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Chemical Review Committee
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Item 7 (j) of the provisional agenda*

Inclusion of chemicals in Annex III of the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: benzidine

Benzidine: supporting documentation from Canada

Note by the secretariat

The secretariat has the honour to provide, in the annex to the present note, the supporting documentation received from Canada in support of its notification of final regulatory action on benzidine. The focused summary is attached in annex I, the assessment report on benzidine is attached in annex II and the Strategic Options for the Management of Toxic Substances is attached in annex III.

* UNEP/FAO/RC/CRC.1/1.

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Annex I

Focussed Summary for Benzidine

By Canada

Introduction

Overview of Canada's regulatory system

The *Canadian Environmental Protection Act* (CEPA) is an important part of Canada's federal environmental legislation. Under the Act, the Ministers of the Environment and of Health are required to prepare and publish a Priority Substances List identifying substances that may be harmful to the environment or constitute a danger to human health. The Act also requires both Ministers to assess these substances and determine whether they are "toxic" as interpreted in the Act.

Substances assessed as "toxic" may be placed on the List of Toxic Substances (Schedule 1 of CEPA). Consideration can then be given to developing guidelines, codes of practice, pollution prevention plans or regulations to control any aspect of their life cycle, from the research and development stage through manufacture, use, storage, transport and ultimate disposal.

Events that led to the regulatory action in Canada

In 1988, the Ministers of the Environment and of Health established the first Expert Advisory Panel, made up of representatives from various stakeholder groups including industry, environmental groups, other levels of government and the academic community, to recommend a priority substance list. The first Priority Substances List (PSL1) was published in 1989 and included 44 substances or groups of substances. Benzidine was placed on the PSL1 and assessed on a priority basis to determine whether it is toxic, as interpreted under CEPA, and poses a risk to the health of Canadians or to the environment.

The Assessment Report for benzidine was completed and published following a critical review of relevant identified data. The report concluded that the substance constitutes a danger to human life or health, but does not have harmful effects on the environment. The *Prohibition of Certain Toxic Substances Regulations* was the regulatory tool used to protect the Canadian public from possible risks of exposure to benzidine.

Significance of the regulatory action

The *Prohibition of Certain Toxic Substances Regulations* replaced all previous regulations of toxic substances for which it had been determined that their use should be prohibited to protect the environment or health life or health.

Benzidine is not currently in Canadian commerce and was included in the Regulations as a preventative measure.

Scope of the regulatory action

The Regulations prohibit the manufacture, use, processing, sale, offer for sale and importation of benzidine and benzidine dihydrochloride (benzidine salt) that have the molecular formulas $C_{12}H_{12}N_2$ and $C_{12}H_{12}N_2 \cdot 2HCl$ respectively. These Regulations do not apply for the following uses:

- in a laboratory for scientific research,
- as a laboratory analytical standard,
- in staining for microscopic examination, such as immunoperoxidase staining, histochemical staining, or cytochemical staining,
- in niacin tests to detect some microorganisms,
- as a reagent for detecting blood in biological fluids, and,

- as a reagent for detecting chloralhydrate in biological fluids.

Risk Evaluation

Risk assessment

The assessment for benzidine was based on the determination of whether it enters or is likely to enter the Canadian environment in a concentration or quantities or under conditions that could lead to exposure of humans or other biota to levels that could cause harmful effects.

Data relevant to the assessment of whether benzidine is "toxic" under CEPA were identified through evaluation of existing review documents, as well as an unpublished review of the environmental behaviour and health effects of this substance prepared under contract, supplemented with information from published reference texts and literature identified through on-line searches of various databases. In addition, a number of provincial authorities were requested to provide any available information on the levels of benzidine in drinking water. Data relevant to the assessment of the effects of benzidine on the environment and human health obtained after November 1992 and February 1993, respectively, were not considered for inclusion. The assessment was further reviewed by experts outside of the review committee. The final assessment was published in 1993.

Effect on the environment

Available data on the toxic effects of benzidine on aquatic organisms indicate that surface water concentrations in the range of 0.1 mg/L would be required before adverse effects on fish would be expected. Since benzidine is not currently produced or imported into Canada, and since its half-life in environmental media is less than a few weeks, concentrations of benzidine in surface water in the range of the estimated effect threshold are considered very unlikely. No information on the toxicity of benzidine to wildlife was identified. However, due to the low accumulation of benzidine in aquatic organisms, adverse effects on aquatic based wildlife due to decreased availability of prey are considered unlikely.

Effect on the environment on which human life depends

Due to its low volatility, and because it is expected to photooxidize rapidly in air, benzidine is not expected to contribute to ozone depletion, global warming or the formation of ground-level ozone.

Effect on human life or health

Benzidine has been shown to cause cancer, particularly of the bladder (predominantly transitional cell carcinoma), in occupationally exposed workers and experimental animals and is therefore considered to be a "non-threshold" toxicant (i.e., a substance for which there is believed to be some chance of adverse effect at any level of exposure). For such substances, where data permit, estimated exposure is compared to quantitative estimates of cancer potency to characterize risk and provide guidance for further action (i.e., analysis of options to reduce exposure). For benzidine, such values would be expected to be low, owing to the lack of confirmed sources of exposure to the general population of Canada to this substance.

Based on these considerations, the Ministers of the Environment and of Health concluded that benzidine is not entering the environment in a quantity or concentration or under conditions that constitute a danger to the environment or to the environment upon which human life depends. If benzidine were to enter the Canadian environment as a consequence of its commercial use, however, it might constitute a danger to human life and health. Therefore, benzidine is considered to be "toxic" as defined under CEPA.

Risk Reduction and Relevance to Other States

Uses

Benzidine has been used primarily as an intermediate in the manufacture of dyes and pigments, but it is no longer used by the industry in North America. It has been replaced by benzidine cogeners, which are chemically related compounds.

Benzidine is still used in specialty laboratory applications, including the analytical determination of various inorganic cations and anions, in various organic analyses, in the determination of blood in forensic and clinical medicine and as a stain in microscopy.

Production, importation and exportation

Benzidine and its salt are not produced in Canada, and the quantity imported into Canada was approximately 60 grams per year in 1995 and 1996. These substances are currently used only in the very limited specialty laboratory applications described above and for research and development purposes. Essential specialty laboratory applications for which there are no substances are not targeted by the Regulations.

The Regulations were put in place as a precautionary measure to protect the health of Canadians and Canadian ecosystems by ensuring that future production, importation and use of benzidine and benzidine salt is prohibited with very limited exemptions.

List of Supporting Documents

1. *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Benzidine

2. Regulatory Impact Analysis Statement, *Prohibition of Certain Toxic Substances Regulations, 2003*

3. Strategic Options for the management of toxic substances: Benzidine and 3,3-Dichlorobenzene, Report of Stakeholder Consultations

Annex II

Canadian Environmental Protection Act

Priority Substances List
Assessment Report

Benzidine

Government of Canada
Health Canada
Environment Canada

Publié également en français sous le titre de :
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Liste des substances d'intérêt prioritaire
Rapport d'évaluation : Benzidine

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Synopsis

Benzidine has been used primarily as an intermediate in the manufacture of dyes and pigments. It is not produced in Canada, and although it may have been imported in small amounts between 1980 and 1987, there no longer appears to be any commercial activity in Canada involving this substance. No conclusive information on the release or occurrence of benzidine in the Canadian environment was identified. Based on available data, benzidine is not expected to persist in the environment.

Available data on the toxic effects of benzidine on aquatic organisms indicate that surface water concentrations in the range of 0.1 mg/L would be required before adverse effects on fish would be expected. Since benzidine is not currently produced in or imported into Canada, and since its half-life in environmental media is less than a few weeks, concentrations of benzidine in surface water in the range of the estimated effect threshold are considered very unlikely. No information on the toxicity of benzidine to wildlife was identified. However, due to the low accumulation of benzidine in aquatic organisms, adverse effects on aquatic-based wildlife due to decreased availability of prey are considered unlikely.

Due to its low volatility, and because it is expected to photooxidize rapidly in air, benzidine is not expected to contribute to ozone depletion, global warming or the formation of ground-level ozone.

Benzidine has been shown to cause cancer in occupationally exposed workers and experimental animals and is therefore considered to be a “non-threshold toxicant” (i.e., a substance for which there is believed to be some chance of adverse effect at any level of exposure). For such substances, where data permit, estimated exposure is compared to quantitative estimates of cancer potency to characterize risk and provide guidance for further action (i.e., analysis of options to reduce exposure). For benzidine, such values would be expected to be low, owing to the lack of confirmed sources of exposure of the general population of Canada to this substance.

Based on these considerations, the Ministers of the Environment and of Health have concluded that benzidine is not entering the environment in a quantity or concentration or under conditions that constitute a danger to the environment or to the environment upon which human life depends. If benzidine were to enter the Canadian environment (as a consequence of its commercial use), however, it might constitute a danger to human life and health. Therefore, benzidine is considered to be “toxic” as defined under section 11 of the *Canadian Environmental Protection Act*.

1.0 Introduction

The *Canadian Environmental Protection Act* (CEPA) requires the Ministers of the Environment and of Health to prepare and publish a Priority Substances List that identifies substances, including chemicals, groups of chemicals, effluents and wastes, that may be harmful to the environment or constitute a danger to human health. The Act also requires both Ministers to assess these substances and determine whether they are "toxic" as interpreted in section 11 of the Act, which states:

> ". . .a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions
>
> (*a*) having or that may have an immediate or long-term harmful effect on the environment;
>
> (*b*) constituting or that may constitute a danger to the environment on which human life depends; or
>
> (*c*) constituting or that may constitute a danger in Canada to human life or health."

Substances assessed as "toxic" according to section 11 may be placed on the List of Toxic Substances (Schedule I of the Act). Consideration can then be given to developing guidelines, codes of practice, or regulations to control any aspect of their life cycle, from the research and development stage through manufacture, use, storage, transport and ultimate disposal.

The assessment of whether benzidine is "toxic", as interpreted under CEPA, was based on the determination of whether it **enters** or is likely to enter the Canadian environment in a concentration or quantities or under conditions that could lead to **exposure** of humans or other biota to levels that could cause harmful **effects**.

Data relevant to the assessment of whether benzidine is "toxic" under CEPA were identified through evaluation of existing review documents (ATSDR, 1989; U.S. EPA, 1980, 1986, 1987; IARC, 1982, 1987), as well as an unpublished review of the environmental behaviour and health effects of this substance prepared under contract by Cambridge Environmental Inc. (Croy and DeVoto, 1990), supplemented with information from published reference texts and literature identified through on-line searches (from 1965 to 1992) of various databases (HSDB, RTECS, IRIS, CCRIS, TOXLINE, TOXLIT, MEDLINE, ENVIROLINE, CHEMICAL ABSTRACTS, BIOLOGICAL ABSTRACTS, ELIAS, AQUAREF, MICROLOG, CODOC). In addition, a number of

provincial authorities were requested to provide any available information on the levels of benzidine in the drinking water in their provinces. The Quebec Ministry of the Environment was requested to provide available quantitative data on potential release of this substance from petrochemical facilities. Data relevant to the assessment of the effects of benzidine on the environment and human health obtained after November 1992 and February 1993, respectively, were not considered for inclusion.

