slaughter pigs 25-105 kg	0.6	65
Poultry		
Laying Hens	0.03	1.6
Broilers, 1.8 kg	0.02	1.0
Ducks, 3.3 kg	0.03	1.6
Turkeys, 13 kg	0.07	6.5
Sheep		
Ewes with lambs till 40 kg	1.1	75 adult; 20 kg per lamb (n=1.6 lambs)
Goat		
Females with kids till 7 kg	1.1	65 adult; 3.5 kg per kid (n=1.8 kids)
Rabbit		
Females with kittens	0.3	2 kg adult; 1 kg per kitten (n=8 kittens)
Horses	2.9	400

3. Scenarios for climate and soils in the EU

3.1 Groundwater leaching scenarios

Groundwater models and scenarios are to describe relevant conditions under which groundwater concentrations are to be calculated. However, a number of factors can make simulations of chemical transport in subsoil difficult. These include lack of information on subsoil properties, lack of information of chemical-specific properties of crop protection products and their metabolites, model limitations, and sometimes fractured rock or other substrates which cannot be properly simulated using existing models. Information on degradation of active substance and metabolites in subsoil is especially important, since in the absence of degradation the main change in concentration profiles is only the result of dispersion.

3.1.1 Screening level box models

The screening level box model for groundwater (porewater) as described in the EMEA guidance [16] contains few considerations on scenario definition (see Table 3-2).

Table 3-1 Default settings of the screening module for ground water.

parameter	symbol	unit	value
bulk density of fresh soil (not dry soil!)	RHOsoil	[kg.m-3]	1700
density of soil solids	RHOsolidsoil	[kg.m-3]	2500
fraction air in soil	Fairsoil	[m3.m-3]	0.2
fraction water in soil	Fwatersoil	[m3.m-3]	0.2
fraction solids in soil	Fsolidsoil	[m3.m-3]	0.6
weight fraction organic carbon in soil	Focsoil	[kg.kg-1]	0.02
temperature at air-water interface	TEMP	[K]	285
gas constant	R	[Pa. m3.mol-1.K-1]	8.314

Weather or crops are not considered. Soil is defined through compartment volumes for solids, water and air, dry bulk density and texture (mineral and organic fraction). Water movement is not considered, as the porewater is considered to be the groundwater.
Depending of the mixing depth in the soil, the groundwater level is defined. For example: at a mixing depth of 20 cm, groundwater levels are set at 20 cm.
Although this box models is considered a worst case because retention of chemicals during water and solute transport to deeper layers is not considered, it is not an unrealistic situation. In fact, shallow groundwater levels are typical for grassland areas in polders or lowland areas around river estuaries.

Variations in scenarios may be based on different soil bulk densities due to differences in soil texture and volume fractions, different organic carbon contents, or different mixing depths. The scenario does not consider a typical pH range. Therefore, substance input will have to consider the pKa of the substance and pH related sorption. Sorption is modelled through Koc, and other types of sorption are not accounted for.

3.1.2 Primary level models: FOCUS

Climate and soils are important factors in the determination of chemical concentrations in the environment. In 1993, the European Commission and the European Crop Protection Association jointly established FOCUS (Forum for the Co-ordination of pesticide fate models and their Use) who, as one of its tasks, established standard leaching and surface water exposure scenarios for pesticide registration in Europe. These scenarios are probably also appropriate for use in the environmental risk assessment of veterinary pharmaceuticals. Therefore we base the further description on the FOCUS report.

Locations were selected by an iterative procedure with the objective that they should:

- represent major agricultural regions (as much as possible).
- span the range of temperature and rainfall occurring in EU arable agriculture.
- be distributed across the EU with no more than one scenario per Member State.

However, there is no restriction or decision making criterion as to the depth at which a certain threshold has to be calculated or for which probability. This problem has been signalled by the FOCUS working group of groundwater and all model shells report integrated fluxes of water and relevant compounds at a depth of one metre.

3.1.2.1 Soils

The selection of soils was based on the properties of all soils present in the specific agricultural region represented by a location. Thus unrealistic combinations of climatic and soil properties were avoided. The intent was to choose a soil that was significantly more vulnerable than the median soil in the specific agricultural region, but not so extreme as to represent an unrealistic worst case. Soils that did not drain to groundwater were excluded when possible. Vulnerability was defined with respect to chromatographic leaching (that is, leaching is greater in sandy soils than in loam soils). The selection of appropriate soils was performed by expert judgement, except for the Okehampton location where SEISMIC, an environmental modelling database for England and Wales, was used to select a suitable soil. Soil maps were used to obtain information on the average sand and clay fractions and the organic matter in a region. Based on these average values, target values for soil texture and organic matter were developed for each location. In consultation with local experts, soils were selected which met these target values. In some cases special consideration was given to soils at research locations where measurements of soil properties were readily available. In a few cases the target values had to be re-examined during the process of picking specific soils.

Table 3-2 Overview of the nine FOCUS groundwater scenarios.

Location	Mean annual temp. (ºC)	Annual rainfall (mm)	Soil texture	Organic matter (%)
Châteaudun	11.4	648 + I	Silty clay loam	2.4
Hamburg	9.2	786	Sandy loam	2.6
Jokioinen	4.3	638	Loamy sand	7.0
Kremsmünster	8.8	900	Loam/silt loam	3.6
Okehampton	10.4	1038	Loam	3.8
Piacenza	13.3	857 + I	Loam	1.7
Porto	14.8	1150	Loam	6.6
Sevilla	18.1	493 + I	Silt loam	1.6
Thiva	16.2	500 + I	Loam	1.3

Figure 7 FOCUS groundwater scenario locations

3.1.2.2 Climate

As part of the scenario selection process, targets for annual rainfall were also developed for each site based on tables of annual rainfall (Heyer, 1984). These target values were used by the weather subgroup to identify appropriate climatic data for a 20-year period. The resulting average values for rainfall at each site (Figure 7) are shown in Table 3-2. Four locations (Châteaudun, Piacenza, Sevilla, and Thiva) were identified as having irrigation normally applied to at least some crops in the region.

