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Regulatory Appendix

United States

California Proposition 65 (Prop 65). Created to protect the drinking water of the State of California, Prop 65 requires businesses to advise customers if their products contain chemicals determined by the State of California to cause cancer, birth defects, or other reproductive harm. Any product containing a Prop 65 chemical above 'Safe Harbor' limits must be labeled.

Learn more: <https://oehha.ca.gov/proposition-65>

The Food and Drug Administration (FDA). Title 21 Code of Federal Regulations (CFRs) 175-179 are mainly focused on the substances used to create food contact materials. These regulations are geared towards chemicals used in adhesives, polymers used in plastics, paper, and additives; however, the FDA does not currently have a specific regulation or guidance for printing inks.

Learn more: <https://www.fda.gov/food/food-ingredients-packaging/packaging-food-contact-substances-fcs>

The Model Toxics in Packaging Legislation. The Model (formerly known as CONEG legislation), prohibits the use of lead, mercury, cadmium, and hexavalent chromium in any packaging or packaging component.

Learn more: <https://toxicsinpackaging.org/model-legislation/>

ASTM Standard Consumer Safety Specification on Toy Safety. Considered the toy safety "gold standard", ASTM among other things restricts the use of certain chemicals used in the surface coating of toys. Of specific importance to ink formulators is the restriction on unbound copper.

Learn more: <https://www.astm.org/toys.html>

European Union

Regulation (EC) No. 1935/2004 as amended, known as The Framework Regulation. The principles set out in The Framework Regulation require that materials do not release their constituents into food at levels harmful to human health and do not change food composition, taste, and odor in an unacceptable way. While there is currently no specific guidance or requirement for printing inks in this regulation, it should still be confirmed that the entire packaging including the ink is indeed safe for its intended end use.

Learn more: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R1935-20210327&from=EN>

Regulation (EC) No. 2023/2006, known as the GMP Regulation. The Good Manufacturing Practice (GMP) Regulation requires quality management systems, to ensure the consistency and conformity of food contact materials. It applies to manufacturing as well as to the handling and storage of printed materials.

Learn more: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R2023-20080417&from=EN>

European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH). REACH is the EU regulation that applies to all chemicals in the EU. REACH requires that consumers be made aware of any classified chemical present in a product, chemicals over certain volumes be registered, and the use of certain chemicals be restricted.

Learn more: <https://echa.europa.eu/regulations/reach/understanding-reach>

Substances of Very High Concern (SVHC) Candidate List, known as the SVHC List. Part of REACH Authorisation, the SVHC list is a list of chemicals that are under consideration for restricted use only. EU and EEA producers or importers of anything that contains a SVHC substance must report it to the EU authorities. There is currently no specific mention of ink requirements in this regulation.

Learn more: <https://echa.europa.eu/candidate-list-table>

RoHS 3 Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU (RoHS 2) and EU 2015/863, commonly referred to as RoHS 3. This is an electrical and electronic equipment regulation. Annex II restricts the use of: lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP). There is currently no specific mention of ink requirements in this regulation.

Learn more: https://ec.europa.eu/environment/topics/waste-and-recycling/rohs-directive_en

European Standard EN71-3, known as Safety of Toys. Often considered the EU version of ASTM, EN71-3 outlines restrictions on aluminum, antimony, arsenic, barium, boron, cadmium, Chromium (III), Chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin, and zinc in toys. EN71-3 does not consider packaging materials to be part of the toy unless they have intended play value.

Learn more: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1728&from=EN>

Directive (EU) 2018/852 of the European Parliament and of the Council of 30 May 2018, amending Directive 94/62/EC on Packaging and Packaging Waste. Meant to ensure sustainable packaging in the future for EU customers, this directive harmonizes several standards, creates timelines, and specifies actions like requiring all EU packaging be reusable or recyclable by 2030. There is currently no specific mention of ink requirements in this regulation.

Learn more: <https://eur-lex.europa.eu/legal-content/en/LSU/?uri=CELEX%3A32018L0852>

Restriction on Epoxy Derivatives Regulation EC No 1895/2005. This regulation is specific to the use of certain epoxies in articles meant to come into contact with food. It sets specific migration limits for 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether ('BADGE' i.e. Bisphenol-A DiGlycidyl Ether), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers ('BFDGE' i.e. Bisphenol-F DiGlycidyl Ether) and novolac glycidyl ethers (NOGE) and some of their derivatives.

Learn more: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32005R1895>

LOI n° 2020-105 du 10 février 2020 relative à la lutte contre le gaspillage et à l'économie circulaire. This regulation is part of France's promotion of a circular economy, and fight against waste. Article 112 outlines when prohibitions against the use of mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in packaging and printed materials come into force.

