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PHARMACEUTICALS AND PERSONAL CARE PRODUCTS IN THE ENVIRONMENT: A SUMMARY OF PUBLISHED LITERATURE

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Cosmetics and Personal Care Products			
Cosmetics and Personal Care Products	Canada - Health Canada	There are no Health Canada regulations or requirements for environmental assessment of cosmetics and personal care products. However, any new ingredients may theoretically be subject to assessment under CEPA, 1999, prior to this all ingredients regulated under another act (i.e. Food and Drug Act) were exempt from CEPA. To date there have been no environmental assessments conducted for Health Canada on cosmetic ingredients.	Health Canada, 2000; Health Canada personal communication 2001.
Cosmetics and Personal Care Products	US FDA	In general, the FD&C Act in the U.S. does not provide a mandate for FDA to require premarket approvals for finished cosmetic products or constituent raw materials, nor are environmental assessments generally required (with the possible exception of certain rulemaking proceedings).	FDA/CFSAN/OCAC/HFS personal communication 2001
Cosmetics and Personal Care Products	EU	There is no legal requirement for environmental risk assessment of cosmetics and personal care products. However, it is likely that in the future some form of evaluation of possible environmental effects will be required in the form of a simple algorithm(s) using information on release routes, and levels, rates, together with physchem data, similar to that taken for veterinary drugs. Tiered approach is seen as cost-effective but stress the scientific basis of the protocol must be guaranteed. Potential for significant effects at very low doses is acknowledged. A common framework for dealing with environmental issues is desirable (across human/animal health care, pesticides and cosmetics) and the adoption of	1st Report on Harmonization of Risk Assessment Procedures Part 1: report of the Scientific Steering Committee's Working Group on Harmonization of Risk Assessment Procedures in the Scientific Committees Advising the European Commission in the area of human and environmental health 26-27 October, 2000

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		an integrated approach to risk assessment (i.e. human and environmental risks alongside one another) as is discussed in the 1st Report on Harmonization of Risk Assessment Procedures.	(published on the internet 20/12/2000) http://europa.eu.int/comm/food/fs/sc/ssc/out83_en.pdf;
Cosmetics and Personal Care Products	EU	The classification of substances as ingredients of cosmetic products is recommended by the Scientific Committee on Cosmetic products and Non-Food Products intended for Consumers (SCCNFP). The classification is made on the basis of scientific evaluation of data pursuant to the Guidelines on the Safety Assessment of Cosmetic Ingredients. The overriding consideration is that products should be safe for consumer use under conditions of intended exposure at the relevant concentrations - there is no consideration of environmental effects of cosmetic ingredients.	Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers - The Classification of Substances adopted by the SCCNFP during the 11th Plenary meeting of 17 February 2000 http://europa.eu.int/comm/food/fs/sc/sccp/out110_en.html
Nitro Musks - Fragrances	EU	Since 1994 efforts have been taken by the fragrance industry in Switzerland to reduce the amount of musk xylene in detergents and cleaning agents. The use of musk ambrette was ban in the EU in 1995 and it has been included in the list of banned components in cosmetics. As of 1998 musk ambrette has been forbidden in Switzerland. Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) on Musk Xylene-estimated exposure through cosmetic use is 207 ug/kg/d or 20.7 ug/kg/d theoretically absorbable. SCCNFP recommended the absorbable dose be reduced to 10 ug/kg/d based on quantitative risk assessment and lifetime cancer risk of 1x10-4 for non-genotoxic carcinogen. Does not consider exposure to musk xylene through sources other than fine fragrance, eau de toilette, fragranced cream, body lotion, other cosmetics (e.g. laundry products not included in risk assessment).	Berset et al. 2000; SCCNFP/0163/99 Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers Concerning Musk Xylene. Adopted by the plenary session of the SCCNFP 8 December, 1999.

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Human Health Products			
Human Health Pharmaceutical/ Biological Products	Health Products and Food Branch, Healthy Environments and Consumer Safety Branch	In progress is the development of environmental assessment regulations appropriate for F&DA products while meeting Health Canada's obligations under CEPA.	Health Products and Food Branch, Healthy Environments and Consumer Safety Branch, June 2001.
Human Health Pharmaceutical/ Biological Products	Health Canada, Therapeutic Products	Currently there are no specific regulations/guidelines established pertaining to the environmental assessment of drugs for human health which are covered under the Food and Drug Act and thereby formally exempt from CEPA. However, all new substance to Canada are subject to CEPA, 1999. Thus any new pharmaceutical ingredient to Canada would theoretically require environmental review in accordance with CEPA, 1999. To date (February 2001) no new human health pharmaceutical ingredients have been reviewed under CEPA 1999.	Health Canada. 2000; Health Canada personal communication 2001.
Human Health Pharmaceutical products - OTC	Health Canada, Therapeutic Products	TPP completed an assessment of phenol in OTC medications in August 1999. The review was in response to CEPA Priority substance list assessment report for phenol that was published in Canada Gazette part I, May 1, 1999. Emphasis was human health effects and derivation of TDI for phenol; it did not address potential for environmental effects through use of these products. Aluminum salts are present in OTCs and cosmetics. Environment Canada published a State of the Science Report for Aluminum Chloride, Aluminum Nitrate and Aluminum Sulfate, December 2000. Industry paper entitled Aluminum in Drugs by NDMAC and CCTFA was submitted to Mr. Joel Paterson, Priority Substances Section of the Environmental Health centre, March 28, 2000. The report on aluminum discussed use in OTCs and exposure through drugs and	Nonprescription Drug Manufacturers Association of Canada, letter from Robert White, Director of Scientific Affairs, January 31, 2001

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		food; it did not address potential environmental effects through use of these products. OTCs do not commonly use new chemical entities.	
Pharmaceutical Products-Environmental Concentrations	US	Responsibility for monitoring drugs in the environment does not lie with either USEPA or USFDA.	
Human Health Pharmaceutical Products (Synthetic and naturally occurring drugs)-Environmental Assessment	USFDA	FDA requires Environmental Assessments under the National Environmental Policy Act of 1969 (NEPA). Concern is for acute and chronic effects as determined in standardized toxicity tests. Recognizes "extraordinary circumstances" with potential to "significantly affect the quality of the human environment" and would include ecosystem effects/changes. Intensity and severity of the environmental impact is considered. The FDA approach is based on the calculation of predicted environmental concentration (EEC or PEC) at the point of entry to the aquatic environment. If the expected introduction concentration (EIC) > 1ppb an EA is required. FDA uses a tiered approach based on assessment factors (e.g. EC50/max EEC) and bioaccumulative potential. Three tiers of testing are defined: Tier 1: acute tox in one suitable test organism – if LC50 (or EC50)/MEEC <1000 go to tier 2; Tier 2: acute tox in organisms from 3 trophic levels – if LC50 (or EC50) for most sensitive/MEEC < 100 go to tier 3; Tier 3: chronic tox testing if agent bioaccumulates (Kow > 3.5), is indicated based on tier 1 or 2, or is converted to more toxic compound.	FDA (Food and Drug Agency) Guidance for Industry: Environmental Assessment of Human Drug and Biologics Application. CDER/CBER CMC 6, rev 1. 39 pp.July 1998. http://www.fda.gov/cber/guidelines.htm [cited: 1 Sept. 1999]