3.1.2.3 Macropore Flow

The main reason for including macropore flow is that it can be an important process, especially in structured soils [20], [26]. Macropore transport is more affected by site characteristics and less by compound-specific properties than chromatographic flow. Reasons for not considering macropore flow would include

- although great progress have been made in the past few years, current estimation procedures for crucial macropore flow parameters are not yet sufficiently robust in comparison to chromatographic-flow models
- few of the normal regulatory models consider macropore flow, and
- sensitive sites for chromatographic flow are usually not the sites most sensitive to macropore flow (sites most sensitive to macropore flow are often finer-textured soils with drainage systems).

The FOCUS work group decided to develop parameters for one scenario to be able to compare differences between simulations with and without macropore flow to help demonstrate to Member States the effect of macropore flow. The Châteaudun location was chosen for this scenario because soils at this site are heavier than at most of the other sites and because experimental data were available for calibrating soil parameters. The macropores in the profile at Châteaudun are present to about 60 cm depth. Note that macropore flow is just one form of preferential flow. Forms of preferential flow other than macropore flow are not considered by current models and were not considered by the workgroup.

3.1.2.4 Crops

The use of various crops for each location necessitated the development of crop-specific irrigation schedules for the four irrigated locations, namely Châteaudun, Piacenza, Sevilla and Thiva. All major crops including grassland and maize are represented for the specific agricultural conditions (see Table 3-3).

3.1.2.5 Information on Crop Protection Products and Metabolites

Information on the chemical properties of the substance of interest, application rates, and application timing are left to the user to provide. Because the vulnerability of the scenarios is to be reflected in the soil properties and climatic data rather than in the properties chosen for the crop protection products and their metabolites, and because each simulation consists of twenty repeat applications, mean or median values are recommended for these parameters.

3.1.2.6 Implementation of Scenarios

Models The remit of the FOCUS workgroup was to develop scenarios generally suitable for evaluating potential movement to groundwater. The intent was not to produce model-specific scenarios but rather describe a set of conditions that can continue to be used as existing

Table 3-3 Crops included in FOCUS Scenarios by location

Crop	C	H	J	K	N	P	O	S	T
apples	+	+	+	+	+	+	+	+	+
grass (+ alfalfa)	+	+	+	+	+	+	+	+	+
potatoes	+	+	+	+	+	+	+	+	+
sugar beets	+	+	+	+	+	+	+	+	+
winter cereals	+	+	+	+	+	+	+	+	+
beans (field)		+		+	+				
beans (vegetables)							+		+
bush berries			+						
cabbage	+	+	+	+			+	+	+
carrots	+	+	+	+			+		+
citrus						+	+	+	+
cotton								+	+
linseed					+				
maize	+	+		+	+	+	+	+	+
oilseed rape (summer)			+		+		+		
oilseed rape (winter)	+	+		+	+	+	+		
onions	+	+	+	+			+		+
peas (animals)	+	+	+		+				
soybean						+			
spring cereals	+	+	+	+	+		+		
strawberries		+	+	+				+	
sunflower						+		+	
tobacco						+			+
tomatoes	+					+	+	+	+
vines	+	+		+		+	+	+	+

models are improved and better models developed. However, simulating any of these scenarios with an existing model also requires the selection of many model-specific input parameters. Therefore, for uniform implementation of these standard scenarios, computer shells were developed to generate the input files needed for the various computer models. Such shells, which include all scenarios, were developed for three widely used regulatory models (PELMO 3.2, PEARL 1.1, and PRZM 3.2). A shell for MACRO 4.2, another widely used model (and the most widely used considering macropore flow), was developed for the macropore flow scenario at Châteaudun. These shells also included post-processors to calculate and report the annual concentrations used as a measure of the simulation results.

Simulation Period As mentioned earlier, a simulation period of 20 years will normally be used to evaluate potential movement to groundwater. When applications are made only every other year or every third year the simulation period will be increased to 40 and 60 years respectively. In order to appropriately set soil moisture in the soil profile prior to the simulation period and because residues may take more than one year to leach (especially for persistent compounds with moderate adsorption to soil), a six year 'warm-up' period has been added to the start of the simulation period. Simulation results during the warm-up period are ignored in the assessment of leaching potential.

Calculation of Annual Concentrations The method for calculating the mean annual concentration for a substance or associated metabolites is the same for all models. The mean annual concentration moving past a specified depth is the integral of the solute flux over the year (total amount of active substance or metabolite moving past this depth during the year) divided by the integral of the water flux over the year (total annual water recharge). In years when the net recharge past the specified depth is zero or negative, the annual mean concentration should be set to zero. All mean concentrations are based on a calendar year. When applications are made every other year or every third year, the mean concentrations for each of the 20 two or three year periods are determined by averaging the annual concentrations in each two or three year period on a flux-weighted basis.

Simulation Depth All simulations have to be conducted to a sufficient depth in order to achieve an accurate water balance. For capacity models such as PRZM and PELMO, this means that simulations must be conducted at least to the maximum depth of the root zone. For Richard's equation models such as PEARL and MACRO, the simulations should be conducted to the hydrologic boundary. With respect to concentrations of active substances and metabolites, the EU Directive 80/68/EEC refers to concentrations in groundwater. However, a number of factors can make simulations of chemical transport in subsoil difficult. These include lack of information on subsoil properties, lack of information of chemical-specific properties of crop protection products and their metabolites, model limitations, and sometimes fractured rock or other substrates which cannot be properly simulated using existing models. Information on degradation of active substance and metabolites in subsoil is especially important, since in the absence of degradation the main change in concentration profiles is only the result of dispersion. Therefore, all model shells report integrated fluxes of water and relevant compounds at a depth of one metre. Models may also report integrated fluxes at deeper depths such as at the hydrologic boundary or water table, where technically appropriate. As more information becomes available and improvements to models occur, the goal is to be able to simulate actual concentrations in groundwater. Soil properties below 1 m are included in the soil property files for each scenario, along with the depth to groundwater.

Model Output The model shells rank the twenty mean annual concentrations from lowest to highest. The seventeenth value (fourth highest) is used to represent the 80th percentile value associated with weather for the specific simulation conditions (and the overall 90th percentile concentration considering the vulnerability associated with both soil and weather). When applications are made every other or every third year, the 20 concentrations for each two or three year period are ranked and the seventeenth value selected. In addition to the concentration in water moving past 1 m, the outputs also include at a minimum a listing of the input parameters and annual water and chemical balances for each of the simulation years. Water balance information includes the annual totals of rainfall plus irrigation, evapotranspiration, runoff, leaching below 1 m, and water storage to 1 m. Chemical balances (for the active substance and/or relevant metabolites) include the annual totals of the amount applied (or produced in the case of metabolites), runoff and erosion losses, plant uptake, degradation, volatilisation losses, leaching below 1 m, and storage to 1 m. All variables may additionally be reported at a depth greater than 1 m, as discussed previously.