Review articles were consulted where appropriate. However, all original studies that form the basis for determining whether benzidine is "toxic" under CEPA have been critically evaluated by the following staff of Health Canada (human exposure and effects on human health) and Environment Canada (entry and environmental exposure and effects):

R.G. Liteplo (Health Canada)
R.J. Maguire (Environment Canada)
M.E. Meek (Health Canada)

In this report, a summary of technical information critical to the assessment is presented in section 2. The assessment of whether benzidine is "toxic" is presented in section 3. Supporting documentation that discusses the technical information in greater detail has also been prepared and is available upon request.

The environmental sections of this report were reviewed by Drs. C.M. Auer and W.H. Farland of the U.S. Environmental Protection Agency. Sections related to the assessment of effects on human health were approved by the Standards and Guidelines Rulings Committee of the Bureau of Chemical Hazards of Health Canada. The entire Assessment Report was reviewed and approved by the Environment Canada/Health Canada CEPA Management Committee.

Copies of this Assessment Report and the supporting documentation are available upon request from:

Environmental Health Centre
Health Canada
Room 104
Tunney's Pasture
Ottawa, Ontario, Canada
K1A 0L2

Commercial Chemicals
Branch
Environment Canada
14th Floor
Place Vincent Massey
351 Saint-Joseph Boulevard
Hull, Quebec, Canada
K1A 0H3

2.0 Summary of Information Critical to Assessment of "Toxic"

2.1 Identity, Properties, Production and Uses

Benzidine (Chemical Abstracts Service Registry Number 92-87-5) is a primary aromatic amine with the molecular formula $C_{12}H_{12}N_2$. Synonyms for benzidine include 4,4'-bianiline, 4,4'-biphenyldiamine, 4,4'-diaminodiphenyl and 4,4'-diphenylenediamine (ATSDR, 1989; Croy and DeVoto, 1990). At room temperature, benzidine is white or slightly red, and in the form of either crystals, powder or leaflets (Ferber, 1978). Benzidine has a vapour pressure of 6.6×10^{-2} Pa at 25°C (Mabey *et al.*, 1982), a water solubility of 500 mg/L at 25°C (Bowman *et al.*, 1976) and a log n-octanol/water partition coefficient of 1.34 (Lu *et al.*, 1977).

The commercial manufacture of benzidine involves the alkaline reduction of nitrobenzene (Ferber, 1978). Currently, benzidine does not appear to be produced in or imported into Canada, since no company in Canada reported commercial activity involving more than 10 kilograms of this substance in 1990 (Environment Canada, 1991a, 1991b). Available data indicate that benzidine has been sporadically imported into Canada since 1980: 1980, 4 tonnes; 1981, 12 tonnes; 1982, 0.1 tonne; 1983, 0 tonne; 1984, 0 tonne; 1985, 0.3 tonne; 1986, 0 tonne; and 1987, 1.9 tonnes (Statistics Canada, 1990).

Benzidine has been used primarily as an intermediate in the manufacture of dyes and pigments, and may also be used in the analytical determination of various inorganic cations and anions, in various organic analyses, in the determination of blood in forensic and clinical medicine and as a stain in microscopy (Ferber, 1978; Budavari, 1989).

2.2 Entry into the Environment

No conclusive data on the environmental release of benzidine in Canada were identified. It can enter the environment from any stage in the production, storage, transport, use and disposal of benzidine itself or benzidine-containing materials (such as dyes and pigments), or possibly by atmospheric and water-borne transport from other countries. In water, benzidine can be produced by the photodegradation of 3,3'-dichlorobenzidine (Banerjee *et al.*, 1978). No information on the extent to which benzidine may be formed and released into the environment by this mechanism was identified. Approximately 100 tonnes of 3,3'-dichlorobenzidine were imported into Canada in 1989 (Statistics Canada, 1990). 3,3'-Dichlorobenzidine is on the CEPA Priority Substances List.

2.3 Exposure-related Information

2.3.1 Fate

Oxidation, photochemical transformation, partitioning to sediment or soil, and microbial degradation are expected to be the main pathways of distribution and transformation of benzidine in the environment. Benzidine is not expected to persist in the environment, with overall half-lives in water, soil and air of less than a few weeks. The products formed by the degradation of this substance have not been well characterized.

Benzidine is expected to be slightly volatile (from water), based on its low Henry's law constant of 2.2×10^{-2} Pa m^3/mol (Smith *et al.*, 1980). In water, although oxidation (by hydroperoxyl radical or molecular oxygen), biodegradation (Baird *et al.*, 1977; Tabak and Barth, 1978) and photolysis (Bilbo and Wyman, 1953; Larson and Zepp, 1988; Lu *et al.*, 1977; Freitag *et al.*, 1985) may be significant processes, the most important process controlling the fate of benzidine appears to be oxidation by naturally occurring metal cations; the half-life is approximately a few hours (Callahan *et al.*, 1979). Benzidine is quickly absorbed into clays and subsequently oxidized. Although the environmental fate of such complexes is not known with certainty, it is assumed that further oxidation would be facile (Callahan *et al.*, 1979). Estimated half-lives for the biodegradation of benzidine in surface water and groundwater are 31 to 192 h and 96 to 384 h, respectively (Syracuse Research Corp., 1989).

Benzidine is quickly bound in soils and sediments; however, information on the bioavailability of such bound residues was not identified. Zierath *et al.* (1980) noted that benzidine adsorption to soil or sediment was favoured by low pH, and highly correlated with the surface area of the soil or sediment. In soil, benzidine is degraded microbially (Graveel *et al.*, 1985, 1986; Lu *et al.*, 1977). The half-life of benzidine was estimated to be 48 to 192 h for aerobic degradation (Lu *et al.*, 1977).

In air, benzidine is expected to photooxidize moderately rapidly, with an estimated half-life ranging from 0.3 to 3.2 h (Syracuse Research Corp., 1989).

2.3.2 Concentrations

Benzidine was not detected (detection limit = 2 μg/L) in 34 samples of raw and 1 015 samples of treated drinking water obtained in the province of Alberta between 1987 and 1991 (Alberta Environment, 1992). No other data on the concentrations of benzidine within Canada in drinking water, surface water, groundwater, air, biota, soil or sediment, foodstuffs or products containing dyes derived from this substance were identified.

In the United States, benzidine was not detected in a survey of biota and sediment; however, it was detected (but not quantitated) in 1.1% of 1 235 samples of industrial effluent and 0.1% of 879 samples of natural water collected between 1980 and 1982 (Staples *et al.*, 1985).

Benzidine accumulates only moderately in aquatic biota. Bioconcentration factors (after 3 days) were 55 for mosquito fish (*Gambusia affinis*), 293 for *Daphnia magna*, 456 for mosquito larva (*Culex pipiens quinquefasciatus*), 645 for snail (*Physa* sp.) and 2 617 for a filamentous green alga (*Oedogonium cardiacum*) [Lu *et al.*, 1977]. Freitag *et al.* (1985) reported a 5-day bioaccumulation factor in activated sludge of 1 200, a 1-day bioaccumulation factor in algae (*Chlorella fusca*) of 850, and a 3-day bioaccumulation factor in fish (golden orfe, *Leuciscus idus melanotus*) of 83. While some of the results may suggest some potential for the bioaccumulation of benzidine by predator organisms, none has been observed, nor would it be expected for a chemical with a log octanol-water partition coefficient of 1.34.

2.4 Effects-related Information

2.4.1 Experimental Animals and In Vitro

Based on data derived from studies involving predominantly experimental animals, it is apparent that benzidine may be metabolized via a number of metabolic routes (reviewed in Hein, 1988; and Weber and Hein, 1985). One metabolic pathway involves the acetylation of benzidine by cytosolic (acetyl-coenzyme A-dependent) N-acetyltransferase enzymes, which are present in many tissues. Humans (as well as some animal species) may be classified as either “fast” or “slow” acetylators, based on the extent to which they are able to acetylate a variety of chemical substances (Hein, 1988). Based on results of studies on individuals with and without bladder tumours, it has been proposed that this “acetylation polymorphism” may be associated with the development of bladder cancer in individuals exposed to aromatic amines—individuals with a “slow acetylator phenotype” may be more predisposed to develop bladder cancer than individuals with a “fast acetylator phenotype” (Weber and Hein, 1985;

Hein, 1988; Peters *et al.*, 1990 and references therein). Humans are capable of metabolizing benzidine-based azo dyes to benzidine (Martin and Kennelly, 1985; Gregory, 1984).

The carcinogenicity of benzidine has been assessed in a number of animal species. An increased incidence of hepatocellular tumours (carcinomas, adenomas) has been observed in mice exposed to benzidine (in drinking water or in the diet) compared to unexposed controls (Littlefield *et al.*, 1983, 1984; Nelson *et al.*, 1982; Osanai, 1976; Vesselinovitch *et al.*, 1975). Rats administered benzidine (by gastric intubation of the substance dissolved in sesame oil) had a greater incidence of mammary lesions (i.e., carcinomas, adenomas, fibromas and hyperplasia) compared to controls administered vehicle alone (Griswold *et al.*, 1968). The incidence of liver tumours ("hepatomas and cholangiomas") was increased in Syrian hamsters administered benzidine (in the diet), compared to unexposed controls (Saffiotti *et al.*, 1967). In a limited study, Spitz *et al.* (1950, cited in ATSDR, 1989; and U.S. EPA, 1986) reported the development of bladder carcinomas in 3 of 7 dogs administered (orally) benzidine for a period of 5 years. Benzidine is carcinogenic following injection (intraperitoneally; subcutaneously) in rodents (i.e., rats, mice), although such routes of exposure are considered less relevant to the assessment of risk than those by which humans are generally exposed (i.e., oral; inhalation). Results of a limited study in mice indicate that benzidine may induce tumours transplacentally (Vesselinovitch, 1983).

Though benzidine was not mutagenic nor did it bind covalently to DNA in some mammalian cells *in vitro* (Phillips *et al.*, 1990; Oglesby *et al.*, 1983; O'Brien *et al.*, 1990), the weight of evidence convincingly indicates that benzidine is mutagenic and genotoxic (reviewed in ATSDR, 1989; IARC, 1982; U.S. EPA, 1980, 1986; Beland *et al.*, 1983; Beland and Kadlubar, 1985). It is mutagenic in prokaryotic and eukaryotic cells, has transformed a variety of rodent cells in *in vitro* assays, and increased sister chromatid exchange, unscheduled DNA synthesis and induced chromosomal aberrations in eukaryotic cells in *in vivo* and *in vitro* assays. Benzidine induced DNA damage in eukaryotic cells following *in vitro* or *in vivo* exposure, and the covalent binding of benzidine (i.e., its metabolites) to DNA has been observed following the *in vivo* exposure of experimental animals to this substance.