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Human Health Drugs and Therapeutic Biotechnology Products	USFDA	Refers to Environmental Risk Assessment Guidance for Industry: Environmental Assessment of Human Drugs and Biologics Application July 1998.	http://www.fda.gov/cber/gdlns/indbiodft.pdf . Summary: Guidance for Industry INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology- Derived Products Chemistry, Manufacturing, and Controls Content and Format DRAFT GUIDANCE. October 4, 1999
Human Health Pharmaceutical Products	EU	No regulations/guidelines established pertaining to the environmental assessment of drugs for human health. New regulations concerning the assessment of potential environmental risks posed by medicinal products for human use are planned in the EU draft guideline III/5504/95 but they have not been passed by EU. Any new EU guidelines would only refer to the registration of new pharmaceutical chemicals. Guidelines for already registered pharmaceuticals are not planned.	Daughton and Ternes (1999); EU Draft Guideline IIII/5504/94 (Draft 4): Assessment of potential risks posed by medicinal products for human use (excluding products containing genetically modified organisms). European Commission, Directoral-General Industry, III/E/3 Pharmaceuticals Service. 1994 cited in Stan and Heberer, 1997.
Disposal of Pharmaceuticals - expired or unused products	Canada	BC- Post-Consumer Pharmaceutical Stewardship Association operates the "Medication Return Program"; a regulated program providing year round collection at pharmacies. Alberta - The Alberta College of Pharmacists operates "EnviRx", a program providing year round collection at pharmacies. Saskatchewan - The Saskatchewan Pharmaceutical Association operates a year round pharmaceutical waste disposal program.	Nonperscription Drug Manufacturers Association of Canada,letter from Robert White, Director of Scientific Affairs, January 31, 2001

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		Ontario - Ontario municipalities accept expired and unused pharmaceuticals at hazardous waste depots and on special "days". Industry and municipalities are currently involved in discussions to provide sustainable funding for household special waste programs. Pharmacies in various municipalities (Toronto and Ottawa) have yearly programs to return products. Nova Scotia - The Pharmacy Association of Nova Scotia operates "Drug Net" to collect and dispose of unwanted drugs. Most dispose of collected materials by incineration at approved facilities. NDMAC members offer financial support to regulated programs and most voluntary programs.	

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Animal Health			
Veterinary Medicinal Products (excluding biologics)	European Agency for the Evaluation of Medicinal Products – EMEA/CVMP/055/96 EU	European Commission- Pharmaceuticals and Cosmetics (early 1980's) expressed concern for release of veterinary pharmaceuticals and their metabolites into environment (e.g. via fish farms, parasite dips, farm runoff); EMEA/CVMP/055/96-final gives guidance for veterinary medicinals, excluding biologics based on the phased-assessments approach of EEC Directive 92/18/EEC; Phase I involves calculation of predicted environmental concentrations (PEC) see OECD (1999); Phase II consists of two tiers: tier A evaluates fate and effects and tier B (cause for concern based on results of tier A) addresses effects on specific biota potentially exposed.	EudraLex (Rules Governing Medicinal Products in the European Union). Vol. 5: Pharmaceutical legislation: Veterinary Medicinal Products. http://dg3.eudra.org/eudralex/vol-5/home.htm [cited 31 Aug]. EMEA (The European Agency for the Evaluation of Medicinal products: Veterinary Medicines Evaluation Unit). Note for Guidance: Environmental Risk Assessment for Veterinary Medicinal Products other than GMO-Containing and Immunological products. The European Agency for the Evaluation of Medicinal Products Veterinary medicines Evaluation Unit. EMEA/CVMP/055/96-Final, 1997. http://www.eudra.org/vetdocs/PDFs/GUIDE/005596en.pdf [cited 11November 1999]. OECD. 1999. (Organisation for Economic C0-Operation and Development) Environmental Exposure

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			Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries. Series on Testing and Assessment No. 11. ENV/JM/MONO(99)10. http://www.oecd.org/ehs/ehsmono/index.htm#TESTING [cited 1 Sept. 1999].
Veterinary Medicinal Products (excluding biologics)	European Agency for the Evaluation of Medicinal Products – EMEA/CVMP/055/96 EU	ERA are required for all new veterinary drugs and consists of a discussion of potential for environmental exposure (including use and route of administration, metabolism/excretion and disposal) and mandates the use of worst-case exposure scenarios. EMEA guidelines are being developed specifically for environmental impact assessment of veterinary medicinal products.	EMEA (The European Agency for the Evaluation of Medicinal Products: Veterinary Medicines Evaluation Unit. Guideline on Environmental Impact Assessment (EIAS) for Veterinary Medicinal Products – Phase I. The European Agency for the Evaluation of Medicinal Products Veterinary Medicines Evaluation Unit. Canary Wharf, England. EMEA/CVMP/592/98-consultation, 10 December 1998. http://www.eudra.org/vetdocs/PDFs/VICH/059298en.pdf [cited 11 November 1999]
Veterinary Medicinal Products (excluding biologics)	European Agency for the Evaluation of Medicinal Products	The Phase I approach has been updated and recommended for acceptance in the EU, Japan and the US (EMEA, 2000). Based on trigger values determined on the basis of predicted environmental concentrations, ~~biodegradation potential, type and use of the drug and mitigation~~	EMEA 2000; (Monforts et al. 1999)

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		biodegradation potential, type and use of the drug and mitigation strategies proposed by the proponent of the drug a decision is made as to whether a Phase II assessment involving effects testing is warranted (EMEA, 2000). These trigger values are based on a consensus decision of a working group consisting of all interested parties, and are not scientifically based (Monforts et al. 1999)	
Veterinary Medicinal Products (excluding biologics)	European Agency for the Evaluation of Medicinal Products	In Phase II assessment, adverse effects are considered and risks are characterized based on comparison of the PNEC (predicted no effect concentration) with the PEC (predicted environmental concentration). When a new pharmaceutical product enters Phase II testing there is a considerable burden of effects testing placed on the notifier. Since there is an "escape route", by way of the trigger levels described above that would allow a product to be developed without environmental effects testing, it is considered important by the regulatory authorities that the initial exposure assessment be thorough {Montforts, Kalf, et al. 1999 #840}. If a Phase II assessment is required, then a second decision tree is followed and additional information, including effects data, is required (EMEA, 1998). The decisions in these trees are based on trigger values for the ratio of PEC/PNEC and also on sorption, half life and Kow values. If a moderate to high risk to the environment is expected based in this screening exercise, then a complete environmental assessment is conducted and risk management options are evaluated.	(Monforts et al. 1999) ;EMEA, 1998
Veterinary Medicinal Products (excluding biologics)	European Agency for the Evaluation of Medicinal Products	Other exemptions from ERA are given for the following: physiological substances such as vitamins, amino acids, electrolytes and herbs; products used specifically for companion animals (excluding horses); and products intended for use on a small number of animals (as opposed to mass treatment). Also, Phase I assessment does not consider duration of	(Monforts et al. 1999)