Learn more: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000041553759/#:~:text=%2DAfin%20d'am%C3%A9liorer%20l'environnementales%2C%20notamment%20l'incorporation%20de>

EuPIA Exclusion Policy for Printing Inks and Related Products, 4th Edition March 2021. This industry standard was created in part in response to the patchwork of government regulations, and is meant to establish industry wide guidelines and standards for printing ink formulations.

Learn more: <https://www.eupia.org/our-commitment/eupia-exclusion-policy-for-printing-inks-and-rel>

Substances or Products Causing Allergies or Intolerances - Regulation (EU) No 1169/2011. A food labeling regulation, EU 1169/2011 requires, among other things, the presence of any listed allergens in food to be disclosed on the food packaging. There is currently no specific mention of ink requirements in this regulation.

Learn more: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R1169-20180101>

Switzerland

Ordinance on Materials and Articles (SR 817.023.21), known as the Swiss Ordinance. This regulation lists chemicals (along with applicable migration limits), that the Swiss government has approved for use in materials that come into contact with food. In the absence of other robust government regulations, the Swiss Ordinance is used as a guide by the food packaging industry, whether or not such packaging will be sold in Switzerland.

Learn more: <https://www.blv.admin.ch/blv/en/home/gebrauchsgegenstaende/materialien-in-kontakt-mit-lebensmitteln.html>

Nestle Guidance

Nestle Guidance Note on Packaging Inks October 2018, commonly referred to as Nestle Guidance. Part of Nestle's supplier management program, this guidance specifies what is allowed in inks, primers and overprint lacquers/coatings/varnishes used on Nestle packaging. Like the Swiss Ordinance, it is used as a guide by the food packaging industry, whether or not such packaging will be sold to Nestle.

Learn more: <https://www.nestle.com.pe/sites/g/files/pydnoa276/files/nosotros/informacion-proveedores-nestle/documents/actualizacion%202019/guidance%20note%20on%20packaging%20inks%20-%20version%202018.pdf>

Asia Pacific

Administrative Measures for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products - known as China RoHS 2. Like EU RoHS regulations, China RoHS 2 is an electrical and electronics regulation. China RoHS 2 restricts the same six substances as EU RoHS 2: Cadmium (Cd) and its compounds, mercury (Hg) and its compounds, lead (Pb) and its compounds, hexavalent chromium (Cr VI) and its compounds, Polybrominated biphenyls (PBB), and Polybrominated diphenyl ethers (PBDE). There is currently no specific mention of ink requirements in this regulation.

Learn more: <https://www.chinesestandard.net/PDF.aspx/GBT26572-2011>

Japan Printing Ink Makers Association (JPIMA) May 2020 Negative List. This industry standard lists chemicals JPIMA deemed unsafe, and should not be used in printing inks intended for food packaging.

Learn more: https://www.ink-jpima.org/assets/pdf/nflist_en2020.pdf

Substances of Concern

In addition to the regulations and standards described, these substances are commonly called out because of particular concern to recycling operations, municipalities, state and local regulators.

Mineral oil saturated hydrocarbons (MOSH) / Mineral oil aromatic hydrocarbons (MOAH). Mineral oil hydrocarbons can have mutagenic and carcinogenic properties.

Learn more: <https://www.foodpackagingforum.org/food-packaging-health/mineral-oil-hydrocarbons>

Bisphenol-A. The safety of BPA has been a controversial topic in the food packaging industry.

Learn more: <https://www.packagingdigest.com/food-safety/bpa-packaging-defying-pressure>

Per- and polyfluoroalkyl substances (PFAS). Some types of PFAS can accumulate and persist in the human body and environment for long periods of time. It has been suggested that PFAS exposure can lead to adverse health effects.

Learn more: <https://www.epa.gov/pfas/basic-information-pfas>

Benzene, phthalate-esters, toluene, or xylene. These substances have suggested evidence of carcinogenicity. Phthalate-esters are considered a persistent pollutant to the environment.

Learn more: <https://pubmed.ncbi.nlm.nih.gov/3053447/>
<https://www.sciencedirect.com/science/article/abs/pii/S0048969715308093>

Heavy metals such as arsenic, cadmium, chromium, lead, and mercury. These substances may build up in biological systems and can be toxic with potential to cause significant health hazards.

Learn more: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4144270/>

SVHCs. A Substance of Very High Concern (SVHC) is a chemical substance (or part of a group of chemical substances) determined by the European Chemicals Agency (ECHA) that is subject to Authorisation under REACH. Substances on the SVHC list are: carcinogenic, mutagenic or reprotoxic (CMR) category 1 or 2; persistent, bio-accumulative and toxic, substances; or substances for which there is evidence for similar concern.

Learn more: <https://echa.europa.eu/candidate-list-table>

Styrene. Migration of styrene monomers from food packaging can have a negative impact on human health.

Learn more: <https://www.sciencedirect.com/science/article/abs/pii/S0924224419300354>

This document was published as of October 2021 and may be updated from time to time as new information becomes available.