Mice administered drinking water containing benzidine dihydrochloride (20 to 160 mg/L) for their entire lifespan had vacuolation in the brain (Littlefield *et al.*, 1983, 1984). Mice administered (by gavage) benzidine hydrochloride (10.8 to 43.2 mg/kg bw/day) for 5 consecutive days had diminished immunological function (i.e., reduced B- and T-cell mitogenic responses, reduced natural killer cell activity, delayed hypersensitivity responses and reduced resistance to infection) [Luster *et al.*, 1985]. Data on the reproductive and developmental effects of benzidine on experimental animals were limited, and of little significance in assessing the toxicological effects of this substance.

2.4.2 Humans

In case reports and series published since 1927 (cited in IARC, 1982, 1987), the occurrence of bladder cancer in workers in Germany, Switzerland, Italy, England, Japan, France and the United States who had been occupationally exposed to benzidine has been reported.

You *et al.* (1990) reported a significant ($p < 0.01$) standardized incidence ratio (SIR = 19.2) for bladder cancer (14 observed cases) in a group of males (n = 550) employed for at least 6 months between 1946 and 1976 in 7 factories in Shanghai producing benzidine-based dyes. The "standardized rate" for bladder cancer increased with increasing duration of exposure to benzidine. The average periods of exposure to benzidine and latency were 8 and 20 years, respectively.

Meigs *et al.* (1986) reported a significant ($p < 0.01$) SIR (3.4, 95% confidence limit (CL) = 1.5 to 6.8) for cancer of the urinary bladder (8 observed cases/2.3 expected cases) for a group of males (n = 830) employed for at least 1 day between 1945 and 1965 at a chemical plant in Connecticut producing benzidine and substituted benzidine compounds. SIRs for bladder cancer of 1.8 (95% CL = 0.05 to 10.1; 1 observed/0.55 expected), 0 (95% CL = 0 to 4.7; 0 observed/0.79 expected), 1.9 (95% CL = 0.05 to 10.7; 1 observed/0.52 expected) and 13 (95% CL = 4.8 to 28.4; 6 observed/0.46 expected) were reported for males in the unexposed, low-, medium- and high-exposure groups, (classified based on the duration of exposure to benzidine), respectively; however, a similar trend was not observed for "non-bladder" tumours. SIRs for bladder cancer of 0 (95% CL = 0 to 3.2; 0 observed/1.15 expected), 3.4 (95% CL = 0.4 to 12.4; 2 observed/0.58 expected) and 10 (95% CL = 3.6 to 21.7; 6 observed/0.6 expected) were reported for males employed at the plant from 0 to 1, 1 to 5 and more than 5 years, respectively. The SIR for bladder cancer (4 observed cases) for males occupationally exposed to benzidine between 1945 and 1949, was 9.8 (95% CL = 2.7 to 25), while the SIR based on 1 observed case was 2.1 for workers employed between 1950 and 1954 (95% CL = 0.05 to 11.9). Measures to reduce the exposure of workers to benzidine were introduced in 1950. The average latency period was approximately 20.9 years.

You *et al.* (1990) reported a significant ($p < 0.01$) standardized mortality ratio (SMR = 14.7) for deaths due to bladder cancer (5 observed cases) in a group of males (n = 550) employed for at least 6 months between 1946 and 1976 in 7 factories in Shanghai producing benzidine-based dyes.

Morinaga *et al.* (1990) reported a significant ($p < 0.01$) SMR (14.3) for deaths due to cancer of the "urinary organ" (3 observed deaths) in a group of males (n = 155) occupationally exposed (between 1945 and 1971) to benzidine at two chemical plants in Osaka, Japan.

Delzell *et al.* (1989) reported a significant ($p < 0.05$) SMR for bladder cancer (SMR = 12.5; 2 observed/0.16 expected)[1] in a group (n = 379) of hourly paid "azo-dye" employees exposed to benzidine (in addition to other chemical compounds), although the observed cases of bladder cancer occurred in men who had been previously exposed to benzidine and β-naphthylamine (former workers at the Cincinnati Chemical Works). The azo-dye workers had been employed for at least 12 months (between 1952 and 1985) at a chemical plant in New Jersey. Mortality in a subgroup (n = 89) of males previously employed at the Cincinnati Chemical Works was also assessed, and there was a significant ($p < 0.05$) increase in SMRs for deaths due to cancer of the bladder (SMR = 12; 3 observed/0.25 expected), kidney (SMR = 9.5; 2 observed/0.21 expected) and central nervous system (SMR = 9.1; 2 observed/0.22 expected) [Delzell *et al.*, 1989].

Rubino *et al.* (1982) reported a significant ($p < 0.001$) SMR (83.3; 5 observed/0.06 expected) for deaths due to bladder cancer in a group of males (n = 65) employed for at least 1 month between 1922 and 1970 at a dyestuff factory in Northern Italy, who had been exposed to benzidine during its manufacture. The mean latency period was 23.4 years.

Case *et al.* (1954) identified 10 deaths due to bladder cancer from 1921 to 1952 in a group (number not specified) of male workers employed in the chemical industry in Britain who had been occupationally exposed to benzidine; the expected number of deaths due to bladder cancer was 0.72.

2.4.3 Ecotoxicology

Limited data on the acute toxicity of benzidine in aquatic organisms were identified. For the red shiner (*Notropis lutrensis*), a 72- and 96-h LC_{50} of 2.5 mg/L has been reported (Jones, 1980), while for the sheepshead minnow (*Cyprinodon variegatus*), the 96-h LC_{50} was 64 mg/L (Martin, 1982).

Baird *et al.* (1977) reported that benzidine (20 mg/L) had some (unquantified) inhibitory effect on the respiration of organisms in activated sludge while this substance was being degraded, suggesting that a metabolite or metabolites may be responsible for the observed toxicity.

No data on the toxicity of benzidine to wild mammals, birds, sediment or soil biota were identified. Because of the low accumulation of benzidine by aquatic organisms, adverse effects on aquatic-based wildlife due to decreased availability of prey are considered unlikely.

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1. SMRs for death due to all cancers (SMR = 1.9; 16 observed/8.3 expected), cancer of the stomach (SMR = 9.7; 3 observed/0.31 expected), and central nervous system (SMR = 9.1; 3 observed/0.33 expected) were also significantly ($p < 0.05$) increased.

3.0 Assessment of "Toxic" under CEPA

3.1 CEPA 11(*a*): Environment

The most sensitive species of fish identified is the red shiner (*Notropis lutrensis*) with a 72- and 96-hour LC_{50} of 2.5 mg/L. This concentration was divided by a factor of 20 to convert it to a chronic no-observed-effect-level, to account for interspecies differences and to extrapolate laboratory results to the field. This yielded an estimated effect threshold of 0.13 mg/L. Since benzidine is not currently produced in or imported into Canada, and since its half-life in environmental media is less than a few weeks, concentrations of benzidine in surface water in the range of the estimated effect threshold are considered very unlikely.

Therefore, on the basis of the limited available data, benzidine is not considered to be "toxic" as interpreted under paragraph 11(*a*) of CEPA.

3.2 CEPA 11(*b*): Environment on Which Human Life Depends

Benzidine is expected to be slightly volatile and to photooxidize rapidly in air. Therefore, this substance is not expected to contribute to ozone depletion, global warming or the formation of ground-level ozone.

Therefore, on the basis of available data, benzidine is not considered to be "toxic" as interpreted under paragraph 11(*b*) of CEPA.

3.3 CEPA 11(*c*): Human Life or Health

Population Exposure

Quantitative data on the concentrations of benzidine in air, drinking water, soil or foodstuffs within Canada (or elsewhere) were not identified. Consequently, the available data are inadequate to estimate the exposure of the general population of Canada to benzidine.

Effects

The results of a number of analytical epidemiological studies as well as supporting data from case reports and series of workers occupationally exposed to benzidine have provided clear evidence for the carcinogenicity of this substance in humans. Indeed, the observed association between the occurrence of bladder carcinoma and occupational exposure to benzidine fulfils the traditional criteria (consistency, strength, specificity, temporal relationship, exposure-response relationship and plausibility) for assessment of causality in epidemiological studies.

The observed associations have been very specific, in that occupational exposure to benzidine has been associated with an increased incidence of, or death due to, cancer of the bladder—almost exclusively, transitional cell carcinoma. The results have been remarkably consistent, with an association between occupational exposure to benzidine and an increased incidence of, or mortality due to, bladder cancer observed in all the analytical epidemiological studies (Meigs *et al.*, 1986; You *et al.*, 1990; Morinaga *et al.*, 1990; Delzell *et al.*, 1989; Rubino *et al.*, 1982; Case *et al.*, 1954) in which these relationships were examined.

The association between the increased incidence of, or mortality due to, bladder carcinoma is strong. Reported standardized incidence ratios (SIRs) for bladder cancer in occupationally exposed workers are 3.4 (Meigs *et al.*, 1986) and 19.2 (You *et al.*, 1990). Reported standardized mortality ratios (SMRs) for death due to bladder cancer in occupationally exposed workers range from 12 (Delzell *et al.*, 1989) to 83.3 (Rubino *et al.*, 1982).

Although quantitative information on exposure to benzidine was not assessed in any of the available analytical epidemiological studies, a relationship between qualitative measures of exposure and an increased incidence of bladder cancer was reported in two studies (You *et al.*, 1990; Meigs *et al.*, 1986). Although the data are limited, there is evidence indicating that a reduction in the (occupational) exposure to benzidine was associated with a decrease in the incidence of bladder carcinoma (Meigs *et al.*, 1986).

The carcinogenicity of benzidine in humans is plausible, based on the overwhelming evidence of the genotoxicity of this substance. Moreover, the carcinogenicity of benzidine in experimental animals (i.e., rats, mice, hamsters) has been well documented.

Since the observed association of bladder cancer (predominantly transitional cell carcinoma) with occupational exposure to benzidine fulfils the traditional criteria for assessment of causality in epidemiological studies, on the basis of the available data,

benzidine has been classified in Group I (Carcinogenic to Humans) of the classification scheme developed for the determination of "toxic" under paragraph 11(*c*) of CEPA (EHD, 1992).

For such substances, where possible, estimated total daily intake by the general population in Canada is compared to quantitative estimates of carcinogenic potency to characterize risk and provide guidance for further action (i.e., analysis of options to reduce exposure). Owing to the lack of available information on concentrations of benzidine in environmental media to which humans are exposed, it is not possible to quantitatively estimate the total daily intake of this substance by the general population of Canada. Consequently, estimates of total daily intake have not been compared to quantitative estimates of cancer potency, although such values would be expected to be low owing to the lack of reported use of this substance in Canada.

Benzidine has been classified as being "Carcinogenic to Humans", and is therefore considered to be "toxic" under paragraph 11(*c*) of CEPA.

This approach is consistent with the objective that exposure to non-threshold toxicants should be reduced wherever possible, and obviates the need to establish an arbitrary *de minimis* level of risk for determination of "toxic" under CEPA.

3.4 Conclusion

Based on the available data, benzidine is not considered to be "toxic" as defined under paragraphs 11(*a*) or 11(*b*) of CEPA. Benzidine is considered to be "toxic" as defined under paragraph 11(*c*) of CEPA.

