Inspection and Survey of California Sprout Growers - 2004

California Department of Health Services
Food and Drug Branch

California Department of Health Services

Background
U.S. Sprout Industry

- More than 300,000 tons of sprouts produced annually in the United States.
- Industry valued at > $25 million dollars.
- Over 400 growers.

Background
Sprouts and Public Health

- **Since 1996, the FDA has responded to 27 outbreaks of foodborne illness for which raw or lightly cooked sprouts were the confirmed or suspected vehicle.**
- **Causative agents have been *Salmonella* or *E. coli* O157.**

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Sprouts and Public Health

Year	Pathogen	No. of Cases	Location	Type of Sprout	Likely Source of Contamination
1973	Bacillus cereus	NA	Texas	Soybean	Seed
1988	S. saint-paul	NA	Europe	Mung	Seed
1989	S. gold-coast	NA	UK	Cress	??
1994	S. bovismorbificans	492	Sweden/Finland	Alfalfa	Seed
1995	S. stanley	> 300	17 states/Finland	Alfalfa	Seed
1995-1996	S. newport	> 133	Oregon, Canada, Denmark	Alfalfa	Seed
1996	S. montevideo S. melagridis	> 500	California	Alfalfa	Sprouter/Seed
* 1996 *	E. coli O157:H7	> 9,000	Japan	* Radish ??**	??
1997	E. coli O157:H7	> 100	Michigan, Virginia	Alfalfa	Seed
1997	S. infantis S. anatum	109	Kansas, Missouri	Alfalfa	Seed
1997	S. senftenberg	> 25	California	Alfalfa/Clover	Seed
1998	E. coli O157:NM	> 5	California	Alfalfa/Clover	Seed
1998	S. havana	> 15	California, Arizona	Alfalfa	Seed
1999	S. mbandaka	> 68	Oregon, California, Idaho, Washington	Alfalfa	Seed
1999	S. paratyphi B	133	Canada	Alfalfa	??
2000	S. enteriditis	8	Canada	Alfalfa	??
2000	S. enteriditis	>45	California	Mung	??
2001	S. enteriditis	30	Florida	Mung	??
2002	E. coli O157:NM	5	California	Alfalfa	??
2003	S. saint-paul	20	Oregon	Alfalfa	??
2003	E. coli O157:H7	6	Minnesota	Alfalfa	??
2004	S. bovismorbificans	28	Oregon, Washington,	Alfalfa	??

Background
Sprouts and Public Health

- **Alfalfa, clover, and mung bean sprouts are the most commonly produced sprouts and most frequently implicated types in sprout-associated foodborne illnesses and outbreaks.**

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Background
Sprouts and Public Health

- **Seeds used in sprout production are the most likely source of microbial contamination.**
- **Damage to seeds or treatments that scarify the coat increase the risk of internalization of pathogens within the seed and make disinfection more difficult.**

Photo courtesy Dr. Rob Wick

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Inspection and Survey of California Sprout Growers - 2004

HISTORY

California Sprout Industry Inspection Program - Regulations

21 U.S.C. 342 (a)(4)

- "prohibits the production of food under unsanitary conditions which may render food injurious to health."
- Sprout producers are required to implement appropriate practices to ensure that sprouts are not produced in violation.

California Sprout Industry Inspection Program - Regulations

21 CFR Part 110

- **Sets forth good manufacturing practices (GMPs) in manufacturing, packaging, or holding human food including sprouts.**

California Sprout Industry Inspection Program - History

- **1996:**
  - **Statewide sprout grower meeting convened by CDHS-FDB and FDA. Developed a working group composed of industry, academia, and regulatory agencies. Voluntary guidelines disseminated.**
- **1998:**
  - **CDHS-FDB inspects 45 sprout growers in California to assess firm demographics, water, facility design, sanitation/hygiene, seeds, and record keeping.**

California Sprout Industry Inspection Program - History

- **1998:**
  - **CDHS - FDB petitions for U.S. EPA Section 18 registration of a 2% calcium hypochlorite treatment for alfalfa seed as the best available method to ensure elimination of pathogens from the seed.**