3.1.2.7 The use of mean values in worse case scenarios

The FOCUS approach for the assessment of the leaching potential of substances to groundwater is to set up 90th percentile worse case scenarios for simulation model runs to a depth of 1 metre. As many other test scenarios the FOCUS scenarios for main agricultural regions consists of several subscenarios: Weather (precipitation and irrigation), soil, crop and substance (degradation, sorption). The subscenarios (e.g. weather) can be split up further (in precipitation and irrigation) as indicated above. As outlined in the respective chapters, the 90th percentile vulnerability of the scenario is achieved by evenly creating an 80th percentile vulnerability or worse case situation for the soil and the weather subscenarios leading with a high probability to a 90th overall percentile target for the whole leaching scenario. More favourable situations in one subscenario (e.g. weather) can be theoretically balanced by less favourable situations elsewhere (e.g. substance sorption). If the target value for the overall worse case is a 90th percentile and determined by the settings of the vulnerability in the soil and weather scenarios the use of further subscenarios with a significant different percentile than the 50th percentile (median) would probably change the overall targeted value significantly. If further subscenarios are parameterised by a 90th percentile worse case, for example, this would lead to a situation that represents clearly more than a 95 or 99th percentile worse case, at least if the parameters are independent. The addition of several worse case subscenarios may therefore sometimes lead to a very unrealistic overall scenario that hardly can be found in nature.

Soil Properties Due to the variability of nature, a set of measurements of any parameter, even within an otherwise homogeneous field or plot, will produce a number of different values. For hydraulic conductivity, single values may vary with a factor of 1000. This leaves the modeller with the problem of choosing a value to use in modelling. Some scientific efforts have been put into determining ways of estimating ‘effective parameters’ for field scale simulations. An ‘effective parameter’ in this sense means the parameter value which best represents the average conditions for the given parameter within a given area, e.g. a field. The results from literature on whether effective parameters can be used to simulate average field scale behaviour are ambiguous. It is expected that the soil parameters generated by HYPRES, and used in the FOCUS leaching scenarios, produce values that may be assumed to be ‘effective parameter values’.

Substance properties The variability of substance degradation (DT50) in various soils has been estimated to have a coefficient of variation of around 100 %; sorption (K_{oc} value) seems to vary about half of that. The use of appropriate mean values (arithmetic or geometric means/medians) for these relatively variable input values can reduce the uncertainty of model predictions, compared to the use of a single value from one experimental year or soil. Repeated use of the same substance over 20 years is already a worst case assumption. To also assume worst-case substance properties for each of these 20 applications would be truly extreme. Note that although the recommendation is to use an average Kom or Koc value, the Kd value used in the simulation for a given scenario is not a mean, since it depends on the soil %om, which is defined as a part of the set of realistic worst case soil properties, and is in general low. An average Koc value multiplied by a low %oc results in a low soil adsorption coefficient.

3.1.3 Uncertainties related to the choice of groundwater scenarios

The realistic worst case was identified by the concept that scenarios should correspond to 90th percentile vulnerability situations. This is, in reality, a function of all system properties (weather, soil, groundwater, crop, substance application and chemical properties). A correct theoretical approach would imply development of a few hundred scenarios at the EU-level, which should all be run for the specified substance. A 90th percentile vulnerable scenario could then be identified from the resulting frequency distribution. However, the development of hundreds of scenarios was beyond the scope of the working group and databases for soil properties and crop parameters were not available to the working group. It was assumed that the final scenarios should have a probability, pY, of 90 % and that the vulnerability should be divided equally on weather and soil (both equal to pX). Figure 8 illustrates how these percentages were defined and the uncertainty related to this approach. It is not possible to calculate the value of pX exactly, but minimum and maximum values may be established. If the weather and the soil are independent events, we can infer from conditional probability theory that the minimum value of pY, is described by neither the soil nor the weather condition being vulnerable, pXsoil*pXweather (lower boundary) . The maximum value of pY is described by the situation where both the soil and the weather conditions are considered vulnerable, pY = 1-(1-pXsoil)*(1- pXweather) (upper boundary). The probability of one factor being vulnerable, and the other not, makes up the area between the curves.

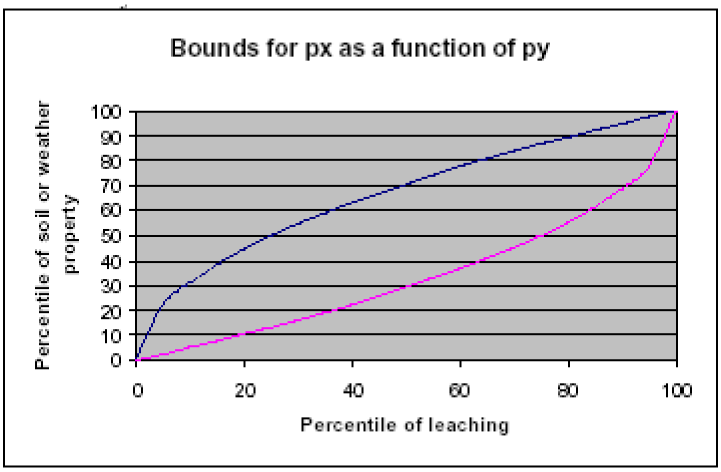

Figure 8 Illustration of the procedure used for defining the desired percentile vulnerability of weather and soil conditions, to result in an overall 90th percentile vulnerability for the scenario as a whole.

From these considerations an 80th percentile was chosen for the weather data. Due to lack of available databases on soil properties at the European scale, the selection of the appropriate soils had to be performed mainly by expert judgement, and based on an assumption of chromatographic flow.

Once suitable datasets are available, the scenario-sites and combinations between weather and soil could be critically reviewed in order to investigate what leaching risk they actually represent. A more detailed evaluation of vulnerability would require simulation of a (large) number of sites within each climatic region, with a few model substances, but this amount of work has not been feasible within the FOCUS framework. From such an evaluation, an ‘80% vulnerable soil’ or soil/weather combination could be chosen on a more scientific basis. However, due to the fact that soil vulnerability depends on many factors, including the substance, this could result in a different number of scenarios to the present nine, and they might be different in character to the present scenarios. In practice, it may not be possible to validate the exact scenarios as they exist at the moment, as they are virtual scenarios that do not exactly represent any specific location that could be located.