4.0 Recommendations for Research

Although a number of data gaps on the effects of benzidine on the environment and human health were identified, because of the negligible exposure of biota and the general population of Canada to this substance the priority for additional research is considered to be low.

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Annex III

STRATEGIC OPTIONS FOR THE MANAGEMENT OF TOXIC SUBSTANCES

BENZIDINE AND 3,3'-DICHLOROBENZIDINE

Report of Stakeholder Consultations

Background

When the Ministers of Environment and Health announced the results of the assessment of the substances on the first Priority Substances List (PSL) that were found to be toxic under the *Canadian Environmental Protection Act* (CEPA), they committed to consult stakeholders. The purpose of these consultations is to recommend options to reduce the exposure and/or environmental impacts of these substances, and to find out whether regulations are warranted under CEPA.

Disclaimer

This report on stakeholder consultation is published by Environment Canada. It presents the results of the consultation, requested by the Ministers of Environment and Health, regarding management options for the substances benzidine and 3,3'-dichlorobenzidine which were assessed as toxic under CEPA.

Publication of this report does not necessarily constitute endorsement/approval by the Ministers of Environment and Health of all the findings contained herein.

Acknowledgement

The Chair of this Issue Table would like to thank all the members, corresponding members and other stakeholders that participated in the development and review of this report.

Abstract

Benzidine and 3,3'-dichlorobenzidine have been assessed and declared toxic under the Canadian Environmental Protection Act. *An Issue Table has been established to make recommendations to Ministers for the management of these substances in Canada. In this report, health, scientific, technical, and socioeconomic factors were studied by the Issue Table members so that recommendations could be made for preferred control options to prevent or minimize exposure to, and/or releases into the environment of benzidine and 3,3'-dichlorobenzidine.*

Résumé

La benzidine et la 3,3'-dichlorobenzidine ont été évaluées et déclarées toxiques aux termes de la Loi canadienne sur la protection de l'environnement. *Une table de concertation a été créée visant à formuler des recommandations aux ministres sur la gestion de ces substances au Canada. Dans le présent rapport, les membres de la table de concertation ont étudié des facteurs liés à la santé, ainsi que des facteurs scientifiques, techniques et socio-économiques en vue de formuler des recommandations portant sur les options de contrôle préférables devant prévenir ou minimiser l'exposition à la benzidine et à la 3,3'-dichlorobenzidine et le rejet de ces substances dans l'environnement.*

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Executive Summary

Benzidine and 3,3'-dichlorobenzidine (DCB) have been declared toxic under Paragraph 11(c) of the Canadian Environmental Protection Act (CEPA). *An "Issue Table", consisting of government, industry, and environmental groups, has been established to consider how benzidine and DCB should be managed in Canada. This report sets out the recommendations of the Issue Table members for the management of benzidine, DCB, and DCB salt.*

At the first Issue Table meeting, it was agreed that the scope of the benzidine/DCB Issue Table be expanded to address the substances/products derived from benzidine and DCB that could be imported into and used in Canada.

Benzidine, DCB, and DCB salt are Track 2 substances under the Toxic Substances Management Policy. The goal is to minimize environmental and health risks by reducing exposure to, and/or release of these substances to the extent possible. The Issue Table members agreed that the target for managing these substances is to ensure that the import, manufacture, and use of benzidine, DCB, and DCB salt are subject to strict life cycle controls designed to prevent/minimize exposure to, and/or the release of these substances into the environment.

Benzidine is not produced and is no longer used in the manufacture of dyes in Canada. Currently, benzidine uses are limited to specialty laboratory uses.

The Issue Table members recommend that "command-and- control" regulations be developed for the management of benzidine in support of the goal and target for this substance, and that Environment Canada consider using performance standards or user controls, or a combination of them, as the basis for these regulations. Appropriate technology controls could be specified in codes of practice or guidelines.

The Issue Table members recommend that the use of benzidine be strictly limited to applications in research and development, as an analytical standard, and in essential applications for which there are no close substitutes such as biochemical analysis for the identification of Mycobacterium tuberculosis. When benzidine is used, it must be subject to appropriate environmental release controls.

3,3'-Dichlorobenzidine itself is not produced, imported, or used in Canada. There is, however, one plant in Canada using DCB in its salt form to manufacture yellow and orange "azo" pigments.

As is required by the Toxic Substances Management Policy, each stage in the life cycle of the DCB salt, as used by this plant, was reviewed to determine whether, and at what intervention point, management of the substance might be required. Following this review, the Issue Table members considered health, scientific, technical, and socioeconomic factors in their evaluation of appropriate economic tools for managing the substance. The Issue Table members concluded that current control practices of the user are adequate to ensure health and environmental protection and that only the efficiency of the scrubber used to control DCB dust will require periodic monitoring. To ensure that the scrubber used operates efficiently, Issue Table members agreed that a verification should be done from time to time without prior notification.

lt was agreed that a similar life cycle review of the substance and an analysis of possible management options would be required, if other uses or users of DCB or DCB salt are identified in the future.

The Issue Table members recommend that the management of DCB/DCB salt be in the form of a structured voluntary agreement (e.g., Memorandum of Understanding) between Environment Canada and the user in Canada. This agreement would incorporate the life cycle control and monitoring commitments of the user and would allow for periodic compliance checks by Environment Canada.

Should new uses or users of DCB or DCB salt be identified, the Issue Table members recommend that a separate life cycle review and evaluation of management options be carried out.

The Issue Table members make the following recommendations for substances and products derived from benzidine and DCB that could be imported into and used in Canada.

The Issue Table members recommend, that to determine whether further action is required, Environment Canada and Health Canada proceed with a preliminary assessment of health and environmental effects of benzidine congeners, benzidine-based dyes, and benzidine congener-based dyes. It is also recommended that a preliminary assessment of the risk of releases of benzidine from products containing benzidine-based dyes and the risk of releases of benzidine congeners from products containing benzidine congener-based dyes, be undertaken.

As DCB-based pigments are nonbioavailable and highly resistant to degradation in the environment, and there is very little unreacted DCB in the pigments, the Issue Table members recommend that no management action is required for these pigments. However, the Issue Table members felt that if studies are done in the future on the environmental/health impact associated with disposal of sludges or wastes from processes handling products containing DCB-based pigments, these studies should address the DCB content.

Glossary

Dyes

The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) has defined dyes as "intensively coloured organic substances, which impart colour to a substrate by selective absorption of light. Dyes are soluble and/or go through an application process which, at least temporarily, destroys any crystal structure of the colour substances. Dyes are retained in the substrate by absorption, solution, and mechanical retention, or by ionic or covalent chemical bonds."

Non-threshold toxicant

Health Canada uses the following definition: substances for which the critical health effect is concluded to have no threshold, and are currently restricted to mutagenesis and genotoxic carcinogenesis. It is assumed that there is some probability of harm to human health at any level of exposure (i.e., there is no threshold below which some effect would not be observed). This classification takes into account the available carcinogenicity database (in humans and/or laboratory animals), as well as its likely mechanism of action (Amdur, 1991; U.S. EPA, 1992; Hayes, 1994; HC, 1994; WHO, 1994; Purchase and Auton, 1995).

Pigments

The Color Pigments Manufacturers Association, Inc. (CPMA) has defined pigments as "Coloured, black, white, or fluorescent particulate, organic or inorganic solids which usually are insoluble in, and essentially physically and chemically unaffected by, the vehicle or substrate in which they are incorporated. They alter appearance by selective absorption and/or by scattering of light. Pigments are usually dispersed in vehicles or substrates for application (e.g., as in the manufacture of inks, paints, plastics, or other polymeric materials). Pigments retain a crystal or particulate structure throughout the colouration process".

1.0 Introduction

1.1 Context

Benzidine and 3,3'-dichlorobenzidine (DCB) have been declared toxic under Paragraph 11(c) of the *Canadian Environmental Protection Act* (CEPA) (EC and HC, 1993a; 1993b). According to this paragraph, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions constituting or that may constitute a danger in Canada to human life or health.

Environment Canada and Health Canada share responsibility for managing certain CEPA toxic substances.

A federal commitment related to DCB was made in 1994 under the Canada-Ontario Agreement Respecting the Great Lakes Basin Ecosystem. Environment Canada will pursue this commitment with stakeholders as part of its implementation agreement.

1.2 Strategic Options Process

To ensure the most effective and efficient options for managing benzidine and 3,3'-dichlorobenzidine, within the context of pollution prevention and sustainable development, recommendations are being made to the accountable federal and provincial ministers, Environment Canada and Health Canada. Key partners have participated in the Strategic Options Process (SOP) (EC, 1994).

Stakeholders were invited to participate in the process by Mr. H.A. Clarke in a letter dated October 21, 1994. A list of the Issue Table members and corresponding members is found in Appendix 1.

The terms of reference for the Issue Table were approved at the June 6, 1995 meeting of the Issue Table (see Appendix 2).

The first of three meetings of the Issue Table was held on December 5, 1994. The agenda and minutes of each meeting are available on public file. In addition, conference calls were held to keep members informed of progress on this file and to solicit their input.

1.3 Strategic Options Report

The objective of the Strategic Options Report (SOR) is to set out, for the Ministers of Environment and Health, recommendations of Issue Table members for the management of CEPA toxic substances.

The recommendations of the Issue Table for the management of benzidine and 3,3'-dichlorobenzidine are summarized in this report.

1.4 Structure of the Strategic Options Report

The scope of the substances and products considered by the Issue Table members is found in Section 2. For substances where sufficient information was available, the Issue Table members determined the point in the life cycle of the substance where some form of control is required. For substances/products where the required health/environmental effects information and/or the import/production and use data was judged to be insufficient to adequately assess management needs, a number of recommendations are made related to further study.

In Section 3, the long-term goal for the management of substances requiring action is outlined and specific targets for each of these substances are described.

In Section 4, the Issue Table members recommend management action for benzidine, DCB, and DCB salt, with respect to the conclusions given in Section 2 and the goals/targets indicated in Section 3.

In Section 5, a summary assessment of the various management options/tools that could be used to achieve the stated targets for each substance is given. Finally, the conclusions of the Issue Table members on the most effective and efficient tools are presented.

2.0 Problem Definition

2.1 Scope

At the first Issue Table meeting, it was pointed out that:

- benzidine is no longer used in the manufacture of dyes imported into Canada; and
- DCB is used only in the salt form in Canada.

The Issue Table members agreed that the scope of the Issue Table should be expanded to address three categories of substances and products:

- the aromatic amines:
    1) benzidine;
    2) 3,3'-dichlorobenzidine (DCB);
    3) 3,3'-dichlorobenzidine dihydrochloride (DCB salt); and
    4) benzidine congeners (predominantly ortho-tolidine, ortho-dianisidine that have replaced benzidine in the manufacture of dyes).
- dyes and pigments derived from these substances:
    5) DCB-based pigments;
    6) benzidine-based dyes; and
    7) benzidine congener-based dyes.
- products (e.g., printing inks, paints, plastics, textiles, etc.) coloured by these dyes and pigments:
    8) products containing DCB-based pigments;
    9) products containing benzidine-based dyes; and
    10) products containing benzidine congener-based dyes.