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		exposure and as such does not provide any mechanism for predicting the possibility of effects on population dynamics in ecosystems.	
Veterinary Medicinal Products -Biologics	European Agency for the Evaluation of Medicinal Products	An approach for the environmental assessment of veterinary biologicals in the EU has also been described.	(EMEA, 1997)
Veterinary Medicinal Products (excluding biologicals and biotechnology products)	Health Canada, Bureau Veterinary Drugs	No specific regulations/guidelines established pertaining to the environmental assessment of veterinary drugs for animal health. However, all new substance to Canada are subject to CEPA, 1999. Thus any new veterinary pharmaceutical ingredient to Canada would theoretically require environmental review in accordance with CEPA, 1999. To date (February 2001) no new veterinary pharmaceutical ingredients have been reviewed under CEPA 1999.	Health Canada, BVD personal communication Jan. 2001
Veterinary Medicinal Products - Biologicals	Canadian Food Inspection Agency (CFIA)	Veterinary biologicals are subject to a requirement for environmental assessment as part of the regulatory approval process in Canada. According the Health of Animals Act (1990) (pg 35) veterinary biologics are defined as follows: 1) any helminth, protozoa or microorganism, 2) any substance or mixture of substances derived from animals, helminths, protozoans or microorganisms; or 3) any substance of synthetic origin manufactured, sold or represented for used in 4) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state or the symptoms thereof, in animals; or 5) restoring, correcting or modifying organic functions in animals.	Silva et al.1995.
Veterinary Medicinal Products - Biologicals	Canadian Food Inspection Agency (CFIA)	ERA of biologics: a qualitative approach can be used to assess the safety of modified and live vaccines with criteria related to the potential for the vaccine agent to be shed from the host and to contaminate and persist in	Silva et al.1995.

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	(CFIA)	the environment, to undergo recombination with similar organisms to produce a virulent organism, to enter the food chain and to impact immunocompromised hosts. The potential for exposure to humans or non-target organisms are also considered and the product is classified as Class I (low risk) or Class II (high risk) according to its potential for harm and the severity of harm it may cause. Thus products requiring further evaluation are identified. Further evaluation involves qualitative risk assessment using a scenario tree analysis to investigate all possible pathways through which a product could cause environmental harm. Mathematical modelling determines the likelihood of occurrence of various outcomes of concern (e.g. human systemic reactions or the establishment of a reservoir of infection in an animal population). The overall assessment considers human health effects, associated economic parameters and environmental impacts of reservoirs of infection in animals.	
Veterinary use of antibiotics	UK	Only antibiotics not used in human medicine and those which do not select for cross resistance with antibiotics used in humans are available for use in UK for performance enhancement in food animals (ie. use at subtherapeutic levels in feed to improve feed conversion efficiency and thus performance in food producing animals). These are only minimally absorbed after oral dosing and do not result in tissue residues. The antibiotic avoparcin has been withdrawn from use as a growth promoter in Europe due to the possible common microbial resistance to avoparcin and that to vancomycin. Use of the growth promoter vinginicmycin is under scrutiny in consideration of the potential use of streptogramins in human medicine and the possible common resistance of these two antimicrobials. Prophylactic use of antimicrobials should only be used when disease spread cannot be contained by vaccination, management changes, or	McKellar, 1998

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		better hygiene and development of disease in animals in contact with infected animals is inevitable without antimicrobial intervention. Antimicrobial agent should be selected on the basis of sensitivity of infecting organism and pharmacokinetics of the drug. Subtherapeutic concentrations of antimicrobials to be avoided.	
Veterinary use of antibiotics	UK	Need to develop appropriate pharmacokinetic-pharmacodynamic relations for antimicrobials used in animals.	McKellar, 1998
Veterinary use of antibiotics	UK	The BVA finalized its guidance paper on the prudent use of antimicrobials. The document combines the policy statement and general guidelines produced by the BVA's Antimicrobials Working party (see VR Nov. 14, 1998 p565) and species specific guidelines produced in conjunction with specialist divisions. The guidelines contain general advice on the principles of antimicrobial use, routine considerations in selecting the appropriate antimicrobial, dosage strategy, and regulatory concerns. Sections on dealing with antimicrobial usage in poultry, horses, pigs, sheep, companion animals, cattle and fish.	The Veterinary Record Journal of the British Veterniary Association. 1999. 145/25pp. 718
New Veterinary drug	US FDA	For new veterinary drug the sponsor must file with FDA a New Animal Drug Application (NADA). The NADA includes results of studies of the drug safety and efficacy in the target species, its safety in the environment, and of manufacturing purity, strength and identity. If a new drug is intended for use in food producing animals then drug residues in food products must be proven safe for human consumption. An Investigational New Animal Drug (INAD) exemption from FDA is obtained to conduct such studies. The results of these studies are reviewed by FDA scientists at the Centre for Veterinary Medicine (CVM). Toxicology tests conducted for new drugs include genetic toxicity studies,	Friedlander et al. 1999. Canada Gazette. 1991: 1478,SOR/91-255, Part II cited in Friedlander et al. 1999.