Further considerations to uncertainty related to preferential flow, hydrodynamic dispersion, input of weather, irrigation, soils, crops and substance parameters, and output of the models (calculation of means or 80 percentiles, time span) are given by the FOCUS working group.

Uncertainty related to variability in actual groundwater levels has not been considered.

3.2 Surface water scenarios

3.2.1 Screening level box models

Ideally, when calculating $PEC_{\text{surface water}}$ for European registration purposes, modellers should be able to draw on a limited number of well defined European scenarios. Worst case loadings are based on maximum annual applications and no specific climate, cropping, topography or soil scenarios are necessary. It is therefore recommended that a single, agreed *'Step 1 standard European surface water scenario'* be defined based on the following elements:

- Dimensions of the water body - *width, surface area, and depth of water*.
- Flow regime in the water body - *Static*.
- Suspended solids - *Mass per unit volume, organic carbon fraction*.

In the first tier run-off and drainage are modelled in box models assuming 10% transport to surface water and a surface water/land area ratio of 1:5. This applies for the total load of the substance in one year. If repetitive treatments are accounted for, transport coefficients are differentiated [19].

The screening level box model for groundwater (porewater) as described in [16] and [32] contains few considerations on scenario definition.

The EMEA model (1997) contains a transport model (soil-to-water transport) and a catchment model (distribution and concentration in surface water). Substances not adsorbed to soil particles may be present in the soil water and thus be prone to run-off during rainfall events. The amount of rainfall relative to interstitial pore water, and subsequent dilution will influence the concentration in surface waters by the receiving water. The concentration of substance in the interstitial pore water can be estimated using the formula:

$Ciw = Cs/Koc*foc$

where

Ciw = concentration in interstitial water (μg/L);
Cs = concentration in soil (μg/kg dry soil) and
foc = fraction of organic carbon in soil (kg oc/kg dry soil). [16].

It is assumed that catchment areas tend to be proportional in size to the receiving stream therefore no account is taken of the size of the catchment or receiving water. It is assumed that soil moisture increases by 10% when run-off occurs. Further dilution occurs on entry of run-off into the receiving water. It can be assumed that two parts receiving water will dilute one part run-off water. The total dilution factor of porewater then amounts to 3.3.
The Montforts model (1999) uses the same concepts, using the porewater calculus for groundwater and a dilution factor of 10 (instead of 3.3).

3.2.2 Primary level scenarios: FOCUS

Unfortunately, the FOCUS scenarios for surface water have not been finalised before the end of 2002 and are not discussed in this report.

3.2.3 Primary level scenarios: Mediterranean scenarios

The standard European scenarios do not address properly the conditions of certain Mediterranean crops. The problems observed for pesticides can be extrapolated to veterinary medicines, because they are based on differences in geographical, climatic, and agricultural conditions that are similar for all agrochemicals. In summary:

- The local edge of field scenarios developed for Atlantic and Central Europe conditions are not directly applicable to the Mediterranean region.
- These scenarios overestimate the $PEC_{\text{surface water}}$ for chemicals with low persistence in soil, while can underestimate the value for persistent chemicals, particularly for those with low mobility in soil where manure run-off and soil erosion represents the most significant routes for surface water contamination.
- Monte Carlo analysis offers a suitable alternative for setting probabilistic estimations accounting the degradation kinetics of the assessed chemical.

3.2.3.1 Scenarios definition

Figure 9 presents the distribution of Geographical regions in Europe, obtained from the European Environmental Agency. Setting strict limits between areas is obviously difficult and therefore the conditions in the borderline area should be assumed as transition bounders. The Figure clearly shows that regions are not associated to the traditional North/South scheme frequently employed in the risk assessment of pesticides. Spain and Portugal offer a perfect example of Southern countries where part of the territory is in the Atlantic region and other part in the Mediterranean region. Similarly, Greece covers part of the Mediterranean and the Central regions, the North of Italy has a strong Alpine influence, and up to four different regions can be found on the French territory.

The regional characteristics have obvious influence on the agricultural conditions; include manure application and the risk associated to this practice. Risk of groundwater contamination by nitrogen is regulated at the EU level, while models covering other environmental hazards, such as surface water pollution due to inputs of organic matter and nitrogen compounds are available [55]. The exposure assessment of chemicals presents in fertilisers, obviously including veterinary medicines, also present significant differences in the Mediterranean region. Two main differences determine the kind of exposure scenario required for the Mediterranean region: relatively large river basins feed low flow rivers, and the role of soil erosion. Additional differences have been presented elsewhere [45].These differences must be considered when setting the $PEC_{\text{surface water}}$.

Figure 9 Distribution of geographical regions in Europe. Taken from EEA website, 2003.

The suitability of a local scenario, based on edge of field estimations, must be considered, particularly, when most current agricultural practices for manure application establish buffer zones between the treated area and aquatic systems [31]

Figure 10 presents a screening comparison of $PEC_{surface\ water}$ estimations for edge of field and three regional scenarios based on the percentage of chemical transport from soil to surface water. The edge of field estimation follows the principles settled for pesticides, considering an static water body 30 cm depth. The regional scenarios are based on data for the Ebro river and two tributaries, Zaorra, with a river basin surface of 1023 km^2, and Bayas with a river basin surface of 187 km^2. Total basin and agricultural surfaces, annual and daily rainfall, river flow and rainfall to flow ratios, are employed for quantifying the expected river concentration. For the large and medium river basins (Ebro and Zaorra) it is assumed that the manure will be used on 25% of the total agricultural surface within the basin. For the small Bayas river, the application on 50% of the agricultural surface is assumed.

Three main exposure routes, drainage, run-off and soil erosion, are considered relevant in the area. Drainage is not relevant at the local level as due to the scarcity of water (typical Mediterranean conditions are defined by an annual rainfall lower than 500 mm) no drainage channels are required within the area. However, a combination of drainage and leaching is relevant at the regional level, as a significant contribution of the water flow comes from this route.