2.2 Need for Management Action

On the basis of the available information, the Issue Table members concluded that:

- management action is required for 1) benzidine, 2) DCB, and 3) DCB salt;

- management action is not required for 5) DCB-based pigments, and 8) products containing DCB-based pigments because, due to their insoluble nature, pigments tend to be nonbioavailable, and are highly resistant to degradation in the environment. There is very little unreacted DCB in these pigments; and

- insufficient information was available to determine whether management action was required for 4) benzidine congeners, 6) benzidine-based dyes, 7) benzidine congener-based dyes, 9) products containing benzidine-based dyes, and 10) products containing benzidine congener-based dyes.

The Issue Table members recommend that to determine whether further action is required, Environment Canada and Health Canada proceed with a preliminary assessment of the health and environmental effects of:

- benzidine congeners;
- benzidine-based dyes; and
- benzidine congener-based dyes.
- It is also recommended to conduct a preliminary assessment of the risk of releases of:
  - benzidine from products containing benzidine-based dyes; and
  - benzidine congeners from products containing benzidine congener-based dyes.

2.3 Substances

2.3.1 *Benzidine*

Production, Importation, and Use in Canada. Benzidine was an important chemical in the manufacture of dyes some years ago, but is no longer used by the industry in North America. It has been replaced by benzidine congeners, which are chemically related compounds.

Benzidine is only used to analyze samples in laboratory applications; for research on toxicity, mutagenicity, or DNA damage; in studies on cholesterol or steroids; and for environmental standards. Few, if any, new uses are expected.

Benzidine is not produced in Canada, but it was imported sporadically in small quantities

between 1980 and 1987 (Margeson, 1994).

Health and Environmental Effects. Based on data demonstrating that benzidine causes cancer in occupationally exposed workers and experimental animals, and other supporting information, benzidine is considered by Health Canada to be a "non-threshold toxicant"[1], (EC and HC, 1993a; HC, 1994).

Partitioning to soil, biota, and sediment are likely to be the main pathways for distribution of benzidine to the environment. Photolysis, photooxidation, and microbiological degradation are the main modes of destruction of benzidine in the environment.

Based on available data, benzidine is not likely to persist in the environment because its half-life in water, soil, and air is estimated to be less than a few weeks. Due to its relatively low volatility, and because it is expected to photooxidize rapidly in air, benzidine is not expected to contribute to ozone depletion, global warming, or the formation of ground-level ozone (EC and HC, 1993a).

Conclusion. It was concluded that the most efficient way to manage benzidine would be through the control of its import, manufacture, and use.

2.3.2 *Preamble for 3,3 '-Dichlorobenzidine and 3,3'-Dichlorobenzidine Salt*

3,3'-Dichlorobenzidine has been assessed under CEPA to be toxic. At the first Issue Table meeting, the question was raised as to whether the assessment for health risk included the DCB salt (DCB.2HCl). In the Supporting Document to the Assessment Report on DCB (EC March 1993; HC, March 1993), no distinguishable variation in result was found between DCB salt and other forms of DCB regarding the toxic effects. Although the DCB salt was not listed on the Priority Substances List, the Issue Table members concluded that it fell within the terms of reference of the Benzidine and DCB Issue Table.

2.3.3 *3,3 '-Dichlorobenzidine*

Production, Importation, and Use in Canada. Although DCB is not produced, imported, or used in Canada, it might be imported and used in the future.

Health and Environmental Effects. Available information is considered inadequate to assess the carcinogenicity of DCB in humans. However, DCB has been shown to cause cancer in

[1] Some members disagree with the non-threshold toxicant classification and policy for benzidine and 3,3'-dichlorobenzidine. These members concur with the findings that no one really understands what happens when people are exposed to very low levels of chemicals (Wildavsky, 1995).

a number of animal species. 3,3'-Dichlorobenzidine is therefore considered by Health Canada to be a "non-threshold toxicant" [1] (EC and HC, 1993b; HC 1994).

Partitioning to soil, biota, and sediment are expected to be the main pathways for distribution of DCB to the environment. Photolysis, photooxidation, and microbiological degradation are expected to be the main modes of destruction of 3,3'-DCB in the environment.

3,3'-Dichlorobenzidine is not expected to be persistent in the environment, as its half-life in water, soil, and air is less than a few weeks. Due to its relatively low volatility, very short residence time, and low concentrations in the atmosphere, DCB is not expected to contribute to the greenhouse effect, depletion of the ozone layer, or the formation of ground-level ozone (EC and HC, 1993b).

Conclusion. It was concluded that the import, manufacture, and use of DCB, if it is used in the future, should be controlled throughout its life cycle, identical to the management of the DCB salt so as to prevent or minimize its releases to the environment.

2.3.4 *3,3 '-Dichlorobenzidine Salt*

Production, Importation, and Use in Canada. The dihydrochloride salt of 3,3'-dichlorobenzidine is the only form of DCB currently used in Canada. It is used primarily for the manufacture of yellow and orange “azo” pigments. 3,3'- Dichlorobenzidine-based pigments are mostly used for printing inks; almost all yellow printing inks are coloured with this type of pigment. Other uses include the colouration of plastics such as PVC and polyethylene, and some paints.

There is only one user of DCB salt and manufacturer of DCB-based pigments in Canada. The 3,3'-dichlorobenzidine salt content in the pigment is known to be extremely low (less than 0.1%) because virtually complete chemical conversion of the DCB salt occurs during the manufacturing process. There is no indication that any other company will manufacture DCB-based pigments in Canada in the future.

Health and Environmental Effects. These effects are the same as the effects for DCB.

Life Cycle. Each stage of the life cycle (see Appendix 6) of the DCB salt as used by the only DCB-based pigments manufacturer in Canada was reviewed to determine whether, and at what intervention point, management of the substance might be required. Note that this life cycle

[1] Some members disagree with the non-threshold toxicant classification and policy for benzidine and 3,3'-dichlorobenzidine. These members concur with the findings that no one really understands what happens when people are exposed to very low levels of chemicals (Wildavsky, 1995).

ends when DCB-based pigments are formed.

(1) transportation

a) description: The DCB salt is imported by truck or by sea followed by truck transportation. The salt is supplied in sealed fibre drums.

b) assessment: No spills or other releases have occurred to the knowledge of the Issue Table members. It appears that adequate precautions have been taken to prevent spills or releases.

c) conclusion: No action is required.

(2) storage

a) description: The DCB salt is stored in sealed fibre drums in a warehouse in the plant where they are used. The drums are not opened in this room.

b) assessment: It appears that adequate precautions have been taken to prevent spills/releases.

c) conclusion: No action is required.

(3) 3,3'-dichlorobenzidine salt dumped into the “tetrazo” tank

a) description: The drums are emptied in a small “dedicated” room equipped with strip curtains on the doorway to eliminate drafts. An air exhaust (system) puts the entire room under negative pressure thus preventing the escape of air and any DCB contamination.

The contents of the drums are emptied into the tank through a small opening that maintains the integrity of the negative pressure provided by the exhaust fan. Water from a hose is used to flush any remaining DCB into the “tetrazo” tank.

b) assessment: There appears to be no risk of spills/releases.

c) conclusion: No action is required.

(4) 3,3'-dichlorobenzidine dust

a) description: The DCB salt is used because it is inherently less dusty than DCB. In addition, it normally is slightly damp (4% moisture) which further reduces any tendency to form dust. There is little dust, if any, from the dumping of the DCB salt into the "tetrazo" tank. Any dust that is created would be carried through the exhaust system to a scrubber where it is destroyed using potassium permanganate.

b) assessment: Dust problems seem to have been carefully considered. However, to ensure that there are no emissions of DCB, it is necessary that the scrubber operates efficiently.

c) conclusion: The Issue Table members concluded that it will be necessary for the user to maintain the efficiency of the scrubber and desirable to have government inspectors verify this efficiency from time to time.

(5) empty drums and operator's clothing

a) description: Before the next batch of pigment is made, the drums are chemically decontaminated by using an oxidizing agent to destroy any remaining DCB salt. Empty decontaminated drums are not reused; the drums are crushed and sent to landfill.

Protective clothing is washed down and treated with an oxidizing agent to chemically destroy any DCB.

b) assessment: There appears to be no risk of spills/releases.

c) conclusion: No action is required.

(6) colourmaking

a) description: Sodium nitrite is added and the DCB salt is chemically transformed into the “tetrazo” compound (tetrazonium chloride). After the “tetrazo” solution has been formed, and at this point all DCB salt is reacted, a valve is opened and the solution is added to the colourmaking tank. The “tetrazo” tank is washed down and the washing liquid is added to the colourmaking tank.

b) assessment: There appears to be no risk of spills/releases during the colourmaking operation.

c) conclusion: No action is required.

Conclusion. The Issue Table members concluded that the import, manufacture, and use of DCB salt should be controlled throughout its life cycle so as to prevent or minimize its releases to the environment.

Following an assessment of the life cycle of DCB salt, as used by Canada's sole importer, it was concluded that current life cycle control practices are adequate to ensure health and environmental protection and that only the efficiency of the scrubber to control DCB dust will require periodic monitoring.

2.3.5 *Benzidine Congeners*

Production, Importation, and Use in Canada. Benzidine congeners are not produced in Canada, but some were being imported in very small quantities between 1984 and 1986 and these appear on the Domestic Substances List (DSL). As no recent data are available, it is not known if benzidine congeners are still being imported into Canada. Also, some other benzidine congeners are listed on the Non-Domestic Substances List (NDSL). Consequently, imports of less than 1000 kg/year could be imported into Canada by a company without a notification requirement.

Benzidine congeners are substituted forms of benzidine and include several chemical substances, none of which occur naturally and all of which are chemically related to benzidine. These compounds are important as precursors in the synthesis of a large number of dyes. The two primary congeners used in North America are 3,3'-dimethylbenzidine (ortho- tolidine) and 3,3'-dimethoxybenzidine (ortho-dianisidine). Both of these congeners are on the DSL.

Health and Environmental Effects. Environment Canada and Health Canada have not assessed the health and environmental effects of benzidine congeners. A number of studies have been conducted in the United States, however, that could be very helpful in the assessment of the benzidine congeners.

Conclusion. It was concluded that an evaluation of health and environmental effects of benzidine congeners will be needed before any action can be recommended.

2.3.6 *3,3'-Dichlorobenzidine-based Pigments*

Production, Importation, and Use in Canada. Some DCB-based pigments are on the Domestic Substances List (DSL). They were being imported in quantities greater than 300 tonnes in 1986 and are still being imported. There is only one manufacturer of DCB-based pigments in Canada.

Health and Environmental Effects. Environment Canada and Health Canada have not assessed the risk of releases of DCB from pigments. However, most pigments due to their insoluble nature, tend to be nonbioavailable and are highly resistant to degradation in the environment. There is little or no evidence that DCB-derived pigments degrade in a pathway that leads to DCB formation. Thus, the only DCB that might be released would be any unreacted DCB. While analytical work with pigments is usually difficult due to their insolubility in the vehicle or substrate in which they are incorporated, the scientific literature generally indicates that less than 0.1 % of unreacted DCB remains in the pigment (Marr, 1995).