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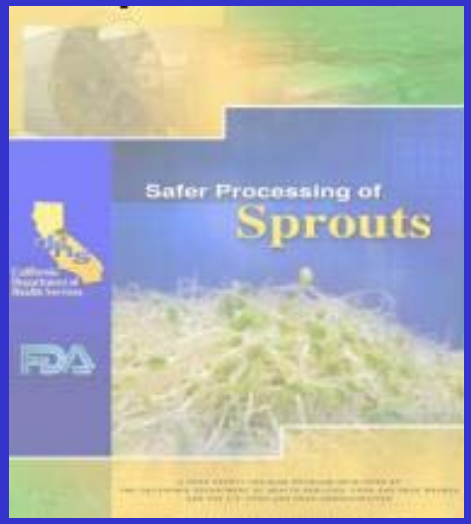
California Sprout Industry Inspection Program - History

- **1999**
  - **FDA issues 2 guidance documents:**
    - ***"Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds"***
      www.cfsan.fda.gov/~dms/sprougd1.html
    - ***"Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"***
      www.cfsan.fda.gov/~dms/sprougd2.html

California Sprout Industry Inspection Program - History

- **2000**
  - **– *"Safer Processing of Sprouts"* video produced and distributed by the CDHS – FDB and the FDA in cooperation with industry and academia.**



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California Sprout Industry Inspection Program - History

- **2002**
  - **Updated consumer advisory issued by FDA for mung bean sprouts.**
    www.cfsan.fda.gov/~lrd/tpsprout.html
  - **Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires all sprout firms be registered with the FDA.**

Inspection and Survey of California Sprout Growers - 2004

METHODS

California Sprout Industry Inspection Program - Methods

- **CDHS – FDB and FDA inspectors visited every active sprout grower in California in February 2004.**
- **A standardized questionnaire was used to evaluate compliance with current GAPs and GMPs before sprouts enter the food supply.**

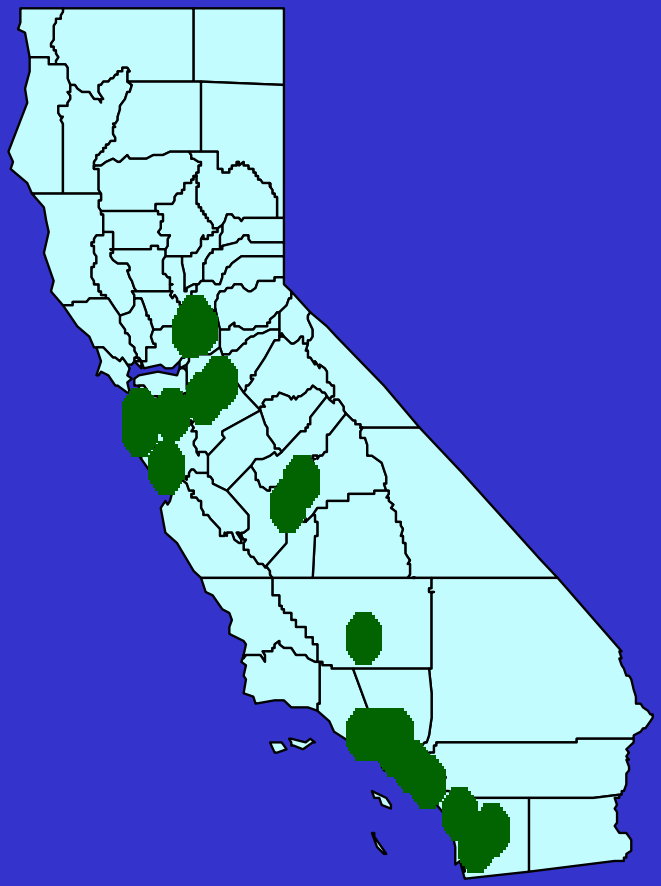
California Sprout Industry Inspection Program - Methods

- **Checklist for Sprout Producer Inspections**
  - **Seed Storage**
  - **Pest control**
  - **Sprout Production**
  - **Seed Treatment**
  - **Testing for Pathogens**
  - **Storage and Distribution of Sprouts**
  - **Traceback Capability**
  - **Cleaning and Disinfection**

