Exporter Overview: Regulations Keep on Coming

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Exporter Overview: Regulations Keep Coming
Tuesday, 3:00-4:30pm
So Many Issues, So Little Time….and Stamina!

- Issues vary by market
- Often triggered by unrelated events, market situations
- Technical or Political?
- Longer term view needed to find a “permanent” fix
- Relationships need to be established before they are needed
Food Safety Concerns Evolving

- Government priorities
- Regulatory environment
- Consumer perceptions
- Monitoring data
- Technology improvements
- Access to information

KEY ISSUES

- Aflatoxin
- Pathogens
- Heavy Metals
- Pesticides
- Additives, Flavorings
- Documents
- Goods Return
What we Plan to Cover

• Pesticide MRLs
  – Country Updates
  – Fosetyl or Phosphonic Acid?

• Asia Legislation
  – Grades Standards
  – India Labeling

• EU Pre-Export Certification

AND HOPEFULLY LOTS OF QUESTIONS AND DISCUSSION
Pesticide Issues
Pesticides – MRLs not that easy….

- State/Federal vs global
- Increasing MRL focus
- “Positive lists” more common overseas
- No harmonized approach to MRL establishment
- U.S. registers compounds faster than other countries
- Analytical methods keep improving….
- Gaining more attention in export markets – if it’s there, it’s “bad” …

US Almond MRLs/Tolerances
(# lower than US)

<table>
<thead>
<tr>
<th>Country</th>
<th>Compounds Registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>170</td>
</tr>
<tr>
<td>EU 28</td>
<td>108</td>
</tr>
<tr>
<td>Codex</td>
<td>59</td>
</tr>
<tr>
<td>Japan</td>
<td>96</td>
</tr>
<tr>
<td>Canada</td>
<td>45</td>
</tr>
<tr>
<td>India</td>
<td>59</td>
</tr>
<tr>
<td>China</td>
<td>?</td>
</tr>
</tbody>
</table>
**BUT** Complying with U.S. ≠ Meeting Export MRLs

- Residue monitoring demonstrates ongoing compliance with U.S.
- No non-approved or exceeding U.S. tolerances
- But an example of residues that could be non-compliant with EU limits:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>EU (ppm)</th>
<th>US (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dichlorvos</td>
<td>0.01</td>
<td>0.5</td>
</tr>
<tr>
<td>Iprodione</td>
<td>0.02</td>
<td>0.2</td>
</tr>
<tr>
<td>Glyphosate</td>
<td>0.10</td>
<td>1.0</td>
</tr>
<tr>
<td>Methoxyfenozide</td>
<td>0.02</td>
<td>1.0</td>
</tr>
<tr>
<td>2,4-Dimethylamine</td>
<td>0.05</td>
<td>0.2</td>
</tr>
</tbody>
</table>
Case in Point: Fosetyl and Phosphonic Acid in Europe

- EU MRL defined as all sources – but a common metabolite: phosphite
- Residue can result from fertilizer rather than pesticide usage
- European position to advise growers not to use
- U.S. effort to establish appropriate MRL

April 2013 – EU commission evaluates Phosphonic Acid as a pesticide (regulation 369/2013) instead of foliar fertilizer or plant strengthening agent

October 2013 – Regulation 369/2013 entries into force

October 2013 – Ökotest Magazine blames organic grapes for residues of phosphonic acid due to use of „pesticides“

December 2013 – German Authorities force wholesalers to withdraw walnuts from the markets due to exceedings of MRL of Fosetyl containing only Phosphonic Acid

January 2014: Different efforts by Import and Trade to avoid market disruptions by „Phosphonic Acid“

EFSA Statement on dietary risk assessment for proposed temporary MRLs for Fosetyl –Al

May 2014

Scofah: new temporary MRLs expected: 75 mg/kg instead of 2 mg/kg – June 2014

Regulation 991/2014: temporary MRLs enter into force – September 2014

If nothing happens: temporary MRLs fall back to „zero“ – January 2016
Korea – Example of Evolving Landscape

