FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12707 - Routes of Exposure

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health & Saf. Code Sec. 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health & Saf. Code Sec. 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which it is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health & Saf. Code Sec. 25249.10 and 25249.11).

A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Agency) (Section 12701 to 12721, Title 22, California Code of Regulations) (unless otherwise specified, all section references are to Title 22, CCR). These regulations provide that one method of making a determination that a given level of exposure poses no significant risk is by application of Section 12707.

Procedural Background

On June 1, 1990, the Agency issued a notice of proposed rulemaking advising that the Agency intended to amend Section 12707 to add "nickel and nickel compounds" to subsection (b), which lists the chemicals which the Agency has determined as posing no significant risk by route of ingestion. Pursuant to such notice, on July 20, 1990, a public hearing was held to receive public comments on the proposed regulation. Five pieces of correspondence commenting on the proposal were received. No comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12707, and responds to the objections and recommendations submitted regarding the regulation. Government Code section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended or adopted

regulation contain a summary of each objection or recommendation made regarding the adoption or amendment, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. It specifically provides that this requirement applies only to objections or recommendations specifically directed at the Agency's proposed action or to the procedures followed by the Agency in proposing or adopting the action.

Some parties included in their written or oral comments remarks and observations about the regulation which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response in this final statement of reasons to such remarks should not be construed to mean that the Agency agrees with them.

Specific Findings

Throughout the adoption process of this regulation, the Agency has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed regulations. The Agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected persons than, the adopted regulation.

The Agency has determined that the regulation imposes no mandate on local agencies or school districts.

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for Section 12707.

Necessity for Adoption of Regulations

For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposures which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical

exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

As a result of the court decision in AFL-CIO, et al. v. Deukmejian (1989), 212 California App. 3d 425, the Agency added "nickel and certain nickel compounds" to the list of chemicals known to the State to cause cancer on October 1, 1989. Unless they are able to demonstrate no significant risk, persons responsible for exposures to nickel and nickel compounds must provide warnings beginning October 1, 1990, and persons responsible for discharging or releasing nickel and nickel compounds into sources of drinking water must discontinue such release or discharge beginning June 1, 1991.

Nickel carbonyl, nickel subsulfide and nickel refinery dust, which were listed on October 1, 1987 following a recommendation by the Scientific Advisory Panel, are already subject to both provisions of the Act.

This regulation will allow persons responsible for an exposure, discharge or release involving nickel and nickel compounds to determine whether such exposure, discharge or release is exempt from the Act.

Section 12707

Section 12707 provides that where scientifically valid absorption studies conducted according to generally accepted standards demonstrate that absorption of a chemical through a specific route of exposure can be reasonably anticipated to present no significant risk of cancer at levels of exposure not in excess of current regulatory levels, the lead agency may identify the chemical as presenting no significant risk by that route of exposure. For purposes of the Act, an exposure, discharge or release of such a chemical is deemed to pose no significant risk if it results in exposure to humans by the identified route, and does not exceed the level established in any other applicable federal or state standard, regulation, guideline, action level, license, permit, condition, requirement or order.

The Agency has previously identified the following chemicals as posing no significant risk of cancer by route of ingestion, in subsection (b) of section 12707: asbestos, beryllium and beryllium compounds, cadmium and cadmium compounds, and chromium (hexavalent compounds). This amendment to Section 12707 adds "nickel and nickel compounds" to this list of chemicals.

The final statement of reasons for the regulatory action adopting Section 12707 enumerated the reasons for listing asbestos, beryllium and beryllium compounds, cadmium and cadmium compounds, and hexavalent chromium compounds, under subsection (b): "First, the Agency believes the available data to suggest that the cancer risk from ingestion of these listed substances is minimal, principally due to the poor absorption of these substances across the intestinal mucosa and into the blood stream of those who may ingest them. Second, the Agency believes

that, because many of these substances occur in nature, there is difficulty in identifying them, and there is difficulty in taking action to remove them, particularly when their presence may be widespread. Third, the Agency believes that current regulation of these substances, where it exists, together with the evidence of poor absorption, should adequately protect the public from any significant risk of cancer from such chemicals by the route of ingestion."

The Agency has concluded that these reasons also apply to nickel and nickel compounds.

Nickel exists throughout the environment (International Commission on Radiological Protection, Report of the Task Group on Reference Man, 1975, page 397). The U.S. Environmental Protection Agency (EPA) (U.S. EPA, Health Assessment Document for Nickel and Nickel Compounds, September 1986, pages 2-1 to 2-4) reports that nickel is present in the atmosphere as a constituent of suspended particulate matter; it is found in ambient waters as a result of chemical and physical degradation of rocks and soils, deposition of atmospheric nickel-containing particulate matter, and discharges from industrial processes; it is naturally occurring in soils, and is accumulated in vegetation via root uptake.