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		90-day feeding studies in a rodent and a non-rodent mammalian species, a two generation reproduction study with teratology component. Additional tests may be conducted to selectively target toxic endpoints of concern (e.g. reproductive organs for synthetic hormones). Antimicrobials may need studies of the effect of residues on human intestinal microflora (e.g. development of resistance, alteration of barrier effect, overgrowth of potentially pathogenic microorganism). Chronic studies may be conducted. All toxicity studies are conducted by the oral route.	
New Veterinary drug	US FDA	In 1989, the US CVM and Canada Bureau of Veterinary Drugs initiated the harmonization of tolerances for approved drugs and evaluation procedures for new drugs. Canada has published (Canada Gazette, 1991) a list of 37 drugs for which Canada and the US have identical tolerances.	Friedlander et al. 1999. Canada Gazette. 1991: 1478,SOR/91-255, Part II cited in Friedlander et al. 1999.
Veterinary drug	USFDA	All new veterinary drugs undergo tiered testing on a case-by-case basis to ensure that there are no adverse environmental effects associated with the use of the drug [21 CFR 25.31a(a)]. These rules apply to drugs for use in food animals. An abbreviated ERA is required for companion animals, horses and zoo animals [21 CFR 25.31a(b)(4)]. The short form assessment includes environmental exposures associated with manufacturing, but not use of the product. When the use of a product involves treatment of food animals such that environmental exposure could occur through direct application to the environment or through excretion of the product or it's metabolites, then a full ERA is required. This includes an exposure assessment based on use volumes, environmental fate, biodegradation and procedures used for disposal of animal waste (often this includes spreading on agricultural land). Based on expectations of environmental fate and predicted concentrations in various environmental compartments it is determined whether the evaluation of toxic effects is required and if	[21 CFR 25.31a(a)]; [21 CFR 25.31a(b)(4)]; CDER guidance document for ERA of veterinary drugs

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		so, which organisms would be most appropriately studied.	
Veterinary drug	US FDA	Under the National Environmental Policy Act (NEPA) an EA is required for new animal drug applications and must include among others the nature and levels of materials leaving the manufacturing facility (i.e. air, water effluents or solid waste) and how these are controlled to meet local, state and federal pollution control requirements. Occupational safety must also be addressed. Safety of wall and solvent ingredients in encapsulation process must be demonstrated. If wall material persists an Environmental Impact Statement may be required.	Arnold. 1988
Sex steroid hormones - natural and synthetic for animal growth enhancement and reproductive aids	US FDA	Six hormonal agents are approved in the US for growth promotion. Natural hormones used exogenously are: 17B-estradiol, testosterone, and progesterone. Synthetic hormones are: trenbolone acetate, melengestrol acetate (MGA) and zeranol; these mimic actions of testosterone, progesterone, and 17B-estradiol, respectively. These are approved as single or combined use in ear implants. Only MGA is a feed additive and is also used to suppress estrus in feedlot heifers. All natural hormones approved for growth promotion in the US have incremental increases of <1% of endogenous level and require no withdrawal period. Synthetic hormones are not readily converted to corresponding natural hormone therefore assessed using battery of toxicity tests. The NOEL was divided by 100-fold safety factor to yield ADI for drug residues. A zero day withholding period is required for use of these synthetic hormones in cattle, a 40-day withholding period for use in lambs. No hormones to increase growth or feed efficiency are approved in US for use in poultry (including laying hens), pork or veal calves.	Leighton 1999.
Sex steroid hormones - natural and synthetic for	EC	Banned the exogenous use of natural and synthetic hormones for growth promotion in food animals. Banned the import of meat from animals	Leighton 1999; Fara GM., Del Corvo G., Bernuzzi S, et al. 1979.

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natural and synthetic for animal growth enhancement and reproductive aids		promotion in food animals. Banned the import of meat from animals treated with growth promotion hormones. EC 1988 ban on the use of hormonal growth promotants was reaffirmed in 1996 despite JECFA's safety assessment and acceptance by CODEX Alimentarius Commission. Incited by the finding of DES residues at hormonally active levels in baby food made from veal produced in France (Hoffman and Evers, 1986) and implicated contaminated beef and poultry in an epidemic of breast enlargement in Milan in 1977 (Fara et al., 1979). EC Directive 81/602/EEC initiated control of certain substances with hormonal activity and prohibited any substance with thyrostatic action, with exception for therapeutic use and zootechnical purpose (herd management), and according to regulations for growth promotors. New uses were prohibited. Directive 88/146/EEC banned use of hormones for growth promotion but allowed the use of natural hormones for zootechnical and therapeutic uses under certain conditions with strict controls. It also prohibited the import of animals or meat from animals treated with substances with thyrostatic, estrogenic, androgenic, or gestagenic action.	Corvo G., Bernuzzi S, et al. 1979. Epidemic of breast enlargement in an Italian school. Lancet 2:295. Cited in Leighton. 1999; Hoffman B, Evers P. 1986. Anabolic Agents with sex hormone-like activities. Problems of residues. In Rico AG (ed): Drug residues in Animals. new York, Academic press, 1986 cited in Leighton. 1999.
Sex steroid hormones - natural and synthetic for animal growth enhancement and reproductive aids	EC	Directive 88/299/EEC addresses conditions for animal trade. As of July 1, 1997 Directive 96/22/EC took effect and repeals the previous mentioned directives but maintains the ban on the use of hormones for growth promotion in food animals and includes a new prohibition on the use of beta-agonists for growth promotion.	Leighton 1999; Fara GM., Del Corvo G., Bernuzzi S, et al. 1979. Epidemic of breast enlargement in an Italian school. Lancet 2:295. Cited in Leighton. 1999; Hoffman B, Evers P. 1986. Anabolic Agents with sex hormone-like activities. Problems of residues. In Rico AG (ed): Drug residues in Animals. new York, Academic press, 1986 cited in Leighton.

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			1999.
Beta agonists in food animals	US	not currently approved for use in any food animal species.	
Bovine Somatotropin	US	used in US to increase milk production in dairy cows. Not considered a growth promotant by definition.	Leighton 1999.
Beta agonists in food animals	EC	use in food animals as growth promoters is banned as of July 1, 1997 Directive 96/22/EC	Leighton 1999.
Veterinary Drugs	Australia	Objectives of registration clearance and licensing includes the recognition of special needs of several different interests namely, end-users concerned with efficacy and hazards; consumers of food products of treated animals; stock owners and vendors; wildlife and other ecological considerations; and protection of overseas markets concern of drug residues. The Technical Committee on Veterinary Drugs (TCVD) is responsible for the preliminary clearance of veterinary products with respect to efficacy, safety and in association with the National Health and Medical Research Council Committees set residue limits and establishes poison schedules. Their recommendations are made to the individual States of Australia who are responsible for administering regulations. Australia's TCVD responsibilities include to evaluate new feed additives, stock medicines, dips, sprays, dusts, vaccines and antihelminthics for mass medication of farm animals, poultry, including bees and fish the possible implications of such use in Australia. It is recognized that the environment in which these products are used or stored should be protected , especially as it affects wildlife and beneficial organisms.	Hotson. 1981