• Korea currently uses a mix MRLs
• Increased trade within Asia
• Public concerned about the safety of their food

➔ Korea decided to move to a positive list system
  – Only residues for which Korea has set MRLs for specific compounds/crops will be allowed
  – Do their own risk assessment
  – Won’t rely on external assessments or MRLs

• New MRLs to apply to Tree Nuts as of 2016 (?)
• Since 2012, ABC has been working with registrants, EPA and USDA to understand process and let all know what needs are for almonds/tree nuts
  – MRL Priority Database
China and India Legislation
China and India – Effort to Implement Wide-Ranging Food Safety Laws

• Government focus on introduction of laws – blend of U.S. and EU approach
• Effort to reduce corruption, increase investment
• Compliance and enforcement is inconsistent
• Biggest issue – who do you contact when there is a problem?
India: New Challenges as FSSAI Enforces Rules

- Regulations announced in 2011 but not previously enforced
- Driven by concerns over wholesomeness
- Pressure on FSSAI from inside and outside
- Bulk vs wholesale labeling only one example
  - Intended use versus pack size
  - Need for better understanding, cooperation
- Still not clear what outcome will be, but consideration is moving forward…
Product Standards – same issue, different approach

**India**

- Recent rejection of consignment in Chennai for excessive foreign material
  - Inspection staff likely do not understand how to classify “foreign material”
  - Almonds come under a generic standard
  - Efforts in 2011 to develop an almond-specific standard were never finalized

- Need to revisit standard to ensure it is accurate and consistent with USDA grades

**China**

- Product standard for kernel and inshell almonds
  - A “voluntary” standard but will be used by local authorities if any controls are done
  - Kernel standard reflects USDA grades
  - Inshell standard does not reflect all changes recommended by ABC regarding defects and crackout

- Need to continue efforts to ensure grades are accurate, commercially realistic
Europe and Pre-Export
(we’re FINALLY almost there!!)
Pre-Export Checks Program

Sampling and analysis remain the same as with VASP + Certificates issued on or AFTER container leaves + Handler has SPI signoff on certificate = Container arrives at EU port; controls at <1%
What’s Different?

- Only applies to bulk kernels and inshell
- Afla certificate does not need “wet signature”
- Additional page for SPI signature
  - Confirming handler is MOU signatory
  - That afla cert matches PEC cert
- No shipping notes, no reissuing
- PEC can be issued *after* container leaves handler (or even sails)
- Puts more logistics control at handler level
- Goods arriving without PEC will not be rejected, but may be subject to additional controls
New Aflatoxin Analysis Certificate Handler Information

<table>
<thead>
<tr>
<th>Lab Name &amp; Address</th>
<th>Certificate Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA/AMS Approved Laboratory for Aflatoxin Testing in Almonds for Export</td>
<td>EU Pre-Export Certificate</td>
</tr>
<tr>
<td></td>
<td>Article 23 (EC)</td>
</tr>
<tr>
<td></td>
<td>Almonds Pre-Export PEC Program</td>
</tr>
<tr>
<td></td>
<td>Commission Decision</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Received:</th>
<th>Date Analyzed:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Issued:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>APPLICANT NAME AND ADDRESS:</th>
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<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT ANALYZED:</th>
<th>COUNTRY OF ORIGIN:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>USA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT IDENTITY:</th>
<th>STATE:</th>
<th>CROP YEAR:</th>
<th>LOT ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CA</td>
<td></td>
<td>pounds</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>
New Aflatoxin Analysis Cert
USDA Lab Results

<table>
<thead>
<tr>
<th>LAB SAMPLE ID:</th>
<th>SUBSAMPLE</th>
<th>B1</th>
<th>B2</th>
<th>G1</th>
<th>G2</th>
<th>TOTAL AFLATOXIN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ppb</td>
<td>ppb</td>
<td>ppb</td>
<td>ppb</td>
<td>ppb</td>
<td>ppb</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

All aflatoxin results are in ppb (ug/kg) and are corrected for recovery.