Inspection and Survey of California Sprout Growers - 2004

RESULTS

California Sprout Industry Inspection Report - 2004 Location of Sprout Growers (n=24)



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Seed Production, Storage and Treatment

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California Sprout Industry Inspection Report - Results

Seed Lots	2004 (n = 23 firms)
Lot Number clearly marked	21 (91%)
Visual inspection upon receipt	22 (96%)
Seed lots kept separate	16 (70%)
Seed log/tracking record kept*	16 (70%)
Production lines and equipment dedicated to one seed type	13 (54%)
Blacklight inspection upon receipt	9 (40%)

*Lot number maintained in order to track seed through receipt, use, or return to suppliers.

California Sprout Industry Inspection Report - Results

Seed Storage Containers	2004 (n = 23 firms)
Off the floor	23 (100%)
Covered/closed	20 (87%)
Identified with lot number	19 (83%)
Clean	18 (72%)
Away from walls	15 (65%)
Emptied and cleaned between lots	6 (26%)

California Sprout Industry Inspection Report - Results

Seed Storage Area	2004 (n = 23 firms)
Dry	20 (87%)
Clean	16 (70%)
Dedicated to seed storage	11 (48%)
Pest Control	**2004 (n = 24 firms)**
Contract for pest control	16 (67%)
Mechanical	16 (67%)
Insecticides	11 (46%)
Glue traps	10 (42%)
Bait	6 (25%)
Other (zapper, pheromone, etc.)	8 (33%)

California Sprout Industry Inspection Report - Results

Deficiencies in Sprout Production	2004 (n = 24 firms)
None	12 (50%)
Unsanitary food contact surfaces	9 (38%)
Evidence of pests	8 (33%)
Personnel cleanliness*	6 (25%)
Water quality deficiencies	2 (8%)

*Categories listed in 21 CFR 110.10 and inadequate or absent hand-washing facilities.

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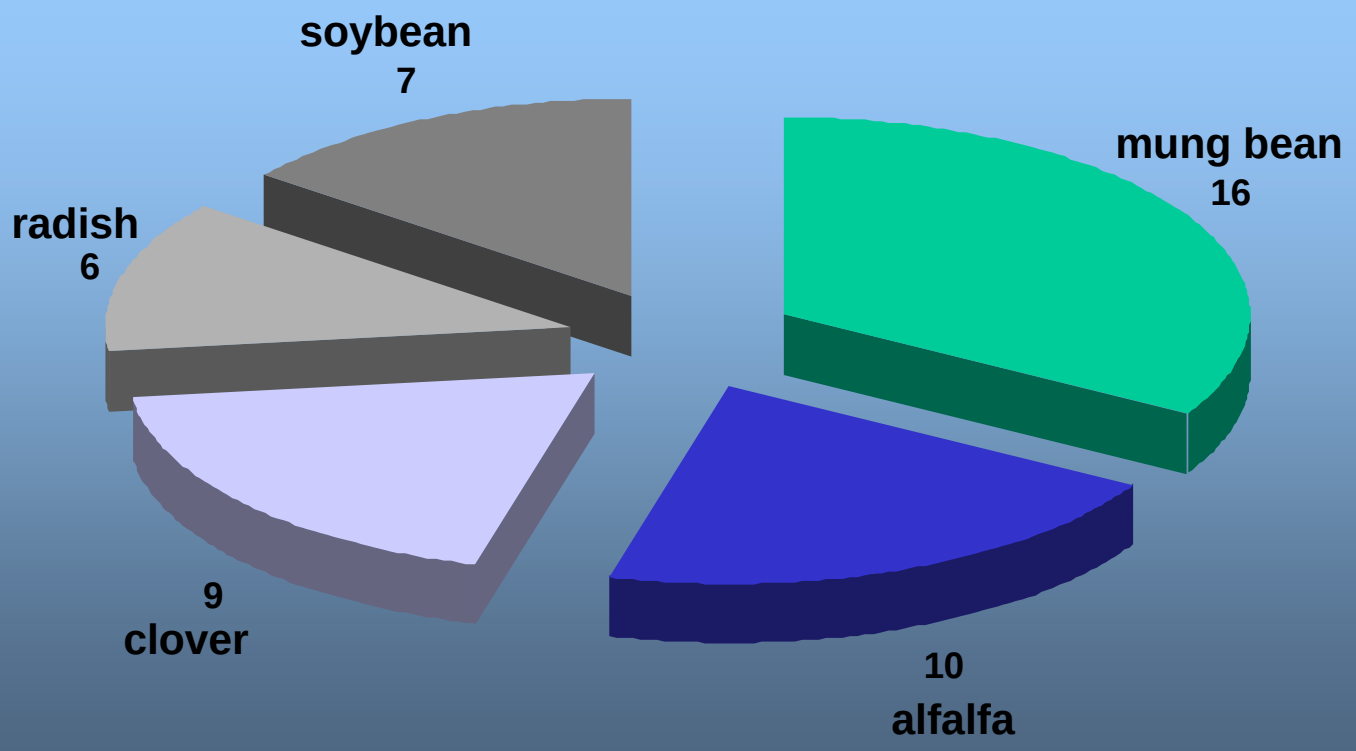
California Sprout Industry Inspection Program - Results

