

# Regulation Development for MCLs

-A brief overview-

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# Maximum Contaminant Level (MCL) development phases

*Once a need for an MCL for a contaminant has been established, the regulatory process for the promulgation of an MCL begins. The process can be broken down into three broad phases:*

- Phase I...Pre-Public Health Goal activities
- Phase II...Regulatory package development
- Phase III...Formal regulation adoption process

# ***Phase I: Pre-PHG activities***

*Although the MCL process is largely dependent on the establishment of a PHG, there are a number of activities that take place prior to receipt of a final PHG*

- Collection of water quality data to define the extent to which the contaminant of concern occurs within California
  - Data has been gathered from over 7,000 sources in California and may be viewed on our website at:

<http://www.cdph.ca.gov/certlic/drinkingwater/Pages/Chromium6sampling.aspx>

## ***Phase I: Pre-PHG activities, cont.***

- Through the State's laboratory, the Department follows advances in analytical techniques available for reliably detecting a contaminant
- Gather information on the most current technologies for the treatment of a contaminant, as well as the costs associated with the treatment technologies
  - Participation on treatment feasibility panels with DWR, U.S. EPA, AWWARF, Glendale, etc.

## ***Phase I: Pre-PHG activities, cont.***

- The Health and Safety Code (Section 116365) mandates that primary drinking water standards be *“set at a level that is as close as feasible to the corresponding public health goal...to the extent technologically and economically feasible...”*

*The Phase I activities provide information that is integral in determining the economic and technical feasibility aspects required by law.*

## ***Phase II: Regulatory package development***

*The PHG is the catalyst for the development of a regulatory package that meets the statutory requirements for setting MCLs. Following receipt of the PHG, the Department evaluates a number of hypothetical MCLs, typically using the final PHG as the starting point.*

## ***Phase II: Regulatory package development, cont.***

*Some of the elements used in the evaluation process include:*

- Treatment costs
- Monitoring costs
- Technical feasibilities
- Population exposures
- Potential health benefits

*After an MCL is proposed based on the evaluation, a formal regulatory package is developed for submission to the Office of Regulations*

## ***Phase II: Regulatory package development, cont.***

*Regulation packages to be submitted to the Office of Regulations consist of the following components:*

- Transmittal memos
- Informative Digest
- Statement of Reasons (including documents relied upon or referenced)
- Statement of Determinations
- Regulation Text
- Fiscal Impact Statement

*The Regulation Text and Statement of Reasons are typically the documents of most interest.*

## ***Phase III: The Formal Regulatory Process***

*The formal regulatory process is an intricate process designed to ensure the interests of the public and the State are addressed, as well as regulatory process requirements set forth in law (i.e. the Administrative Procedure Act).*

## ***Phase III: The Formal Regulatory Process, cont.***

*In brief, this process includes:*

- **Legal reviews by the Office of Regulations**
- **Fiscal impact related reviews by State agencies**
- **Publication in the California Regulatory Notice Register; beginning the 45-day public comment period**
- **Review and evaluation of comments. Subsequent comment periods are required if substantive revisions are made as a result of comments received.**

## ***Phase III: The Formal Regulatory Process, cont.***

- Preparation of responses to each comment received.
- Review by the Office of Administrative Law (OAL) to ensure the requirements of the Administrative Procedure Act are met. OAL has 30 working days to complete their review.
- If approved by OAL, the regulation is filed with the Secretary of State and becomes operative (i.e. enforceable) 30 days later.

## *A few closing notes...*

- The Department is required by law to, among other things, adopt regulations no less stringent than the Federal regulations. Currently, this is not applicable to hexavalent chromium.

## *A few closing notes...*

- The time from the establishment of a PHG to the adoption of an MCL is *extremely* difficult to predict due to the inherent variables in the regulatory process
  - Historically, after a PHG is set (i.e. Phase II + Phase III), the process of MCL adoption has taken about two years
  - SB 1029, signed by the Governor in October 2007, places limits on the time the Department of Finance has to review regulatory packages

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