Although dietary intake of nickel by humans is relatively high, ranging from 300 to 500 micrograms per day, gastrointestinal absorption is low (EPA, September 1986, page 4-21). Data from various studies conducted from 1957 to 1973 indicate that 1 to 10 percent of dietary nickel is absorbed, and in a more recent (1981) study, a minimal gastrointestinal absorption rate of roughly 3 percent was measured (page 4-10).

The identification of nickel and nickel compounds has been based on evidence derived from studies involving routes of exposure other than ingestion. Evidence in humans is based on epidemiological studies involving populations which were occupationally exposed to nickel substances via inhalation. Animal data are derived from studies in which nickel and nickel compounds were administered via injection or inhalation.

The EPA has reviewed the literature on the carcinogenicity of nickel and nickel compounds by the route of ingestion, and concluded that the evidence of carcinogenicity through this route of exposure was inadequate (EPA, September 1986, pages 8-104 to 8-105). Three studies in which nickel salts were administered to mice and rats in drinking water produced negative results. Similarly, the results of chronic studies in which nickel was administered in the diet of rats and dogs indicated a lack of carcinogenic response.

Nickel and nickel compounds are regulated by the EPA as toxic pollutants under the Clean Water Act, and as hazardous wastes under the Resource Conservation and Recovery Act. Discharges or releases of nickel and nickel compounds are therefore subject to standards promulgated pursuant to these laws. Occupational exposures to nickel and nickel compounds are

subject to standards established by the Occupational Safety and Health Administration.

For the reasons described above, the Agency believes that exposure to nickel and nickel compounds via ingestion poses no significant risk of cancer, provided that the exposure to, or discharge or release of nickel occurs at a level which does not exceed applicable standards.

Four of the comments received supported the Agency's proposed action (C-1, C-5, C-6, and C-7); therefore, no Agency response is required.

One commentor (C-9) objected to the amendment. The commentor stated that although data from the EPA document cited by the Agency (indicating that nickel and nickel compounds are poorly absorbed through the gastrointestinal tract) may provide justification for a no significant risk level by route of ingestion which differs from the level by inhalation, they do not provide compelling evidence of lack of carcinogenesis by ingestion.

The commentor should note that the risk assessment guidelines contained in Section 12703 provide that when the quality of the available data allow physiologic, pharmacokinetic and metabolic considerations to be taken into account with confidence, such data may be used in making inter-species, inter-dose and inter-route extrapolations (subsection (a)(7)). This principle was utilized by the Agency in its decision to include nickel and nickel compounds to the list of chemicals in Section 12707(b).

Current data indicating that gastrointestinal absorption of nickel is low, along with the fact that nickel has not been shown to be a carcinogen in oral studies, provide sufficient justification for the listing of nickel and nickel compounds in Section 12707(b). Furthermore, other authorities concur with this conclusion, and examples of scientific opinions that are consistent with the Agency's are included here. (The references cited were not relied upon by the Agency in formulating the regulation.) Contrary to the commentor's concern about the lack of compelling evidence of carcinogenesis by ingestion, these examples indicate that other agencies that have evaluated the data on nickel have arrived at the same conclusion.

The California Department of Health Services, in its risk assessment document prepared for the Air Resources Board, concludes: "...inhalation is the only route of human exposure which needs to be considered when calculating cancer risks. There are no animal or human studies which produce evidence that nickel is carcinogenic when ingested. However, only nickel acetate and nickel sulfate have been tested, in a limited manner, in animals for carcinogenicity following oral ingestion. Although untested, insoluble nickel compounds such as nickel oxide and nickel subsulfide would not be expected to be absorbed from the alimentary tract. Absorption of nickel as soluble compounds is unlikely to result in increased cancer risks...the concentration of soluble nickel

salts would not build up in any organ in the manner in which insoluble nickel compounds do in the lung. Finally, the evidence suggests that some nickel in the diet may be essential...." (California Department of Health Services, Health Risk Assessment for Nickel (Draft), February 1990, page 117-118).

Similarly, the National Institute for Occupational Safety and Health has determined that there is no evidence to suggest that inorganic nickel is carcinogenic when ingested (National Institute for Occupational Safety and Health, Criteria for a Recommended Standard: Occupational Exposure to Inorganic Nickel, May 1977, page 213).