- **Pest Control**
  - **Rodent and/or insect activity was observed at 7 (29%) facilities. Spider webs, gnats, flies, and birds seen in growing areas/green houses. Ants and rodent excrement in food warehouse areas.**
  - **Most facilities contract for pest control services (16). In addition, several reported doing their own monitoring and trapping for pests. Only 1 firm had no pest control.**

Top 5 Sprout Types Grown by California Firms, 2004 (n = 24)



Others: mixed, broccoli, sunflower, pea, onion, lentil, onion, wheatgrass, cabbage, watercress

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California Sprout Industry Inspection Report - Results

Seed Treatment	2004 (n = 24 firms)
At least 1 antimicrobial treatment applied immediately before sprouting	21/24 (88%)
Seed treatment records kept	12/21 (57%)
Seeds pre-rinsed prior to antimicrobial treatment	12/24 (50%)

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California Sprout Industry Inspection Program - Results

- **Types of Disinfectants Used - All Seed Types (n = 51)**
  - **Calcium hypochlorite (70%)**
  - **Sodium hypochlorite (25%)**
  - **Ozone (2%)**
  - **Tsunami 100 (peroxyacetic acid) (2%)**

California Sprout Industry Inspection Program - Results

- **Concentration of biocide ranged from 50 to 25,000 ppm for all seed and treatment combinations in this survey.**

- **Duration of exposure to the biocide ranged from 30 seconds to 8 hours.**

California Sprout Industry Inspection Program - Results

- **Treatment method (n = 51)**
  - **29 (57%) soaked with agitation**
  - **16 (31%) soaked only**
  - **3 (6%) rotated in drums**
  - **2 (4%) poured solution over seeds**
  - **1 (2%) used an ozonator**

California Sprout Industry Inspection Program - Results

- **Only 2 of the firms applied the recommended treatment combination of 20,000ppm calcium hypochlorite for 15 minutes with agitation.**
- **7 other firms used the recommended concentration of Ca(OCl) and time, but had discontinuous or no agitation.**

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Summary of Antimicrobial Treatments as Reported by Firms, 2004

Sprout Seed Type (No.)	Biocide	Avg. Conc (range)	Avg. Duration (range)
Mung (16)	Ca or Na hypochlorite	9,463 ppm (117-25,000)	86 min (0.5-480)
Alfalfa (10)	Ca or Na hypochlorite	17,750 ppm (2,000-20,000)	40 min (10-180)
Clover (9)	Ca or Na hypochlorite	20,000 ppm (all)	46 min (10-180)
Soybean (7)	Ca or Na hypochlorite; or ozone	492 ppm (100-2,000)	174 min (0.5-480)
Mixed (5)	Ca hypochlorite, dry chlorinated, or Tsunami 100	14,017 ppm (50-22,000)	90 min (15-240)
Other*	Ca or Na hypochlorite	17,000 ppm (2,000-20,000)	23 min (10-60)

