

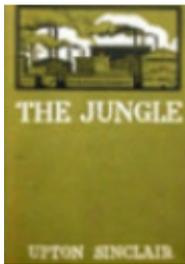
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Betreff: CONUSBAT Regulatory News - Historical Milestone towards Consumer Health Protection - PREVIEW

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Regulatory Affairs 101: Historical Milestones towards Consumer Health Protection

In order to understand today's myriad regulations affecting consumer health products, it is important and helpful to review some historical milestones influencing legislative decisions in the past. Observing this history from an American point of view, this short essay wishes to take the reader through the path of the early 20th-century. This period represents a major implementation phase of regulations towards consumer health protection, which eventually led to the establishment of the US-Food & Drug Administration (US-FDA). Other countries have taken their own approaches, and today, a set of regulations exist for most nations or for economic units (EU, ASEAN, Mercosur, etc.).



Upton Sinclair, one of America's foremost authors who was considered a 'Muckraker', exposed in his book "The Jungle" the poor working conditions of low paid immigrants of eastern European background employed in Chicago's extensive meat packing industry. Mr. Sinclair painted a bleak picture that the meat being processed was unfit for human consumption and although fictitious, the book acted as a 'lightening rod' towards the need for food regulations as well as laws protecting employees' rights.

In the same year of the book's publication (1906), President Theodore Roosevelt signed into law the Food and Drug Act. Known as the "Wiley Act", it was named after its chief advocate, and curiously lobbying for this law was H. J. Heinz, owner of the famous ketchup & '57 Varieties' food processor, which is located in Pittsburgh, Pennsylvania.



In 1933, the tragic medical case of 'Mrs. Brown' going blind along with other women suffering cornea damage due to application of the mascara product, 'Lash Lure' gained huge impetus for the the need for cosmetic and consumer health product protection as well as regulations. The eye lash product contained paraphenylenediamine, an aniline derivative used for dyeing textiles.

By 1938, with the 'Elixir Sulfanilamide' drug scandal, resulting from an untested product which caused >100 people to die, many of whom were children, President Franklin D. Roosevelt signed into law the Food, Drug and Cosmetic Act (FD&C Act). The FD&C law increased federal regulations over pharmaceutical products by mandating a pre-market review of the safety of all new drugs, as well as banning false therapeutic claims in drug labeling without requiring that the US-FDA prove fraudulent intent. The law also authorized factory inspections, expanded enforcement powers, set new regulatory standards for foods, and brought cosmetics and therapeutic devices under the newly created FDA.

For cosmetic color additives, as used in eye lash products, the FD&C Act, which is a pillar of the FDA, requires the colors to be certified as harmless for use in cosmetics. The 1960 color amendments strengthened the safety requirement, necessitating additional testing for many existing color additives. Source: <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>

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- **Regulation (EC) No 1272/2008 on Classification, Labelling & Packaging (CLP):** Classification of substances and mixtures
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ingredients, chemicals

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