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Veterinary Drugs	Australia	TCVD clearance is required before State authorities will allow registration of any new product for mass-medication in food producing animals. The TCVD does not issues clearance for: remedies for companion animals (dogs, cats, horses); products with simple change of brand names; stock feeds other than medicated feeds or pre-mixes; veterinary ethical drugs which are not agents of mass-medication. New chemical requires justification of use, details on identity of constituents, analytical techniques, formulation, stability, efficacy, safety, toxicology and residues. In Australia there are no federal requirements for licensing during a developmental program (unlike the US, UK and NZ). Safety to non-target animals should be evaluated especially for feed additives and medicated feeds which may be eaten by animals other than target animals. Hazards to wildlife, including beneficial insects, birds, fish and other aquatic species, particularly through disposal of unwanted product or used containers should be evaluated. Antibiotics for use as a feed additives requires exemption from a poison schedule and in addition to other information requires information on the development of resistance.	Hotson. 1981
Veterinary Drugs	New Zealand	Objectives of registration clearance and licensing includes the recognition of special needs of several different interests namely, end-users concerned with efficacy and hazards; consumers of food products of treated animals; stock owners and vendors; wildlife and other ecological considerations; and protection of overseas markets concern of drug residues. Similar procedures as Australia for registration of a new drug except that in New Zealand the Animal Remedies Board is solely responsible for the registration of drugs and licensing for use. The Animal remedies Act 1967, controls the manufacture, importation, sale and use of remedies in treating and preventing disease in mammals (not humans), birds, fish and captive reptiles. Provisional licenses for up to 2 years or more may be	Hotson. 1981

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		granted before a full license.	
Veterinary Drug Residues	International- Codex Committee on residues of veterinary drugs in Foods (CC/RVDF)	Objective is to achieve international agreement on veterinary drugs issues - residues and toxicity. The CC/RVDF has established a list of priority veterinary drugs on the basis of their potential to cause trade problems as a result of public health concerns. These are anabolic hormones, chloramphenicol, sulfonamides, nitrofurans, nitroimidazoles, somatotropins, benzimidazoles and trypanocides.	Fitzpatrick. 1990
OP Sheep Dips	UK	Government withdraws OP sheep dips until containers are introduced which will minimize operator exposure to OP concentrate. Recalls OP dip concentrates from distributors and farms.	The veterinary record: Journal of the British veterinary Association .2000. 146/1 pp.3-4; The veterinary record:Journal of the British Veterinary Association. 1999. 145/5 pp.118.
Disposal of Veterinary Products (outdated insecticides, chemicals, drugs, vaccines, and needles)	U.S. EPA - applicable regulations are RCRA, FD&CA, TSCA, FIFRA, SDWA, CAA	Individual states implement and enforce regulations. Most veterinary practices would be "Small Quantity Generator" or SQG. Classification of SQG varies among states. Kansas maximum of 55 lbs/mo for SQG or less than 10 gallons of liquid flea/tick dip/mo. Examples of hazardous vet products are drugs, pesticides(flea/tick dips), vaccines, laboratory reagents, radiographic supplies, volatile anesthetics (esp. ether), cleaning and disinfecting agents, formaldehyde, solvents, empty pesticide containers, paints, batteries, old tires, fuels and motor oil, fluorescent light bulbs. EPA has website (www.epa.gov) and a publication "Understanding the Hazardous Waste Rules, a Handbook for Small Businesses." RCRA hotline 800/424-9346 or consult the Federal Code of Regulations (40CFR, parts 260-299).Vet products regulated by EPA, the FDA or the DEA are probably "hazardous". Information on use, storage and disposal is in the	Miller. 2000

Table 11: Comparison of Policies for Environmental Assessment of PPCPs			(24 pages)
Product Type/Subject	**Regulatory Agency**	**Summary/Comment**	**Reference**
		Material Safety Data Sheet (MSDS) or other warning papers/labels. Minimize waste, recycle when possible and substitute less toxic products when possible. Accurate records of quantity and type of waste should be maintained.	
Disposal of Veterinary Products (outdated insecticides, chemicals, drugs, vaccines, and needles)	U.S. EPA - applicable regulations are RCRA, FD&CA, TSCA, FIFRA, SDWA, CAA	Treatment of vaccines, biologicals and other infectives with a disinfectant, autoclaved, or incinerated and triple rinse of pesticide containers allows their disposal in trash. Small quantities of household hazardous waste (HHW) may be disposed of by local communities. Landfills handle solid wastes only. Outdated, unused pet food should be landfilled (do NOT feed to livestock due to FDA ruminant-to-ruminant consumption ban). Liquids disposed by HHW or licensed waste disposal facility; small quantities to sanitary sewers (need to obtain approval from local agency first). Smaller communities with lagoon sewage treatment are not suitable for liquid disposal of hazardous materials.	Miller. 2000
Other			
Hazardous Chemical	USA - Section 1910.1200© of title 29 CFR	The term "hazardous chemical" does not include 1) any food, food additive, colour additive, drug, or cosmetic regulated by the FDA; 2) any substance present as a solid in a manufactured product such that exposure does not occur; 3) any substance used for personal, family, or household purposes or in the same form, concentration, package; 4) any substance used in research lab or hospital under direct supervision; 5)any substance used in routine agricultural operations or fertilizer held for sale. No disposal recommendations specifically for feed additives were found. American Feed Assoc stated they were unaware of any such regulations for feed additive disposal. Large containers may be triple rinsed and burned on farm or recycled.	Meerdink. 2000

Table 11: Comparison of Policies for Environmental Assessment of PPCPs			(24 pages)
Product Type/Subject	**Regulatory Agency**	**Summary/Comment**	**Reference**
Biocides	EU	EU Biocide Directive covers commercial biocidal agents (e.g. disinfectants) [some are used in personal care products]; equal emphasis on ecotoxicological issues as on human health issues; includes fate and effects.	Directive of the European Parliament and of the Council No. 98/8/EC (16 February 1998); On the placing of biocidal products on the market. http://www.retroscreen.com/BiocidalDirective/biocidal_directive.htm [cited 10 November 1999].
New Food Ingredients	US, FDA	EA required for all new food ingredients under the National Environmental Policy Act of 1969 (NEPA). EPA . 1992. Framework for Ecological Risk Assessment provides a framework consisting of: problem formulation, analysis, and risk characterization (characterization of exposure and effects). Risk may be expressed qualitatively or quantitatively. Use of generic assessment endpoints consistent with EPA approach used for new chemicals under the Toxic Substances Control Act (TSCA).	National Environmental Policy Act (NEPA) FDA USEPA. 1992. Framework for ecological risk assessment. EPA/630/R-92/001. Risk Assessment Forum, Washington, DC. A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective, Vol. 2. EPA/630/R-94/003. Risk Assessment Forum, U.S. EPA, Washington, DC.
Environmental Risk Assessment Harmonization	US Federal, State and International symposium	There are fundamental differences among nations in their view of the relative seriousness of environmental insults and solutions e.g different definitions of an adverse effect. International harmonization approaches need to be flexible/accomodate views of all nations. Canada uses internal, external and public comment on RA, a multimedia approach, has a strategy for threshold and non-threshold substances. Naturally occurring toxic substances (e.g. mycotoxins) treated differently from contaminants. Recommend a move towards: incorporation of all relevant information not	Kamrin, M. 1997.Environmental Risk Harmonization: Federal/State Approaches to Risk Assessment and Management (summary of Symposium on the Harmonization of State/Federal Approaches to Environmental Risk. May 20-21, 1996. Michigan