The representative incremental sample collected from the lot must all be mixed together to be sure that each sub-sample contains portions of the whole lot. Grinding should be accomplished by a method which not only reduces the particle size but also is effective in thoroughly mixing the particles to a homogenous grind and conforms to the USDA/AMS Laboratory Approval Program procedures.

Sample has been analyzed using HPLC with a limit of quantification (LOQ) of ______ ppb for total Aflatoxin Quality Control/Spike.

Recovery sample analyzed using HPLC gave recoveries of ______ % for total Aflatoxin and XXX.XXX% for Aflatoxin B1.

Sampling:
All PEC Applicants have signed a memorandum of understanding (MOU) with the Almond Board of California declaring that the almonds have been produced, handled, processed, packaged and transported in line with good hygiene practices. Representative incremental samples have been collected from throughout this lot to equal an aggregate sample weight in accordance with the Commission Regulation (EC) No. 401/2006, as amended.

This is a USDA/AMS Approved Laboratory for Aflatoxin Analysis in almonds. Official methods of the AOAC as approved by the USDA/AMS are used in all analyses unless otherwise stated. Reported results are not corrected for recovery or expanded measurement of uncertainty. Reports are for the exclusive use of the applicant. We certify to the truth and accuracy of this report as applying to the samples tested only. Unless otherwise noted, all samples were received in acceptable condition.

Reviewed and Approved by:

DROP DOWN WITH SIGNATORIES FROM LAB
Annex 1 Document Handler Completes

- can be completed up to 14 days after shipment
- many fields are auto-populated
- consignees can be programmed in by handler
- requires container number
- Handler enters actual number of packages and type/size of packages actually loaded in container and a formula computes total lbs. shipped (not to exceed total size of lot analyzed).
- there is a field for customer number if required
- original Lot ID is noted on all pages
- No signature required on Annex 1
Annex 2 Document
SPI Signs & Issues

• handler prints out Annex 1, Annex 2 and Analysis certificate and staples together for SPI to sign

• some fields are auto-populated

• once SPI verifies that handler has signed a PEC MOU they will issue by signing and stamping with official stamp

• Annex 2 certificate is valid for 4 months from date SPI issues

According to the provisions of European Commission Regulation XXX approving the pre-export checks carried out by the United States of America on almonds as regards the presence of aflatoxin, the commodities described in Part 1 have been produced in line with the Pre-Export Checks (PEC) program Memorandum of Understanding administered by the Almond Board of California. The MOU states the commodities have been produced, sorted, handled, processed, packaged and transported in line with good hygiene practices.

I undersigned James Jackson, authorized representative of the Competent Authority referred to in Article 1, certifies that the Applicant of the commodities described in Part 1 is a signatory of the Pre-Export Checks (PEC) program Memorandum of Understanding administered by the Almond Board of California.

According to the aflatoxin certificate number ______, samples from this consignment were taken on 9/19/12 (date), subjected to laboratory analysis on 9/19/12 (date) in the JEJ LLA Analytical (name of laboratory) and the details of the sampling, methods of analysis used and results are attached.

Notes
The certificate is valid for 4 months after issuance.
PEC Flowchart

1. Handler Sampling → Handler Creates Lab Pre-certificate → Sample sent to Lab → Lab Analysis → Passed Analysis Electronically → Handler Notified Electronically → Handler Completes Pre-Export Checks (PEC) Certificate → Handler Prints Pre-Export Certificate + Aflatoxin Analysis Page (Total <= 3 ppb) and requests SPI signature. (Certificate must be issued within 10 business days of truck bill of lading date) → SPI Signs PEC Certificate.

2. Lot is Reworked → Alternate Use.
Transition Timeline

• ABC, USDA/FAS confirmation of regulatory language in December
• Completion and testing of ABC electronic system in January 2015
• Handler visits February/March 2015
  – New PEC Manual and MOU
  – eVASP enhancements (ePEC)
• Tentative effective date April 1, 2015
Now Let’s Hear from YOU!

• Issues you’ve encountered?
• Countries we have not mentioned?
• Changes you are worried about?
• Requirements your customer says are official?
• Other ways we can help?
Thank You