Dear Interested Stakeholder:

As you may know, the U.S. Food Safety Modernization Act (FSMA), signed into law in 2011, enables the U.S. Food & Drug Administration (FDA) to focus its food safety efforts on preventing problems rather than relying primarily on reacting to problems after they occur. Since January 2013, the FDA has proposed seven risk-based, foundational rules to implement FSMA.

The FDA conducted extensive outreach to industry, academia, consumer groups, tribal governments, trading partners, international stakeholders, and the agency's counterparts at the federal, state and local levels and received thousands of comments in response to the proposed rules published in the Federal Register. In October 2014, FDA re-proposed four of the seven rules based on feedback from the public comments. The agency has crafted the rules in a way that is flexible and practical, and seeks voluntary compliance before enforcement.

Once all seven foundational FSMA rules are finalized in 2016, they will work together in a risk-based way to systematically prevent food contamination throughout the food production process, strengthening the food safety system, and better protecting the public. The earliest compliance dates for certain firms begin in late 2016.

These final rules rely on strong partnerships with industry and foreign governments to ensure the safety of their human and animal food products. They are the result of extensive outreach by the FDA with domestic and international stakeholders. These final rules, including the amendments FDA made to the original proposed rules, illustrate the importance of stakeholder input, including the public comment process. The FDA will continue to make every effort to engage with all stakeholders -- including international stakeholders - throughout implementation of the final regulations.

CONTENT OF THE FINAL RULES

-The Preventive Controls for Human Food final rule will update current good manufacturing practices to require companies to evaluate potential hazards and institute preventive controls to mitigate those hazards.

-The Preventive Controls for Animal Food rule requires preventive controls and establishes, for the first time, current good manufacturing practices for animal food.

-The rules are risk-based. Facilities that produce either human food or animal food are not required to implement new controls for foods that do not pose a hazard to health. Additionally, facilities have flexibility with respect to the types of measures that they can take to control for any particular hazard. They will be able to continue to use the same techniques that they are using today as long as they deem them to be adequate.

-The final rules apply to both domestic and foreign facilities for the portion of the U.S. food supply under FDA jurisdiction. The rules do not apply to meat, poultry, and egg products, which remain under the jurisdiction of the U.S. Department of Agriculture (USDA).

- The FDA encourages foreign industry, government, and other international stakeholders to contact FDA for additional information. http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

FOR MORE INFORMATION:

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM414867.htm

FSMA FAQ:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm

FSMA page:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

Preventive controls for human food:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

Preventive controls for animal food:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm

Foreign supplier verification program:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm

Produce safety:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

Poštovani,

- Zakon o modernizaciji sigurnosti hrane (Food Safety Modernization Act - FSMA), iz 2011. godine omogućava da Agencija za hranu i lijekove (Food Drag Administration – FDA) FDA usmjeri svoje napore iz područja sigurnosti hrane na sprečavanje problema, a ne oslanjajući se prvenstveno na reagiranje na probleme nakon što se oni pojave. Od januara 2013. godine, FDA je predložila sedam osnovnih pravilnika koji su utemeljeni na riziku, za provedbu FSMA.

- FDA je provela opsežno upoznavanje sa novim pravilima industrije, akademskih zajednica, skupine potrošača, plemenskih vlada, trgovinskih partnera, međunarodnim partnerima i kolega iz drugih agencija na saveznoj, državnoj i lokalnoj razini i dobila na hiljade komentara na predložene pravilnike objavljene u Saveznom registru (Službeni glasnik SAD-a). U oktobru 2014, FDA je ponovno predložila četiri od sedam pravilnika na temelju povratne informacije iz javnih komentara. Agencija je izradila pravilnike na način koji je fleksibilan i praktičan, i traži, dobrovoljnu primjenu prije nego ona postane obavezna.

-Nakon što se svih sedam temeljnih FSMA pravilnika dovrši u 2016. godini, oni će djelovati zajedno na temelju rizika kako bi se sistematski spriječila kontaminacija hrane tijekom procesa proizvodnje hrane, ojačao sistem sigurnosti hrane, i bolje zaštitilo javno zdravlje. Najraniji datumi primjene za pojedine kompanije počinje krajem 2016. godine.

Sadržaj finalnih pravilnika

- Finalni Pravilnik o preventivnim kontrolama hrane za ljude će ažurirati trenutne dobre proizvodne prakse kako bi se procijenili potencijalni rizici i uvele preventivne kontrole za ublažavanje tih rizika.

- Finalni Pravilnik o preventivnim kontrolama hrane za životinje/stočne hrane zahtijeva preventivne kontrole i uspostavlja, po prvi put, trenutne dobre proizvodne prakse za stočnu hranu.

- Pravilnici su zasnovani na riziku. Objekti koje proizvode hranu za ljude ili stočnu hranu nemaju obavezu da provedu nove kontrole za hranu koje ne predstavljaju opasnost za zdravlje. Osim toga, objekti imaju fleksibilnost kad se radi o vrsti mjera koje se mogu poduzeti za upravljanje određenim rizikom. Oni će biti u mogućnosti da nastave koristiti iste tehnike koje trenutno koriste sve dok ih smatraju adekvatnim.

- Konačna pravila vrijede i za domaće i strane objekte za dio hrane koja spada pod FDA nadležnosti.

- Pravila se ne odnose na meso, perad i proizvode od jaja, koje ostaju u nadležnosti Ministarstva poljoprivrede SAD (USDA).

- FDA poziva strane industrije, vlade i druge zainteresovane strane da kontaktiraju FDA za dodatne informacije.

http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

- Konačna pravila oslanjaju na čvrstu saradnju s industrijom i stranim vladama kako bi se osigurala sigurnost njihovih prehrambenih proizvoda i stočne hrane.

- Konačna pravila su rezultat opsežnog upoznavanja domaćih i međunarodnih zainteresovanih strana od strane FDA.

- Konačni pravila, uključujući izmjene i dopune izvornih pravila koje je FDA napravila, ilustriraju važnost uloge i doprinosa zainteresovanih strana, uključujući i proces javne rasprave. FDA će i dalje ulagati napore da uključi sve zainteresovane strane - uključujući i međunarodne učesnike - tijekom provedbe konačnih propisa.

ZA VIŠE INFORMACIJA:

Saopćenje: FDA će objaviti saopćenje za stampu ujutro po objavi konačnih pravila:

Saopćenja za štampu mogu se naći na:

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM414867.htm

FSMA često postavljana pitanja:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm

FSMA stranica:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

Preventivne kontrole za hranu za ljude:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

Preventivne kontrole za stočnu hranu:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm

Program verifikacije stranih dobavljača:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm

Sigurnost svjezeg voća i povrća:
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114