Conclusion. It was concluded that no action is required.

2.3.7 *Benzidine-based Dyes*

Production, Importation, and Use in Canada. Benzidine-based dyes are not produced in Canada. Some benzidine-based dyes are on the Domestic Substances List (DSL). It is known that they were imported into Canada between 1984 and 1986. More recent data are not available. Therefore, it is impossible to determine if these dyes are still being imported. It should be noted, that the benzidine-based dyes listed on the Non-Domestic Substances List (NDSL) could be imported in quantities of less than 1000 kg/year by a company without a notification requirement. However, considering the downward trend in the U.S. market, it is probable that they are currently not used in Canada.

Of the nine countries responding to a recent United States Environmental Protection Agency survey (U.S. EPA, 1994), only the United Kingdom reported significant use of benzidine dyes. Other countries reported importing very small amounts, usually for specialty laboratory uses.

In the United States, most members of the dyes industry voluntarily phased out the use of benzidine and benzidine-based dyes in the early 1970's. In 1991, because of the benzidine-based dye concerns, the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) established a manufacturing and sales phaseout requirement of all benzidine-based dyes, as a basis for membership in the Association. However, since there is no restraint on use of these dyes, some could become available in U.S. commerce, in particular through supply by non-ETAD members (U.S. EPA, 1994).

In Germany, the production, importation, and sale of items dyed with certain azo dyestuffs, including benzidine-based dyes, were banned, effective in 1995, according to German Consumer Goods Legislation (ACTS Bulletin, 1994; see Appendix 3).

Health and Environmental Effects. It appears that humans are capable of metabolizing benzidine-based azo dyes to benzidine (Martin and Kennelly, 1985 as cited in EC and HC, 1993a)

but Environment Canada and Health Canada have not assessed the health and environmental effects of benzidine-based dyes.

Conclusion. It was concluded that an evaluation of the health and environmental effects of benzidine-based dyes will be needed before any action can be recommended.

2.3.8 *Benzidine Congener-based Dyes*

Production, Importation, and Use in Canada. The benzidine congener-based dyes have replaced the benzidine-based dyes. Although not produced in Canada, some benzidine congener-based dyes are on the Domestic Substances List (DSL). These dyes were imported in 1986. No recent data are available. However, it can be assumed considering U.S. market trends, that benzidine congener-based dyes are still imported and used in Canada. Currently, only uses of metallized ortho-dianisidine congener-based dyes have increased; uses of other congener-based dyes have decreased.

Some benzidine congener-based dyes are listed on the Non-Domestic Substances List (NDSL). Consequently, quantities less that 1000 kg/year could be imported into Canada by an individual company without a notification requirement.

About half of the countries responding to a recent survey conducted by the U.S. EPA (1994), reported manufacture and/or import of benzidine congener-based dyes. The United States was the largest producer and user of benzidine congener-based dyes; approximately 10 to 20 companies manufacture or import some type of benzidine congener-based dyes.

Health and Environmental Effects. Environment Canada and Health Canada have not assessed benzidine congener-based dyes.

Conclusion. It was concluded that an evaluation of the health and environmental effects of benzidine congener-based dyes will be needed before any action can be recommended.

2.3.9 *Products Containing 3,3'- Dichlorobenzidine-based Pigments*

Production, Importation, and Use in Canada. DCB-based pigments are mostly used in printing inks at a concentration that varies between 2 and 20%. Other uses include the colouration of plastics such as PVC and polyethylene, and some paints. There are yellow pigment substitutes for DCB-based pigments, but they are more expensive and less efficient.

Health and Environmental Effects. Environment Canada and Health Canada have not assessed health and environmental effects associated with the life cycle of products containing DCB-based pigments.

Conclusion. It was concluded that, given the estimate of unreacted DCB in pigments, significant concentrations of DCB in products are not likely. However, the Issue Table members felt that if studies are done in the future on the environmental and health impacts associated with disposal of sludges or wastes from processes, printing, and de-inking among others, these studies should address the DCB content.

2.3.10 *Products Containing Benzidine-based Dyes*

Production, Importation, and Use in Canada. Benzidine-based dyes are used primarily in paper, textiles, and leather. The importation of products made with benzidine-based dyes is possible.

Health and Environmental Effects. It is not known if there is degradation of benzidine-based dyes in imported products.

Conclusion. It was concluded that it is necessary to determine if a human exposure problem exists from contact with imported consumer products containing benzidine-based dyes. If a problem exists, a potential means of control could be the *Hazardous Products Act* or, if a significant waste problem occurs, CEPA.

2.3.11 *Products Containing Benzidine Congener-based Dyes*

Production, Importation, and Use in Canada. Benzidine congener-based dyes are used primarily in paper, textiles, and leather. The importation of products made with benzidine congener-based dyes is possible.

Health and Environmental Effects. It is not known if there is degradation of benzidine congener-based dyes in imported products.

Conclusion. It was concluded that it is necessary to determine, first, if benzidine congeners are toxic, and second, if a human exposure problem exists from contact with imported consumer products containing benzidine congener-based dyes. If a problem exists, a potential means of control could be the *Hazardous Products Act* or, if a significant waste problem results, CEPA.

3.0 Goals and Targets

3.1 Goals

The Issue Table members concluded, based on available information, that benzidine, DCB, and DCB salt should be managed throughout their entire life cycle and in a manner consistent with sustainable development under Track 2 of the *Toxic Substances Management Policy*.

"As science cannot always accurately predict the effects that a substance will have on the environment or on human health, managing toxic substances effectively requires taking a proactive, cost-effective approach to prevent pollution, rather than reacting after it has already occurred." (EC, 1995).

The goal is to minimize environmental and health risks, by reducing exposure to, and/or the release of benzidine, DCB, and DCB salt to the extent possible.

3.2 Targets

Health, scientific, technical, and socioeconomic factors have been accounted for in developing the targets for benzidine, DCB, and DCB salt. In pursuit of these targets, pollution prevention and continuous improvement in the environment will be promoted.

3.2.1 *Target for Benzidine*

It is recommended that the import, manufacture, and use of benzidine be subject to strict life cycle controls designed to prevent or minimize exposure to, and/or the release of benzidine into the environment.

3.2.2 *Target for 3,3 '-Dichlorobenzidine and 3,3'-Dichlorobenzidine Salt*

It is recommended that the import, manufacture, and use of DCB and DCB salt be subject to strict life cycle controls designed to prevent or minimize exposure to, and/or the release of DCB from existing sources into the environment.

In addition to the targets, the Issue Table members are making recommendations to Ministers on the management tools that will enable these targets to be met. Environment Canada will monitor and assess the actions taken to manage benzidine, DCB, and DCB salt to determine if the targeted use restrictions and the release and exposure controls are achieved.

4.0 Recommended Management Action

Recommendations for the management of benzidine, DCB, and DCB salt are summarized in this section with respect to the conclusions given in Section 2 and the goals/targets indicated in Section 3.

4.1 Benzidine

It is recommended that the use of benzidine be strictly limited to applications in research and development, as an analytical standard, and in essential applications for which there are no close substitutes such as biochemical analysis for the identification of *Mycobacterium tuberculosis*. When benzidine is used, it must be subject to appropriate environmental release controls.

4.2 3,3'-Dichlorobenzidine and 3,3'-Dichlorobenzidine Salt

Following the assessment of the life cycle of DCB salt (Section 2.3.4), it was concluded that current life cycle control practices of the Canadian user are adequate to ensure health and environmental protection and that only the efficiency of the scrubber to control DCB dust will require periodic monitoring.

To ensure that the scrubber used operates efficiently, the Issue Table members recommend that a verification of the scrubber efficiency be done from time to time without prior notification so that releases of DCB salt into the environment are prevented or minimized.

5.0 Options Evaluation and Recommended Control Options

5.1 Introduction

5.1.1 *Overview*

The options that were considered by the Issue Table members for the management of benzidine are outlined in Table 1. The options for DCB and DCB salt are found in Table 2. More details on the assessment of the preferred options/tools for recommendations to Ministers are summarized in the text. The recommendations of the Issue Table members are also given.

5.1.2 *Management Options*

Three broad categories of management options/tools to achieve environmental targets are:

a) command-and-control tools;

b) market-based tools; and

c) voluntary tools.

Command-and-control tools impose legally binding restrictions subject to prosecution and fines on firms' activities; market-based tools refer to market intervention designed to directly or indirectly modify prices and thus behaviour; and voluntary tools are measures taken that are not enforceable by law. A complete list of the possible options, and their respective definitions, are given in Appendix 4. In addition, the status quo option (i.e., no measure is proposed) was considered by the Issue Table members.

5.1.3 *Evaluation Criteria*

The criteria used in the Issue Table members' assessment of each of these management options included:

a) environmental-effectiveness;
b) cost-effectiveness;
c) enforceability;
d) public acceptability; and
e) growth.

Environmental-effectiveness refers to the extent to which the environmental target can be achieved/ensured with the use of this tool.

Cost-effectiveness refers to the tool's ability to achieve the target in a manner that minimizes the financial burden to industry and to government.

Enforceability refers to the ability of the federal government to monitor and enforce this option.

Public acceptability refers to the readiness with which it is expected the public will accept the implementation of this option for environmental reasons.

Growth refers to the impact of the option selected on economic growth (entry of new producers into an industry, for example) while still meeting the environmental target.

A complete list of the evaluation criteria, and their respective definitions, is given in Appendix 5.

5.2 Substances

5.2.1 *Benzidine*

Target. The Issue Table members recommended (in Section 3) that the import, manufacture, and use of benzidine be controlled throughout its life cycle so as to prevent or minimize releases of, or exposure to, the substance. It was further recommended that benzidine be restricted to: a) use as an analytical standard, b) use in research and development, and c) essential uses for which there are no close substitutes.

Table 1 Options Considered for the Management of Benzidine

Tools		Assessment Summary
a)	**command-and control**	
	. quantity controls	*not recommended* Placing limits on the quantity of benzidine imported, produced, and/or used in Canada was considered. However, as it had been agreed to recommend that essential uses of benzidine should not be prohibited, the quantity controls were rejected.
	. performance standard	*potential tool* It was concluded that performance standards (e.g., exposure/release limits), applied at appropriate points in the benzidine life cycle, could be used to ensure that the release of, or exposure to, benzidine is prevented or minimized.
	. technology controls	*potential tool* Appropriate technology controls (control of processes and/or equipment), applied at specific points in the benzidine life cycle, could be specified in codes of practice or guidelines to ensure that the release of, or exposure to, benzidine is prevented or minimized.
	. user controls	*potential tool* Importation and use controls through licensing, certification, or permitting could be used to ensure strict life cycle control of benzidine in allowable uses.
	. information controls	*not recommended* Strict life cycle control of benzidine cannot be achieved through information disclosure (e.g., reporting requirement) methods and, therefore, this option is not recommended.
b)	**market-based**	
	. trading programs	*not recommended* Because of the very small quantities of benzidine used in Canada, and the limited number of uses and users, the introduction of a trading program would not provide an efficient way to manage the quantity of benzidine used. In

addition, as adequate incentives for life cycle control of benzidine would not be provided through a trading program, this option is not recommended.