The heterogeneous distribution of rainfall around the year determines the relevance of run-off episodes, and combined with the average slope and low vegetation coverage, the soil losses associated to soil erosion.
In Figure 10, the total transport from soil to rivers, as a combination of all three routes, is presented as a percentage of loss.

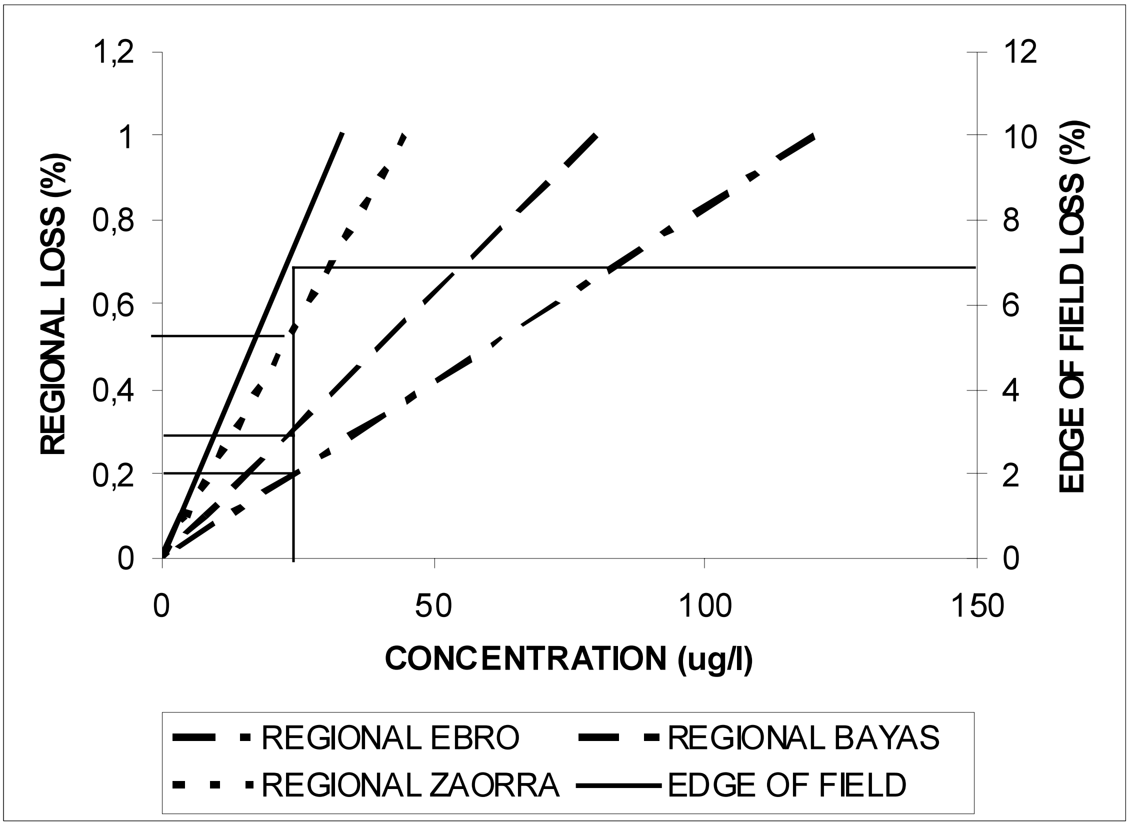

Figure 10. Comparison of regional versus local scenarios for the Mediterranean conditions.

These estimations indicates that relatively small losses, well below 1% of the total applied amount, may result in surface water concentrations above those expected for local, edge of field, estimations.

The likelihood for achieving these losses is discussed below.

Drainage and leaching are strongly dependent of the chemical characteristics. The groundwater estimations, based on mobility and degradation in soil, may offer an estimation of the expected concentration in draining water, the contribution of drainage/ground water to the overall river flow and the percentage of the total surface treated with the chemical allows the estimation of the expected dilution factor.

Run-off is, in principle, also associated to the chemical properties, and expected to be relevant for chemicals with high water solubility and low soil binding capacity. However, as the veterinary drugs will be applied with the manure, run-off of manure particles containing the drug and or metabolites must also be consider, for run-off events occurring shortly after application. Assuming an homogeneous mixing of manure within the top 20 cm of arable soil and the potential run-off of the manure remaining at the top 1 cm layer a loss as high as 5% of the applied dose can be estimated.

Soil erosion distributions for Europe and the Ebro river Basin are presented in Figure 11 and Figure 12, respectively.

Soil losses ranging from 12 to 100 Tm per year are frequently observed for agricultural soil in the Ebro river basin. These values represent a loss of 0.4 to 3.3 % of the arable soil layer per year, and of the chemicals associated to this soil.