Table 11: Comparison of Policies for Environmental Assessment of PPCPs			(24 pages)
Product Type/Subject	**Regulatory Agency**	**Summary/Comment**	**Reference**
		just most sensitive species, > single value; comparative risk analysis using different approaches; greater interlaboratory consistency; develop common framework not set of prescriptions (e.g. common framework with specified set of scientifically accepted procedures for quantitative assessment of each exposure parameter) -leave room for scientific judgement in application of process to specific situations; less-quantitative describe common approach and types of issues need to be addressed (e.g. subpopulations); use of a stepwise process to set priorities; multi-media approach. Harmonization is desirable and feasible.	State University.)
Priority Chemicals	Canada	List of priority chemicals is gazetted annually. Three sets of criteria are: toxicity to human health and environment, persistence, and quantity and use. Chemicals controlled under other federal legislation (i.e. food additives, drugs, pesticides, or environmental contaminants - As, Hg, NOx, S - are excluded from the list).	Somers. 1983
Priority Chemicals	US	TSCA list	
Priority Chemicals	WHO/ILO/UNEP International Programme on Chemical Safety	priority list of > 100 industrial chemicals and groups of chemicals.	
Chemical Testing (i.e. pesticides)	OECD Test Guidelines	testing guidelines have received almost worldwide acceptance. These guidelines harmonize and ease international trade. Similar guidelines in US are TOSCA test guidelines, and the EC guidelines. Some countries however do more than the basic tests. Many new chemicals are modifications of previously registered chemicals. Some countries have developed numerical hazard scoring systems to aid regulators. QSARs and	Dobson. 1993

Table 11: Comparison of Policies for Environmental Assessment of PPCPs			(24 pages)
Product Type/Subject	**Regulatory Agency**	**Summary/Comment**	**Reference**
		distribution models are other tools available to regulators. Principles behind extrapolation methodology as discussed by OECD (1992) are based on statistical assessment of variation in lab tests on individual organisms. Assumption: i) that wild population consists of a large population of moderately sensitive individuals, small pop. of sensitive ones; ii) distribution of large number of lab tests will approximate distribution in sensitivity in wild; iii) no interaction between species. Objective to identify a conc. of chemical that will not adversely affect 95% of organisms in ecosystem through use of safety factors. Field validation needed. Problem is lack of ecologically recognized parameters. Interactions do occur. Worst case theoretical basis for regulation but economic considerations a major factor.	

Table 11: Comparison of Policies for Environmental Assessment of PPCPs			(24 pages)
Product Type/Subject	**Regulatory Agency**	**Summary/Comment**	**Reference**
Methods for Identification of Hazards to Developing Organisms	USEPA Part 1: The Reproduction and Fertility Testing Guidelines; Part 2: The Developmental Toxicity Testing Guideline	The Food Quality Protection Act mandates that the USEPA protect infants and children from effects of toxic chemicals, thus methods for toxicity testing - the Health Effects Test Guidelines or Series 870 Guidelines must be adequate to determine possible toxicity in children. Toxicity testing requirements for industrial chemicals (regulated under TSCA) and pesticides (regulated under FIFRA and FFDCA) have been harmonized into a single set of 59 different tests under the Health Effects Test Guidelines of which only a small no. are required in the testing battery for Tier I testing. Testing includes a developmental toxicity study typically in rabbits and rats, and a reproductive or 2 generation study typically in rats. Overview of study design is presented. Reproduction involves the integrated function of many complex physiological processes involving endocrine, reproductive and central nervous systems. Alternative testing protocols for substances of unknown toxicity are difficult to design. Work is need to develop standard test methods to identify endocrine disrupting substances especially for developing organisms.	Claudio, Luz et al, 1999
Methods for Identification of Hazards to Developing Organisms	USEPA Part 1: The Reproduction and Fertility Testing Guidelines; Part 2: The Developmental Toxicity Testing Guideline	Protocols for developmental toxicity testing guidelines (OPPTS 870.3700, TSCA 799.9370) were also reviewed. Conclusions of an analysis of the Reproduction and Fertility Effects Test Guideline (OPPTS 87.3800, TSCA 799.9380) were that given the limitations inherent in testing for reproduction and fertility effects during development, it is necessary to include a safety factor during risk assessment of chemicals. An additional 10-fold safety factor to account for uncertainty of risk of reproductive and development risks to children is specified by the FQPA unless there is reliable evidence that a different factor should be used. The use of developmental neurotoxicity studies in the evaluation of risk of chemicals was discussed Dec, 1998 during a meeting of the FQPA Review Board.	Claudio, Luz et al, 1999

Table 11: Comparison of Policies for Environmental Assessment of PPCPs			(24 pages)
Product Type/Subject	**Regulatory Agency**	**Summary/Comment**	**Reference**
Detection and Assessment of the Aneugenic Potential of Environmental Chemicals	The European Community Aneuploidy Project	A research project of the Environment Research and Development Programme, the EC DG XII. Aim to develop and validate assay systems for detection and evaluation of chemicals capable of inducing numerical chromosome changes (aneuploidy and polyploidy). The range of test chemicals include the following pharmaceuticals: colchicine, econazole nitrate, chloral hydrate, hydroquinone(also cosmetic ingredient), diazepam, thiabendazole, cadmium chloride, thimersol, pyrimethamine and vinblastine sulphate. Test systems evaluated were tubulin polymerisation, fungal cultures, cultured mammalian cells and in vivo rodent assays.	Parry and Sors. 1993
Detection and Assessment of the Aneugenic Potential of environmental Chemicals	The European Community Aneuploidy Project	It was concluded that systems based on lower eukaryotes (fungi) are unsuitable for the detection of chemicals capable of inducing aneuploidy in higher organisms . Tubulin polymerisation assays appeared to be of limited value. A variety of assays with cultured mammalian cells were effective in detecting the activity of chemicals that modify a range of targets in the dividing cell. In vivo mouse studies were encouraging. particularly assays of timing and fidelity of mitotic division within mouse bone marrow and meiotic division within male germ cells. A high predictive value was demonstrated for these assays as compared to the more demanding micronucleus and chromosome counting methods in the same tissue. Proposed a simple screening procedure involving: 1) analysis of induction of mitotic cell division aberrations in mammalian fibroblast culture; 2) analysis of mitotic arrest and C-mitoses in rodent bone marrow; 3) determine meiotic delay in rodent spermatocytes. Major shortcoming of this would be failure to predict effect of potential aneugens in female germ tissue.	Parry and Sors. 1993

Table 11: Comparison of Policies for Environmental Assessment of PPCPs			(24 pages)
Product Type/Subject	**Regulatory Agency**	**Summary/Comment**	**Reference**

1Information requirements for HC-EA description of product and process; amount of product manufactured or imported per year; location of manufacture, point of entry to environment, location of storage; anticipated nature and extent of release into environment; recommended disposal procedures; transportation and packaging; special requirements for use, storage or disposal affecting nature and amount of release.