*Broccoli, lentil, onion, radish, sunflower, wheatgrass, pea, watercress

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California Sprout Industry Inspection Program - Results

- **Verification of Seed Disinfection**
  - **Approximately half (10 of 24) of the firms verified the concentration of the antimicrobial solution used. Verification methods varied by firm.**
  - **6 of 7 firms evaluated were able to demonstrate that the concentration of the solution was within the target range (3 were not evaluated).**

California Sprout Industry Inspection Program - Results

- For those firms that verified seed treatment concentration, the frequency of testing concentration levels varied from “every antimicrobial rinse” to “every other month.”
- Some reported checking one bin out of every eight.

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California Sprout Industry Inspection Program - Results

- **Methods Used to Check Treatment Concentration**

  - **Lamotte chlorine bleach test kit**
  - **ITS free chloride test strip**
  - **CHEMets chlorine test kit**
  - **Ecolab test strip (peracetic acid)**
  - **Bio-cide International chlorine dioxide test kit***

  -Colorimetric test strip

  -Sensafe test strip

  -HACH chlorine test kit

*Not appropriate for chemicals used

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Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production

California Department of Health Services

California Sprout Industry Inspection Program - Results

- **Testing for Pathogens – Water Collection Methods***

Collection of spent irrigation water for microbial testing	17/24 (71%)
Volume of irrigation water collected per sample	30-3,785 ml (range) 783 ml (average)
Frequency of sample collection**	
1 sample from every drum/cart	3/17 (18%)
Multiple drums/carts per water sample	6/17 (35%)
Samples taken within 48 hours after initiation of seed disinfection	14/17 (82%)

*Data not collected on pathogen testing of final product.
**From the same seed lot.

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California Sprout Industry Inspection Program - Results

- **Spent Irrigation Water – Pathogen Testing**
  - **2/17 (12%) test for *E. coli* (typical)**
  - **16/17 (94%) test for *E. coli* O157:H7**
  - **17/17 (100%) test for *Salmonella* spp.**
  - **0/17 test for *Listeria monocytogenes***

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California Sprout Industry Inspection Program - Results

- **Spent Irrigation Water – Initial Microbial Testing**
  - **3/17 (18%) use the firm's in-house lab while 14 (82%) use a contract laboratory**

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California Sprout Industry Inspection Program - Results

- **Spent Irrigation Water – Initial Microbial Testing**
  - **9/17 (53%) use standard testing methodology (FDA BAM) while 4/17 (24%) use a rapid test kit and 4 did not specify or did not know.**
    - ***Salmonella*: VIP, Reveal, ELISA, PCR**
    - ***E. coli* O157:H7: VIP, Reveal, ELISA, PCR, Qualicon**

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California Sprout Industry Inspection Program - Results

- **Spent Irrigation Water – Confirmatory Microbial Testing**
  - **11/17 (65%) conduct confirmatory testing following an initial positive test result**
  - **4/17 (24%) have never had an initial positive test result but would conduct confirmatory testing if necessary**
  - **5/8 (63%) use spent irrigation water while 3/8 (38%) use enrichment media for confirmatory testing (4 did not specify and 1 firm used both).**

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California Sprout Industry Inspection Program - Results

- **Microbial Testing**
  - 13/17 (76%) firms that conduct microbial testing wait for the initial test results before shipping product.
  - If the initial test result is positive, 5/11 (45%) firms that conduct confirmatory testing wait on shipping until after confirmation test results are received.
  - One firm reportedly ships before test results are received.