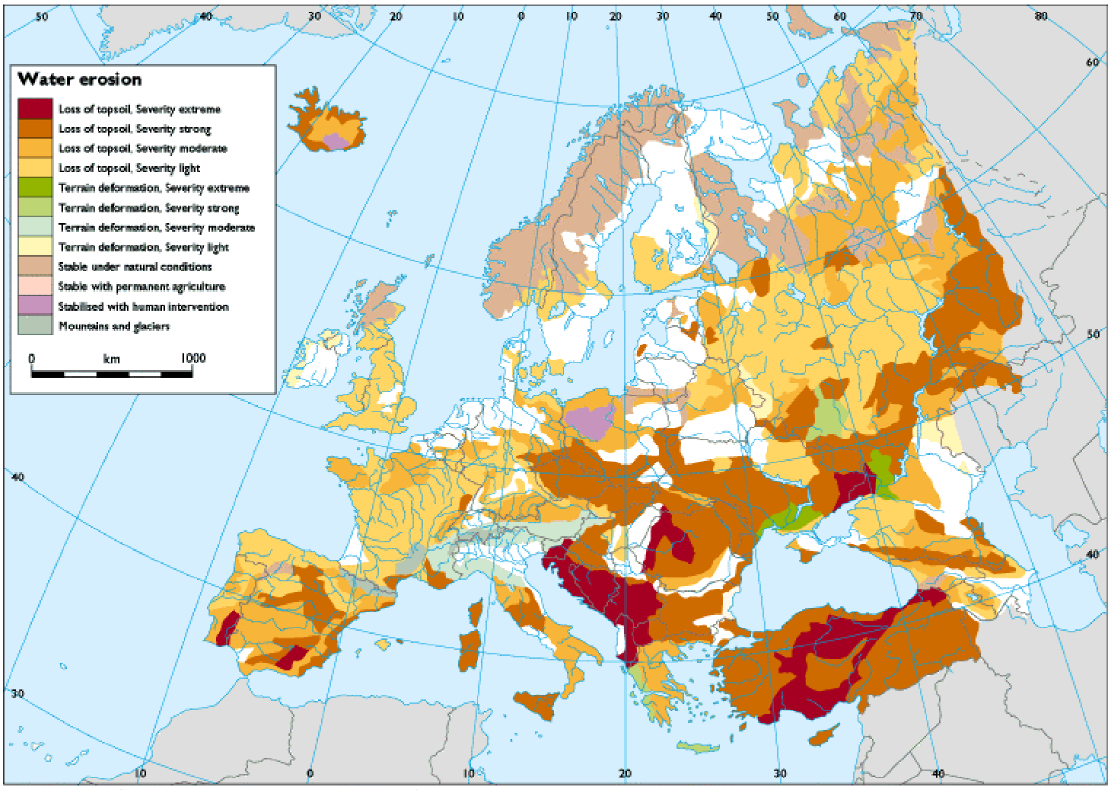

Figure 11 Soil losses in Europe. Take from European Environmental Agency website 2003.

Therefore, the initial non realistic screening assessment indicates that the traditional edge of field approaches does not cover the Mediterranean conditions and regional scenarios are required.

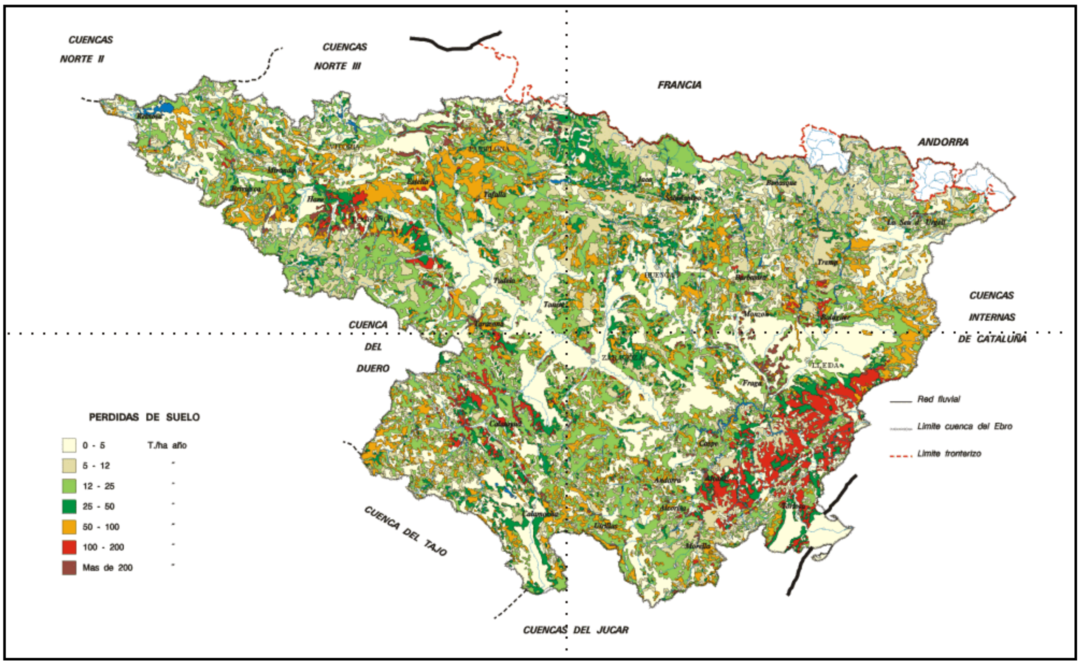

Figure 12. Soil losses in the Ebro river basin. Taken from the Confederación Hidrográfica del Ebro CHE website, 2003.

3.2.3.2 Likelihood for losses associated to drainage/leaching, run-off and soil erosion.

The transfer of the veterinary pharmaceutical from soil to surface water is obviously associated to likelihood for rainfall evens. As mentioned before, the heterogeneity of rainfall distribution within the year is also a relevant characteristic of the Mediterranean region. Two basic factors, the magnitude of the rain even and the concentration of chemical remaining in the soil/manure when the rain even occurs, will regulate the expected concentration in water. Obviously, the second factor depends on the soil dissipation characteristics of each particular chemical. Persistent chemicals will have a much higher probability for reaching surface water than those chemicals which are rapidly degraded in soil.

Monte Carlo analysis, based river flow changes for small rivers within the Ebro river basin, have been employed for refining the likelihood for surface water contamination.

Figure 13 presents the results obtained when the degradation of the chemical is not considered. Results just resemble the distribution of the magnitude of the expected rain evens.

The introduction of the soil degradation rates produces large changes in the outcome of this probabilistic assessment, as presented in Figure 14. The relationship between the soil DT50 and the likelihood for surface water contamination assuming a chemical loss of 0.1% of the amount remaining in the soil at the time the rain even occurs is presented as a trend chard and compared to the outcome of a local edge of field assessment for the same chemical transfer (0.1% of the applied amount).

For this Ebro river tributary, the edge of field deterministic estimation corresponds to the 90th percentile of the $PEC_{surface\ water}$ distribution for a rapidly degraded chemical, while much higher surface water concentrations are expected for more persistent chemicals.