. environmental charges/taxes — *not recommended*

The introduction of an environmental charge or tax on benzidine or on its releases (if any) to the environment would have a very limited effect on reducing the use of benzidine in the targeted applications. In addition, as life cycle control measures for benzidine would be required as well, this option is not recommended.

. financial incentives — *not recommended*

Financial incentives to phase out the use of benzidine, and/or to adopt more environmentally friendly life cycle control of it, would not be required for the targeted uses. In addition, as it was felt that support for using public funds for this purpose would be very weak, this option is not recommended.

. deposit-refund systems — *not applicable*

c) voluntary

. structured — *not recommended*

It was concluded that there would be no efficient way that structured voluntary actions (codes of practice/guidelines and voluntary agreements) could be used to ensure the control of benzidine in the potentially many diverse analytical and research applications. This option is not recommended.

. unstructured — *not recommended*

It was concluded that there would be no efficient way that unstructured voluntary actions could be used to ensure the control of benzidine in the potentially many diverse analytical and research applications. This option is not recommended.

d) status quo — *not recommended*

Despite the very small amount of benzidine used in Canada (at present or expected in the future), and the limited number of uses and users, the option to do nothing would be inconsistent with the goal for managing Track 2 "CEPA toxics" and with the target being recommended in this report. This option is not recommended.

Conclusions. It was concluded that the goal and target for benzidine could only be achieved by directly controlling the uses of benzidine, its import and manufacture, through the implementation of legally binding requirements of a regulation.

imports-The restricted use of imported benzidine would be set out in the regulation and the import of benzidine for re-export would be prohibited.

manufacture-Benzidine is not manufactured in Canada, the quantity of benzidine used or anticipated to be used in Canada is very small, and is being phased out in most applications. The domestic manufacture of benzidine would be prohibited in the regulation.

uses-The allowable uses of benzidine would be clearly set out in the regulation. These would include:

- the use of benzidine as an analytical standard;
- the use of benzidine in research and development laboratories, subject to appropriate exposure/release controls; and
- uses for which there are no close substitutes. Health Canada judges that benzidine remains an essential chemical (in very small quantities) in a limited number of applications. These applications would be precisely defined in the regulations. If a new application is developed in the future, the regulations could be amended. Various methods for identifying new users of any quantity of benzidine would have to be assessed.

exposure/release controls-Regulators would assess and choose from three approaches for controlling exposure to/releases of benzidine.

1) Performance-based exposure/release standards (i.e., standards for releases to air, water, and soil) would ensure the target for benzidine is met while allowing restricted users the flexibility to choose the most cost-effective way to achieve the standard. Monitoring and enforcement would be relatively simple and inexpensive given the limited number of users. This approach would likely be acceptable to the public as it would ensure the control of benzidine at minimal cost to industry and government.

2) Technology-based controls (i.e., regulations specifying the type of equipment that could be used in the handling of benzidine) might prove to be easier to monitor and enforce. However, this type of control may be more costly to develop and to update. In addition, the control will not ensure that environmental and health risks are prevented/minimized unless complementary tools to control the operational efficiency

of the machinery and the quantity of benzidine used are introduced.

3) User controls (importation and use controls through licensing, certification, or permitting) could be used to ensure the environmental goals and targets for benzidine are met. Monitoring and enforcement would be relatively simple and inexpensive given the small number of users. This approach might prove to be the most cost-efficient option for regulatory agencies.

Recommendation.

The Issue Table members recommend that "command-and-control" regulations be developed for the management of benzidine in support of the goal and target for this substance, and that Environment Canada consider using performance standards or user controls, or a combination of them, as the basis for these regulations. Appropriate technology controls could be specified in codes of practice or guidelines.

5.2.2 *3,3'-Dichlorobenzidine and 3,3'-Dichlorobenzidine Salt*

Target. The Issue Table members recommended (in Section 3) that the import, manufacture, and use of DCB and DCB salt be strictly controlled throughout their life cycle so as to prevent or minimize releases of, or exposure to, these substances. Management options considered are in Table 2.

Table 2 Options Considered for the Management of 3,3'-Dichlorobenzidine and 3,3'-Dichlorobenzidine Salt

Tools	Assessment Summary
a) command-and control	
. quantity controls	*not recommended* Controls on the quantity of DCB/DCB salt imported and used in Canada would alone not be sufficient to ensure the protection of human health and the environment. Given that it is possible to prevent/minimize exposure/releases of these substances through life cycle controls and that only a small quantity of DCB in its salt form is used in Canada at present, the Issue Table members concluded that it would not be efficient to include quantity controls as part of the management package. This option is not recommended.
. performance standard	*not recommended* Although performance standards (e.g., exposure/release limits), applied at appropriate points in the DCB/DCB salt life cycle, could be used to ensure that the release/exposure of these substances is adequately managed, developing and updating the standard, and monitoring and enforcing it, would not be the most cost-effective way to manage the one user in Canada. This option is not recommended.
. technology controls	*not recommended* Although technology controls (control of processes and/or equipment), applied at appropriate points in the DCB/DCB salt life cycle, could be used to ensure that the release/exposure of these substances is adequately managed, developing and updating these controls, and monitoring and enforcing them, would not be the most cost-effective way to manage the one user in Canada. This option is not recommended.
. user controls	*not recommended* Importation and use controls through licensing, certification, or permitting could be used to ensure strict life cycle control of DCB/DCB salt. The development and application of these types of controls would not be the most cost-effective way to manage the one user in Canada. This option is not recommended.

	. information controls	*not recommended* Strict life cycle control of DCB/DCB salt cannot be achieved through information disclosure (e.g., reporting requirement) methods; therefore, this option is not recommended.
b)	**market-based**	
	. trading programs	*not applicable*
	. environmental charges/taxes	*not recommended* The introduction of an environmental charge or tax on DCB/DCB salt or on its releases (if any) to the environment would have very limited or no effect on reducing the use of DCB salt by the one user in Canada. In addition, as life cycle control measures for the DCB salt would still be required, this option is not recommended.
	. financial incentives	*not recommended* It was concluded that financial incentives to phase out the use of DCB/DCB salt, and/or to adopt more environmentally friendly life cycle control of it, are not required. In addition, as it was felt that support for using public funds for this purpose would be very weak, this option is not recommended.
	. deposit-refund systems	*not applicable* The Issue Table members noted that as there is a chemical reaction of the DCB/DCB salt when used, recovery of the substance is impossible. This option could not be used.
c)	**voluntary**	
	. structured	*recommended* The most cost efficient way of ensuring the life cycle control of DCB/DCB salt, in line with the recommended target, and given that there is now only one user of the substance in Canada, would be with a structured voluntary agreement (e.g., M.O.U.) between Environment Canada and the user that incorporates specific control and monitoring commitments and compliance checks. This option is recommended.

	. unstructured	*not recommended* Unstructured voluntary actions adopted by the single user would not be sufficient to ensure the life cycle control of DCB/DCB salt in line with the target being recommended for these substances. This option is not recommended.
d)	**status quo**	*not recommended* The Issue Table members concluded that, despite the fact that there are no users of DCB and only one user of DCB salt in Canada at present, and that no new uses/users are anticipated, the option to do nothing would be inconsistent with the goal for managing Track 2 "CEPA toxics" and with the target being recommended in this report. This option is not recommended.

Conclusions. The Issue Table members determined that the goal and target for DCB/DCB salt could be achieved through the promulgation of legally binding regulations based on performance standards, technology controls, supplier controls, or a ban. In addition, it was determined that quantity controls (other than a ban) and/or environmental charges/taxes could be used if part of a broader control package. However, it was concluded that an agreement - a structured voluntary agreement (i.e., Memorandum of Understanding) between Environment Canada and the user, covering life cycle control, monitoring, and compliance checks, would be recommended to Ministers.

uses-The Issue Table members' search for the best management option(s) for DCB/DCB salt was clearly influenced by: a) the fact that there is only one user of this substance in Canada at present; and b) the knowledge (based on advice from experts) that it is very unlikely new uses and/or users of these substances will be introduced/established in the future.

controls-The Issue Table members are convinced that a formal agreement between Environment Canada and the user, one that incorporates life cycle control and monitoring commitments on behalf of the user and allows for periodic compliance checks by Environment Canada, would be sufficient to ensure that human health and the environment are protected. Use of this tool would prove the most cost-effective for government in that it avoids the time and expense of developing a regulation for application to only one user. It would also allow the user to find the most cost-effective measures for ensuring that exposure/releases of DCB/DCB salt are prevented or minimized. The agreement would allow for periodic checks of the operation of the user with respect to all stages of its handling of the DCB salt to ensure that the target for these substances (Section 3) is met. [Only if new uses/users of the substances are established and/or there are concerns with respect to compliance with the intent/terms of the agreement with the

current user, would new agreements or other forms of control (including binding regulations) have to be considered]. Because human health and the environment would be protected from DCB/DCB salt exposure/release in the most cost-efficient manner with the voluntary agreement being recommended, it is expected that the public will accept this management option.

Should other uses or users of DCB or the DCB salt be identified in the future, it was agreed that a similar life cycle review of the substance and of possible management options would be required.

Recommendation.

The Issue Table members recommend that the management of DCB/DCB salt be in the form of a structured voluntary agreement (e.g., Memorandum of Understanding) between Environment Canada and the user in Canada. This agreement would incorporate life cycle control and monitoring commitments of the user and would allow for periodic compliance checks by Environment Canada.

Should new uses or users of DCB or DCB salt be identified, the Issue Table members recommend that a separate life cycle review and evaluation of management options be carried out.

6.0 References

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Appendix 1

Benzidine/3,3'-Dichlorobenzidine Issue Table Members and Corresponding Members

Issue Table members:

Dr. Peter Marr	Dominion Colour Corporation & Color Pigments Manufacturers Association (CPMA)
Dr. Per Stensby	Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD)
Mr. Stéphane Gingras	Great Lakes United
Ms. Lorraine Seed	Health Canada
Ms. Judith Hull	Environment Canada
Mr. Jim Armstrong	Environment Canada
Ms. Nathalie Tremblay	Environment Canada

Corresponding members:

Ms. Doreen Henley	Canadian Manufacturers' Association
Dr. Volken Kaden	Ciba Geigy Ltd.
Ms. Susan F. MacDougall	Ciba Geigy Ltd.
Mr. Walter Banas	Miles Canada Inc.
Mr. Larry Robinson	Color Pigments Manufacturers Association (CPMA)
Mr. Robert White	Non-Prescription Drug Manufacturers' Association of Canada
Dr. Frank Wandelmaier	Health Canada
Dr. Robert Liteplo	Health Canada
Mr. Holmer Berthiaume	National Defense
Mr. Stephen Phipps	Canadian Association of Textile Colourists & Chemists - Ontario

Dr. Shawn Mitton	Occupational Hygiene Officer, Workers' Compensation Board
Mr. Roman Kostiuk	Hoechst Canada Inc.
Mr. A.A. Schuldt	Stelco Inc.
Mr. John Margeson	Industry Canada
Dr. Jim Maguire	Environment Canada

Provinces (corresponding members):

Mr. L. Hubbard	British Columbia
Mr. Phillip Blagden	Newfoundland
M. Jean Lavergne	Quebec
Dr. Victor S. Chang	Saskatchewan
Mr. Mike Murphy	New Brunswick
Mr. Ed Yee	Manitoba

Environmental Non-government Organizations (corresponding members):

Mr. John Jackson	Great Lakes United
Ms. Kathryn Tregunna	Canadian Public Health Association

Environment Canada Regions (corresponding members):

Mr. Les Rutherford	Atlantic
Mr. Stéphane Grenon	Quebec
Mr. J. Smith	Ontario
Mr. Art Beckett	Prairie and Northern
Ms. Liz Gordy	Pacific and Yukon

Appendix 2

Benzidine/3,3'-Dichlorobenzidine Issue Table Terms of Reference

Objective. A multistakeholder Issue Table to develop a Strategic Options Report for examining the need for and method of controlling and\or reducing the emissions of and exposure to benzidine and 3,3'-dichlorobenzidine.