2 Specifically for biotechnology products information requirements for HC-EA: manufacture/importation of recombinant organism/product; parent organism (taxonomy, molecular biology, physiology, reproduction); transgenic organism (identification and function, molecular biology, reproduction); method of transgenesis; fate of transgene (transport, reproduction, transfer, establishment); toxicity of transgene products and effective dose for toxicity; human health effects; introduction to the environment and site characteristics; susceptible non target organisms and effect on non-target organisms; environmental fate and ecological effect; proposed containment level of microorganism; reference to biosafety guidelines for determination of containment level; identification of potential environmental hazards.

Figure 1: Summary of the Acute Toxicity of PPCPs in Aquatic Organisms

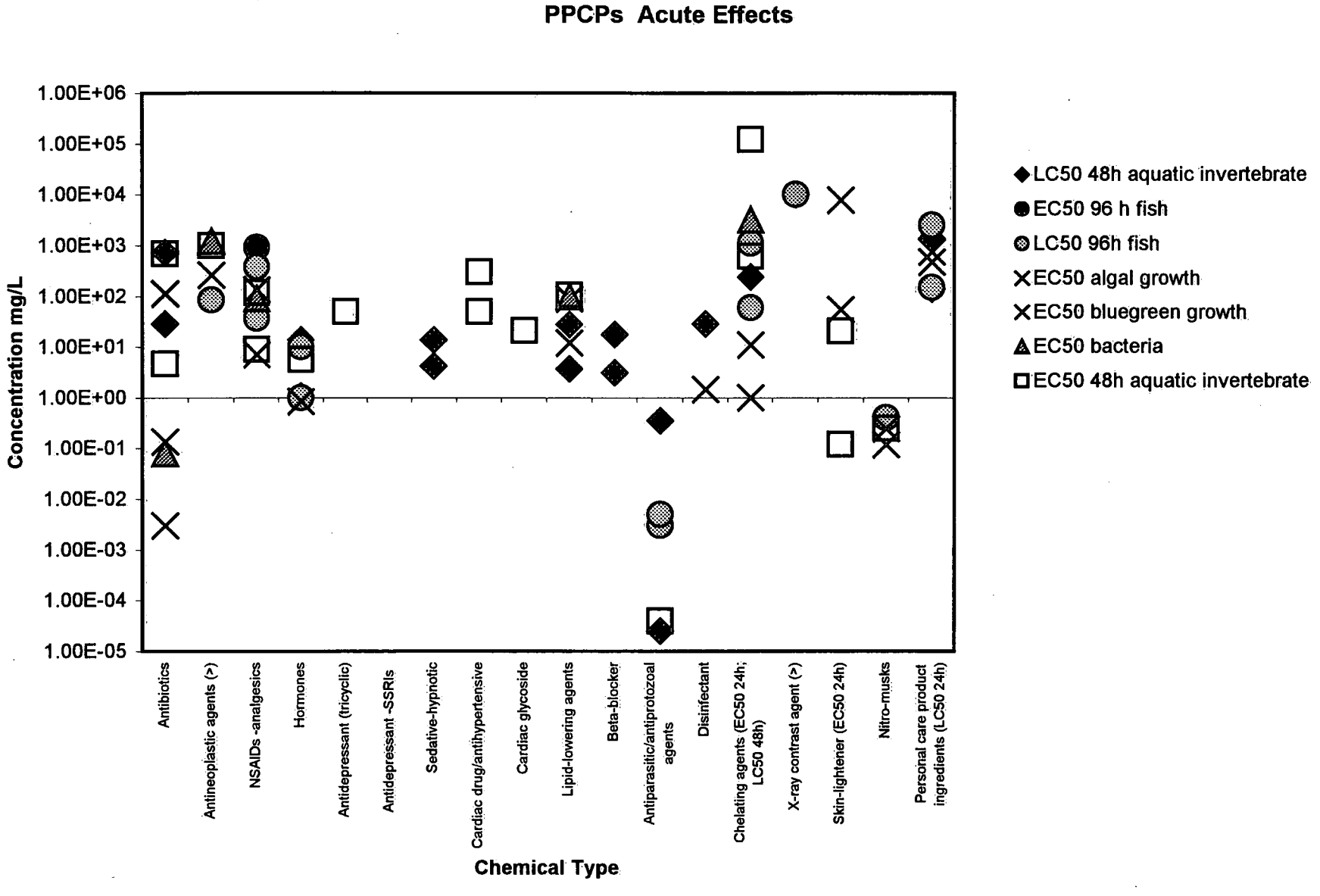
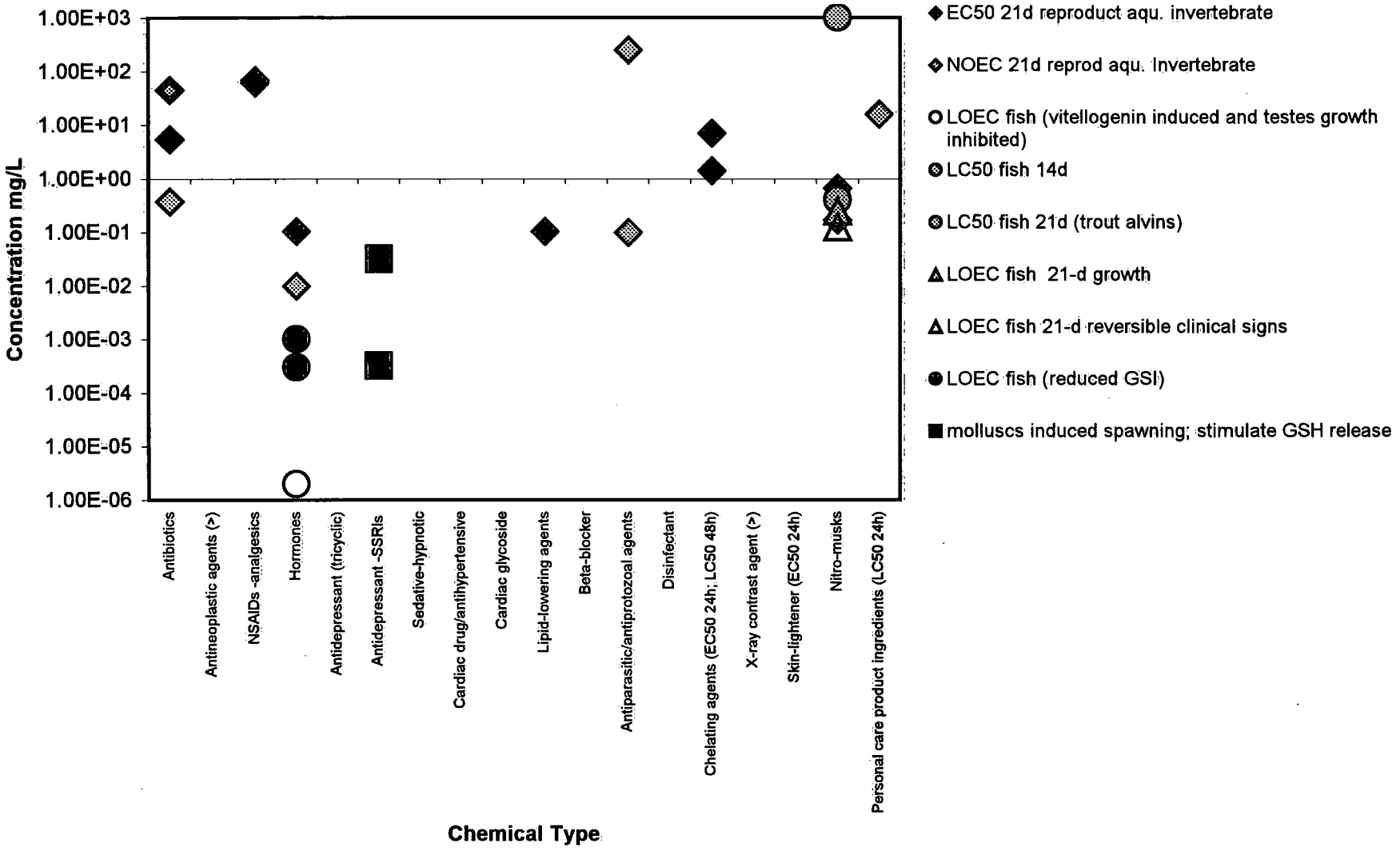