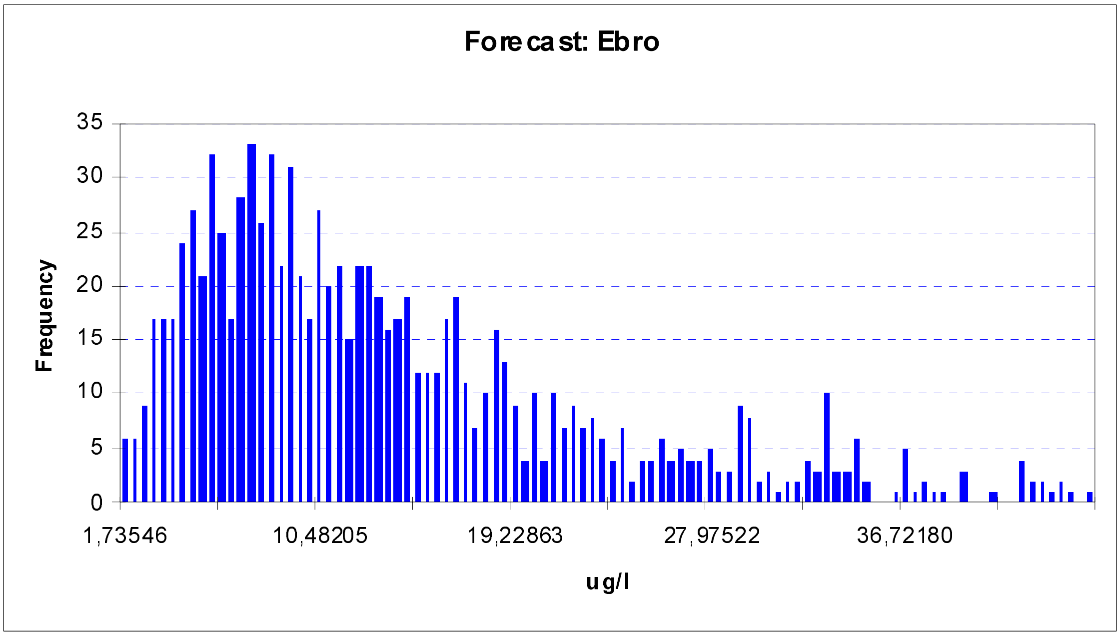

Figure 13. Example of the likelihood for surface water contamination for a persistent chemical.

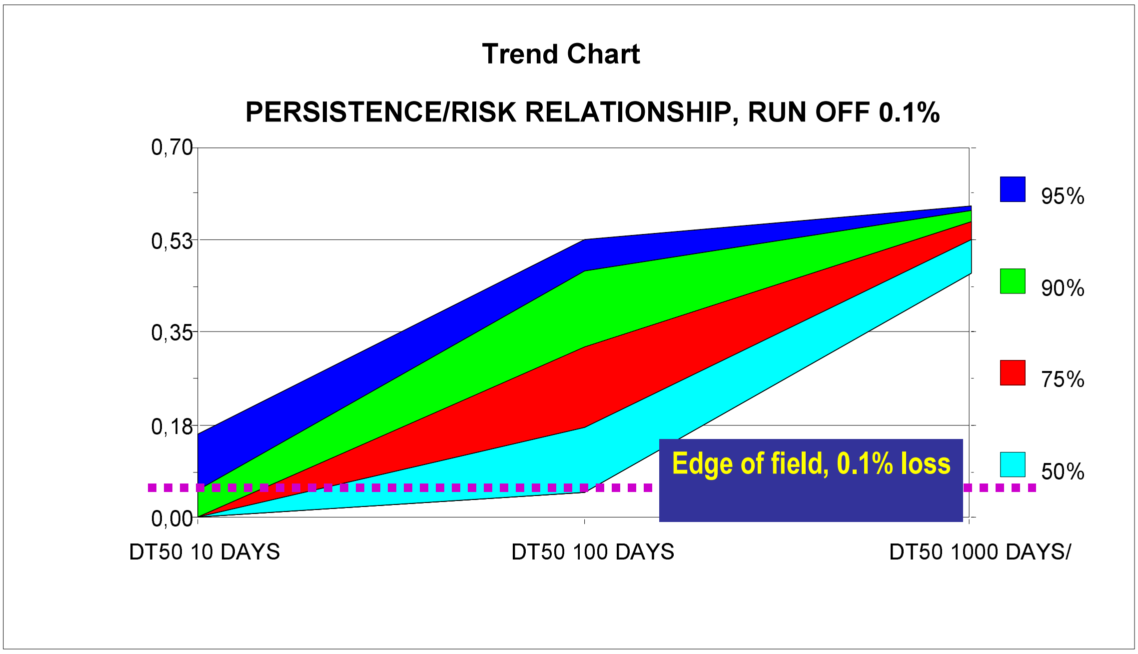

Figure 14. Probabilistic Monte Carlo analysis of the PEC$_{surface\ water}$ water associated to soil losses of 0.1% of the remaining amount for chemicals with DT50 values of 10, 100 and 1000 days.

4. Discussion

In this report animal husbandry, slurry handling and environmental conditions throughout Europe are considered in order to define realistic worst case scenarios, in conjunction with environmental distribution models.

One may find the definition of representative vulnerable conditions (scenario) for a single calculation a suitable option. This has certain advantages: the outcome is fairly simple; this point simulation allows for validation of the model and the characteristics (scenario) can be assigned by means of spatial analysis of all information.

The uncertainty in the slurry exposure parameters, model relations, and results is considerable, also given the variation in the conditions and starting materials. Also, the effect of manure treatment might be considered. In theory, manure fractioning might concentrate residues in the solid or liquid fraction, and depending on the relative effective nitrogen concentration in these fractions, the load to soil might be different from the load when mixed manure is used. Manure treatment may decrease C and N content, hence increase drug residue concentrations and drug loads to soil. On the contrary, dilution with straw, degradation during storage, and slurry treatment, may lower drug residue concentrations.

The amount of slurry present in storage depends on the time of year; and depending on the number of cycles treated during this time, the concentration in the slurry is determined.

Manure storage times ranging from zero weeks to 4 years have been established.

Targeting the marketing Authorisation at a European level, the agricultural practice and standards developed under the Nitrate directive should be used where manure quality at application are concerned [28]. The nitrogen immission standard of 170 kg N/ha/year describes a Communautarian acceptable standard.

Realistic worst case conditions are hence proposed in a simple scenario assuming:
- single treatment per place,
- standard European nitrogen production criteria,
- application of the maximum manure application rate of 170 kg N/ha/year in one time,
- with a manure production volume of 1 month (30 days) containing the full residue [P_N],
- no dissipation during storage, and no after-treatment of slurry.
- Incorporation into 5 cm soil (no tillage) with a dry bulk density of 1500 kg.m^{-3}.

$$PECsoil = \frac{D \cdot T \cdot m \cdot 170}{1500 \cdot 10000 \cdot 0.05 \cdot P_N}$$

The PECsoil can be used in conjunction with screening level models that predict mass transfer to groundwater and surface water.