Background to the Strategic Options Process. To address the environmental and health problems presented by the CEPA toxic substances, Environment Canada has developed a "Strategic Options Process" (SOP). The SOP is a consultative multistakeholder approach designed to identify and evaluate a broad range of options for the effective management of environmental issues before making recommendations to the Minister of the Environment and the Minister of Health on actions. It was developed and refined in consultation with other federal departments, provincial governments, industry, and nongovernmental organizations.

The SOP involves the setting up of an issue table for each substance or industrial sector to be examined. The decision to choose a substance or sector approach is based on the scale and the scope of the issue. In general, a sector approach is recommended for substances whose entry into the environment is predominantly the result of an identifiable industrial process. The substance approach is recommended for substances whose entry is primarily the result of its commercial use.

The membership of an Issue Table should be limited to a maximum of 20 persons. These members must have the authority to talk in the name of their constituents and to make commitments on behalf of their organizations.

Benzidine and 3,3'-dichlorobenzidine have been identified, in the 1994-95 workplan, for a substance SOP.

Background to Benzidine and 3,3'-Dichlorobenzidine. Benzidine has been used primarily as an intermediate in the manufacture of dyes and may also be used in the analytical determination of various inorganic cations and anions, in various organic analyses, in the determination of blood in forensic and clinical medicine, and as a stain in microscopy.

3,3'-Dichlorobenzidine is used as an intermediate in the manufacture of pigments for printing inks, plastics, and paints, etc. It is also reported to be used as a curing agent in the synthesis of polyurethane and for analytical determination of gold.

Neither substance is produced in Canada. Only small amounts (< 10 tonnes/year) of benzidine are

imported, if it all, resulting in low exposure of the general population of Canada. The import of 3,3'-dichlorobenzidine (salt form) can reach 100 tonnes per year.

Benzidine has been shown to cause cancer in occupationally exposed workers and experimental animals. Based on investigations involving animals, 3,3'-dichlorobenzidine is a "probable" human carcinogen. Both substances, based on the findings of the PSL Assessment are considered by Health Canada to be non-threshold toxicants, i.e., substances for which there is believed to be some chance of adverse health effects at any level of exposure.

Statement of Work. The Issue Table members will establish goals and targets for managing the levels of exposure of the general population (i.e., non-occupational) and the environment to benzidine and 3,3'-dichlorobenzidine. The Issue Table will also identify the most cost effective and efficient options for achieving those targets, should any be necessary. This will be accomplished by:

1- gathering the necessary scientific, technical, socioeconomic information; and

2- identifying and evaluating the available control options.

The information gathering phase should be completed no later than 9 months after the issue table has been set up and should be achieved by developing:

1- socioeconomic studies to provide a social and economic profile of benzidine and 3,3'-dichlorobenzidine; and

2- technical background studies identifying and assessing the available and feasible input, process, or abatement technologies to mitigate the environmental and health problems potentially associated with benzidine and 3,3'-dichlorobenzidine.

The options identification and evaluation phase should be completed no later than 18 months after the issue table has been set up and should be achieved by:

1- determining the goals and targets;

2- identifying and assessing all the available control options for meeting the targets;

3- selecting the most feasible options;

4- doing an impact analysis (e.g., costs/benefits) of the selected options; and

5- recommending an option which may range from no action to strong action.

The Issue Table will have to identify what information is already available and what needs to be found. It will also have to decide on the need for outside consultant studies and the level of effort needed to acquire, gather, and analyze the information.

Meetings. A first meeting will be held shortly after the Issue Table membership is established. Its purpose will be to present and agree on a proposed set of ground rules. Items for discussion will cover, among others, the following points:

- the strategic options process;
- discussion on the mandate of the table (objectives, terms of reference, milestones, and work plan);
- developing a consensus approach and fall-back positions; and
- review and define roles and responsibilities.

Approximately one month later, a second meeting should be held to discuss the following:

- confirm or modify our understandings of the process, its objectives, the roles and responsibilities of members;
- confirm or modify the work plan, and schedule;
- table and review data and information available from members;
- establish information gaps; and
- discuss the need for and scope of consultant studies.

Other meetings could be held on an "as needed" basis, depending on how easily the information is accessible and the consensus is reached. Telephone conferences may be considered as alternatives to formal meetings.

Appendix 3

ACTS Bulletin, Ban of Certain Azo Dyestuffs in German Market

ACTS Bulletin, Update on Ban of Certain Azo Dyestuffs in German Market

Appendix 4

Management Options and Their Respective Definitions

The range of tools to achieve environmental objectives has rapidly expanded in recent years. This is a result of the increasing scope and complexity of the environmental issues of interest and of the limitations of the traditional command-and-control tools. An outline of the environmental management options to be assessed (alone or in combination) follows.

Command-and-control Tools

Command-and-control tools are regulations that impose legal restrictions on firms' activities. These tools are generally uniformly applied across pollutant sources and have numerous applications including the following:

1. Quantity Controls - regulations may set limits on the quantity of an input that can be used, goods/services that can be produced, imported, or consumed, and are usually implemented through a quota system.

2. Performance Standards - performance standards prescribe the results or objective to be achieved but do not specify the exact means of compliance. Limitations can be applied on the concentration of pollutants in inputs, products, or wastes.

3. Technology Controls - detailed equipment and/or design requirements can be used to provide highly specific information about what must be done to ensure compliance.

4. Supplier Controls - controls can be applied through licensing and certification, the use of permits or by direct regulation of management practices.

5. Information Controls - controls can require the disclosure of information on attributes of a product, process or situation. This can be accomplished through labelling requirements, advertising controls, and disclosure statements. Some forms of information control incorporate restrictions on inputs, products, and processes.

Market-based Tools

1.	Trading Programs -	under trading programs, government set a total limit on pollutant releases/quantities of a product or input that can be manufactured, imported or consumed; distribute volume or total quantities among the pollutant sources using a permit system, and allow these allocations to be traded among the sources. A wide range of trading variations are possible including point/non-point source trading and cross-pollutant trading.
2.	Environmental Charges/Taxes -	refer to fees levied on processes or products that are sources of environmental problems. These fees can be designed to provide an incentive to modify environmental behaviour, and/or raise revenue to finance environmental protection programs or other government activities.
3.	Financial Incentives -	alleviate the costs for persons/industry who meet or strive to achieve pollution control/reduction goals that are environmentally desirable. Financial incentives include: tax write-offs, investment tax credits, and flow-through arrangements; government loans, loan guarantees, and subsidized interest rates; and grants, subsidies, and cost-sharing programs.
4.	Environmental Liability -	assignment of liability involves the passing of legislation and regulations that hold individuals, firms, or institutions responsible for the costs of environmental degradation. Liability can be used as a policy tool to serve either as a deterent or for revenue generation. (In other cases, liability is the foundation for enforcing a regulation or other tools and is more appropriately discussed as an *intervention*.)
5.	Deposit-Refund Systems -	involve the placing of a surcharge or deposit at the point of final sale on products (or packaging) that may be detrimental to the environment. The surcharge is refunded when the item is returned to the point of sale or to a collection depot. Deposit-refund systems may be used for collection of products for re-use or recycling, and/or for collection of products to prevent environmentally unsafe disposal.

Voluntary Tools

1. Structured Voluntary Action - voluntary action can be structured through codes, guidelines, standards, and agreements. Although the compliance requirements are not legally mandatory, specific rules are developed.

2. Unstructured Voluntary Action - associations of producers/users can develop their own informal voluntary reduction plans. Governments can assist through training or advisory services, rather than through legally binding rules which specify compliance.

Information Provision Tools

1. Environmental Labelling - is a tool to inform consumers about the environmental aspects of a product such as recyclability and biodegradability. Labelling programs may be used to issue guidelines or standardize definitions for descriptors, logos, or other representations that describe or imply environmental features of consumer products.

2. Technology Development and Transfer - programs facilitate greater awareness, innovation and adoption of advanced environmental technologies. Such programs involve the diffusion of technical knowledge and/or provide funds for research and development into environmentally sound technologies.

3. Environmental Quality Standards and Objectives - define the broad goals we as a society would like to achieve. These standards and objectives can provide a framework against which the actions of all levels of government, industry, and the public may be assessed.

4. Environmental Citizenship Programs - provide Canadians with knowledge, skills and values that will lead to enhanced awareness, understanding and commitment to environmental protection goals.

Appendix 5

Evaluation Criteria and Their Respective Definitions

The following are Evaluation Criteria that were used by the Issue Table for the assessment of each management option:

1) **environmental effectiveness-**to what extent can the environmental objective be achieved/ensured with the use of this management tool?

2) **cost-effectiveness/competitiveness-**will this tool minimize the financial burden to industry and to government involved in dealing with the environmental objective? What impact on the international competitiveness of Canadian industry will result from the implementation of this tool to achieve the environmental objective?

3) **incentives-**does the tool directly or indirectly stimulate creativity and innovation through some form of incentive acquired by decision-makers to develop and implement cleaner technologies and ways of operation?

4) **enforceability/compliance-**how easily will we be able to enforce and monitor compliance with this tool?

5) **growth-**can the tool be structured in such a way as to allow for economic growth (entry of new producers into an industry, for example) while still meeting environmental requirements and/or Canadian commitments?

6) **speed-**how quickly will the environmental objective be reached with this tool?

7) **fairness-**does this tool impose an unfair burden on certain individuals/sectors in the market?

8) **intrusiveness/flexibility-**what level of government knowledge and involvement will be required to effectively apply this tool? To what extent does this tool leave to producers and consumers the specific detailed decisions about how to achieve environmental objectives?

9) **data requirements-**what will be the data requirements for the use of this tool (including monitoring data) in terms of quality, intensiveness, and availability?

10) **compatibility-**will the implementation of this tool support or be in conflict with established jurisdictional responsibilities, existing regulations, and/or self-regulation initiatives? Is the enabling legislation for this tool currently available?

11) **public acceptability-**will the use of this tool for environmental management be readily accepted by the public?

Appendix 6

Chart of DCB-based Pigments Process

Schematic of Equipment used to React DCB