§ 2201. Performance standards

(a) In general
The Secretary shall, in coordination with the Secretary of Agriculture, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants.

(b) Guidance documents and regulations
Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 342 of this title or to prevent the spread by food of communicable disease under section 264 of title 42, the Secretary shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. Such guidance, including guidance regarding action levels, or regulations—

(1) shall apply to products or product classes;
(2) shall, where appropriate, differentiate between food for human consumption and food intended for consumption by animals other than humans; and
(3) shall not be written to be facility-specific.

(c) No duplication of efforts
The Secretary shall coordinate with the Secretary of Agriculture to avoid issuing duplicative guidance on the same contaminants.

(d) Review
The Secretary shall periodically review and revise, as appropriate, the guidance documents, including guidance documents regarding action levels, or regulations promulgated under this section.


References in Text
The Secretary, referred to in text, probably means the Secretary of Health and Human Services.

Short Title
Pub. L. 111–353, § 1(a), Jan. 4, 2011, 124 Stat. 3885, provided that: “This Act [enacting this chapter and sections 350g to 350l–1, 379j–31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture, and section 280g–16 of Title 42, The Public Health and Welfare, amending sections 331, 333, 334, 350b to 350d, 350f, 374, 381, 393, and 399 of this title and section 247b–20 of Title 42, and enacting provisions set out as notes under sections 331, 334, 342, 350b, 350d, 350e, 350g to 350j, 350l, and 381 of this title] may be cited as the ‘FDA Food Safety Modernization Act’.”