Screening level and mechanistic models provided by FOCUS are considered as suitable for veterinary drugs as for pesticides and can be run using European scenarios for soil and weather, with and without incorporation of the substance in the topsoil. The FOCUS scenarios and models aim at the same agricultural fields where the slurry will be applied. Application timers in the models should be set to relevant regional conditions for manure application. These may depend on spreading restrictions and where these do not apply, by worst case conditions (e.g. autumn vs. spring conditions).

Several medicinal substances display a sorption behaviour that does not correlate with the organic matter content of the medium [52], [43], [30]. The sorption parameter is used at different levels with different percentages of organic carbon in the model. Therefore, the possibility to use a Kd value instead of Koc values prevails over deriving pseudo-Koc values for the top soil layer.

Distinctions between leaching, run-off en drainage can be made. The drainage and run-off models have not been assessed.

Additionally, for run-off and erosion in Mediterranean regions a river-catchment model is proposed.

Given the variability in manure management a straightforward approach for the manure model was selected. Risk reduction measures related to manure management and manure treatment cannot be assessed using the proposed methodology.

These scenarios do not prejudice the authority of Member States in national authorisations, nor do they prejudice the application of other Community legislation in force. It is recommended that Member States develop their own national and regional scenarios for the assessment to ensure that the national quality standards are met. Amongst others, changes in immission standards, storage times, manure qualities, and differentiations in manure application, animal categories, soil type, land use, and crop are to be considered.

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Appendix 1 Mailing list

1 EC Research DG, Energy, Environment and Sustainable Development programme, K. Haavisto. European Commission, SDME 2/85, B-1049 Brussels - Belgium
2 VROM, Directoraat Generaal Milieubeheer, Directie Bodem, Water en Landelijk Gebied, drs H.G. van Meijenfeldt
3 VROM, Directoraat Generaal Milieubeheer, Directie Bodem, Water en Landelijk Gebied, drs J.de Rijk
4 LNV, Directoraat Generaal Landbouw, Directie Voedings- en Veterinaire Aangelegenheden, drs M.E. Siemelink
5 LNV, Directoraat Generaal Landbouw, Directie Voedings- en Veterinaire Aangelegenheden, drs G.T.J.M. Theunissen
6 VROM, Directoraat Generaal Milieubeheer, Directie Stoffen, Afvalstoffen en Straling, dr J.A. van Zorge
7 Rijksinstituut voor Integraal Zoetwaterbeheer en Afvalwaterbehandeling, dr G. Rijs
8 EMEA, Safety of Veterinary Medicines, London, UK, dr K. Grein
9 CVMP, Bureau Registratie Diergeneesmiddelen, Wageningen, dr J.P. Hoogland
10 Ministry of Health, National Chemical Bureau, Llubljana, Slovenia, dr S. Fajfar
11 AFSSA, ANMV, Fougeres, France, dr J.-C. Faucon
12 BMI, Safety of Veterinary Medicines, Brussels, Belgium, dr M. Goret
13 AUTH, Faculty of Veterinary Medicines, Thessalonike, Greece, dr A.P. Kamarianos
14 UBA, Berlin, Germany, dr J. Koschorrek
15 VMD, Pharmaceuticals and Feed additives, Addlestone, UK, dr C. Long
16 PKKZ, Medical Products Agency, Uppsala, Sweden, dr M. Malmqvist
17 Irish Medicines Board, Dublin, Ireland, dr D. Murphy
18 FEI, Chemicals Division, Helsinki, Finland, dr E. Nurmi
19 NPA, Direcção-Geral de Protecção das Culturas, Oeiras, Portugal, dr B. Oliveira
20 UBA, Berlin, Germany, dr I. Rönnefahrt
21 Danish Medicines Agency, Brønshøj, Denmark, dr C. Sommer
22 VMD, Pharmaceuticals and Feed additives, Addlestone, UK, dr A. Tait
23 UBA, Berlin, Germany, dr E. Thumm
24 IVCA, Department for Residue Research, Athens, Greece, dr A.E. Tyrpenou
25 FEI, Chemicals Division, Helsinki, Finland, dr V. Virtanen
26 IFAH-Europe, FIDIN, Den Haag, mr. M. van Assen
27 Danish Environmental Research Institute, Silkeborg, Denmark, dr J. Jensen
28 INIA, Laboratorio de Ecotoxicologica, Madrid, Spain, dr J.V. Tarazona Lafarga
29 Cranfield University, Centre for Ecochemistry, Derby, UK, dr A.B.A. Boxall
30 Danish University of Pharmaceutical Sciences, Section of Environmental Chemistry, Copenhagen, Denmark, dr B. Halling-Sorensen
31 Rostock University, Institut für Bodenkunde und Pflanzenernährung, Rostock, Germany, dr S. Thiele-Bruhn
32 Tierärztliche Hochschule Hannover, Germany, dr G. Hamscher
33 EAWAG Switzerland, Dübendorf, Switzerland, dr S. Müller
34 IRAS, Utrecht, drs T. van der Laak
35 ECT Oekotoxikologie GmbH, Flörsheim a.M., Germany, dr. J. Moltmann

36	Henkel GmbH & KGaA, Düsseldorf, Germany, dr J. Tolls
37	TUT, Institute of Biotechnology and Environmental Engineering, Tampere, Finland, dr S. Kuusisto
38	Depot Nederlandse Publikaties en Nederlandse Bibliografie
39	Directie RIVM
40	Sectordirecteur Milieurisico's en Externe Veiligheid, dr ir R.D. Woittiez
41	Hoofd Stoffen Expertise Centrum, dr W.H. Könemann
42	dr R. Luttik, RIVM/SEC, projectleider Risicobeoordelingsmethodologie
43	dr J.A. de Knecht, RIVM/SEC
44	ir A.M.A. van der Linden, RIVM/LDL, projectleider Stofstromen
45	ir G.J. Schefferlie, RIVM/SIR, projectleider Beoordeling Diergeneesmiddelen
46	ing P.L.A. van Vlaardingen, RIVM/SEC, projectleider Beoordeling Diergeneesmiddelen
47	ir J.B.H.J. Linders, RIVM/SEC
48	ir P. van der Poel, RIVM/SEC
49	ir A.J. Verschoor, RIVM/SEC
50	Auteur
51	SBC / afdeling Communicatie
52	Bureau rapportregistratie
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55-60	Bureau Rapportenbeheer RIVM