PPCPs Acute Effects
Concentration mg/L
1.00E+06
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
1.00E-03
1.00E-04
1.00E-05
Antibiotics
Antineoplastic agents (>)
NSAIDs -analgesics
Hormones
Antidepressant (tricyclic)
Antidepressant -SSRIs
Sedative-hypnotic
Cardiac drug/antihypertensive
Cardiac glycoside
Lipid-lowering agents
Beta-blocker
Antiparasitic/antiprotozoal agents
Disinfectant
Chelating agents (EC50 24h; LC50 48h)
X-ray contrast agent (>)
Skin-lightener (EC50 24h)
Nitro-musks
Personal care product ingredients (LC50 24h)
Chemical Type
LC50 48h aquatic invertebrate
EC50 96 h fish
LC50 96h fish
EC50 algal growth
EC50 bluegreen growth
EC50 bacteria
EC50 48h aquatic invertebrate

Figure 2: Summary of the Chronic Toxicity of PPCPs in Aquatic Organisms

PPCPs Chronic Response



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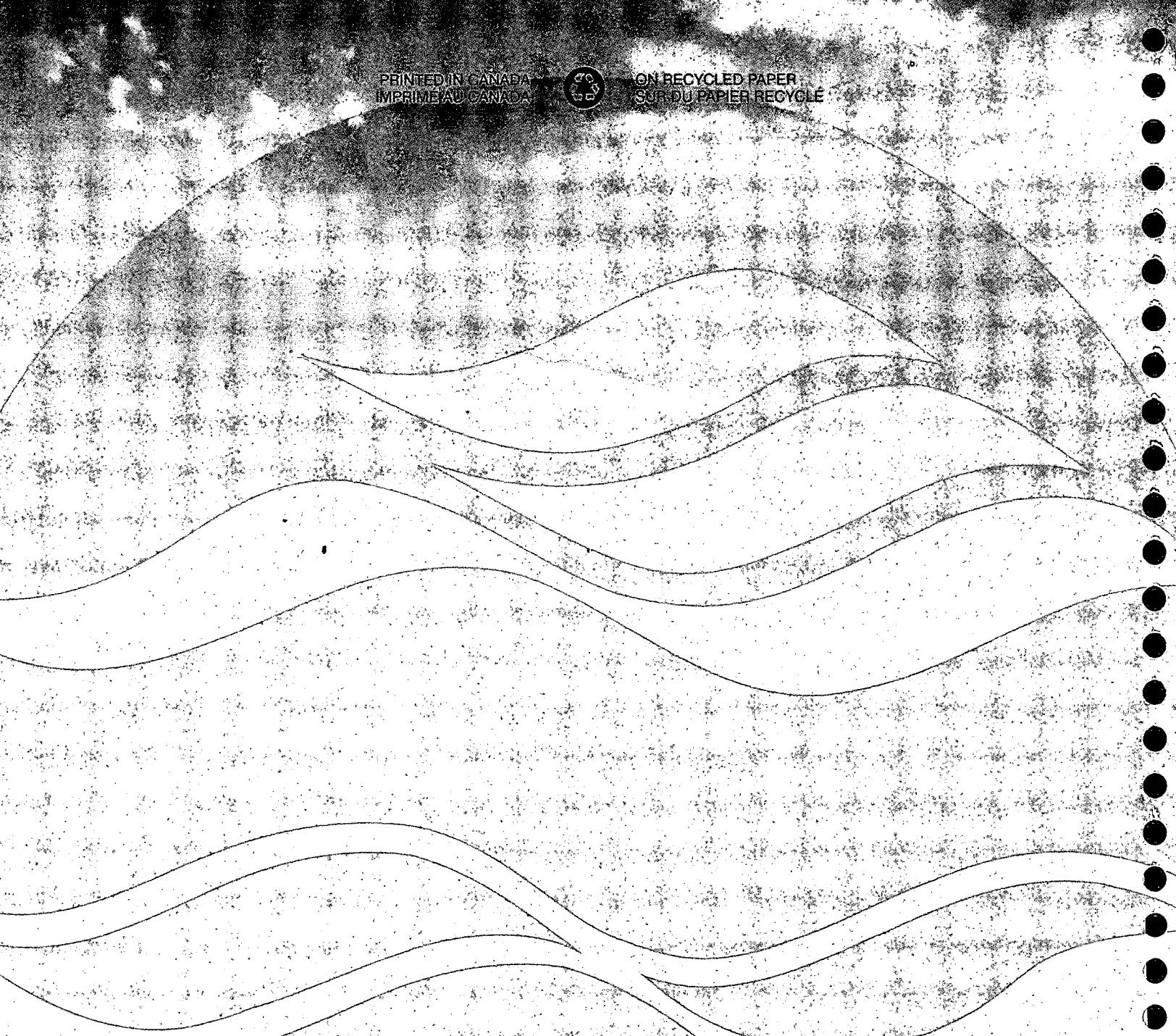

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