California Sprout Industry Inspection Program - Results

- **Microbial Testing – Record Keeping***
  - **15/17 (88%) that conduct testing maintain records of test results from 48 hour spent irrigation water samples.**
  - **1/17 (6%) maintains a record of 48 hour spent irrigation water samples collected but not the results.**

*Data missing from 1 firm

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California Sprout Industry Inspection Program - Results

- **Microbial Testing – Record Keeping**
  - **2/11 (18%) that conduct confirmatory testing maintain records of positive confirmation results.**
  - **Only 2 firms maintain records of the disposition of the product where confirmed positive irrigation water is detected.**

Sprout Storage, Distribution, and Traceback Capability

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California Sprout Industry Inspection Program - Results

Method of cooling and distribution	**n = 24 firms**
Sprouts cooled to ≤45°F before distribution*	24 (100%)
Method of holding during cooling	(more than one possible)
Bagged and cased	13 (54%)
Large bin or bag	8 (33%)
Shallow tray or bin	4 (17%)
Other	6 (25%)
Sprouts distributed under refrigeration	18 (75%)

***Core temperature of sprouts recently placed in refrigerator: 37-62°F (measured by investigators).**
***Core temperature of sprouts placed under refrigeration at the end of the previous day's shift: 35-43°F (measured by investigators).**

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California Sprout Industry Inspection Program - Results

- **Traceback Capability**
  - **17/24 (71%) of firms reported having the ability to trace sprouts back to their source seed supplier.**
  - **The maximum number of seed lots used to produce one finished product lot ranged from 1-10.**
  - **12/24 (50%) of firms identify finished product with a lot number or date designation.**

California Sprout Industry Inspection Program - Results

- **Recall Capability**
  - **15/24 (63%) firms reported having the ability to recall particular lots of finished product if a problem was identified with the finished product.**
  - **However, only 7 (29%) firms could recall a particular lot of finished product if the problem was identified in the spent irrigation water.**

California Sprout Industry Inspection Program - Results

- 6/24 (25%) firms have tested their traceback and recall systems, including one firm that had an actual incident.
- 5 firms reported bi-annual or annual testing in 2003, with notice to customer of the mock recalls.

Cleaning and Disinfection

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California Sprout Industry Inspection Program - Results

- **The majority of firms cleaned and sanitized the production and seed disinfection rooms on a daily basis (one firm did not know and another did not respond).**
- **Cleaning and disinfection schedules for the seed storage and greenhouse rooms were more variable (ranged from “daily” to “as needed”).**

California Sprout Industry Inspection Program - Results

- **Chlorine bleach and quaternary ammonium were the most commonly used sanitizers in the production, seed storage, and greenhouse rooms.**

California Sprout Industry Inspection Program - Results

- Concentration was most often 1 part bleach to 10 parts water (5,000 ppm sodium hypochlorite) or 100-400 ppm quaternary ammonium.
- 12/24 (50%) firms had a written Sanitation Standard Operating Procedure (SSOP).

Inspection and Survey of California Sprout Growers - 2004

DISCUSSION

California Sprout Industry Inspection Report 2004 - Discussion

General Trends in California Sprout Industry

- There are fewer firms actively producing sprouts in California compared with data collected six years ago.
- Mung bean (67% of all facilities), alfalfa (42%), and clover (38%) remain the most popular varieties, but the number of different types of sprouts being produced has also decreased.

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California Sprout Industry Inspection Report 2004 - Discussion

Seed Lots

- The main concerns with regard to seed lots involved lack of record keeping and inadequate inspection of the seed lots upon arrival.
- Almost all firms (91%) had the lot numbers clearly marked on seed bags/containers, but about one-third did not keep a seed log/tracking record.

California Sprout Industry Inspection Report 2004 - Discussion

Seed Lots

- Approximately 5% of firms did not visually check their seed lots upon receipt, and only 40% reported using a blacklight.
- Approximately one-third of the firms do not keep their seed lots separated and about half of the firms do not separate the production lines and equipment used for each seed type.

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California Sprout Industry Inspection Report 2004 - Discussion

Seed Storage Containers

- We had concerns about cleanliness and placement of seed storage containers at a few of the firms inspected during the survey.
- All firms kept their seed storage containers off the floor.
- A majority kept their containers covered (87%) as recommended, but 75% did NOT clean and empty seed containers between lots.

California Sprout Industry Inspection Report 2004 - Discussion

Seed Storage Containers

- About three-fourths of firms had clean containers at the time of inspection and some firms (35%) were still placing them against the walls, which increases the risk of seed contamination by rodents or other pests.

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California Sprout Industry Inspection Report 2004 - Discussion

Seed Storage Areas

- Pest control and cleanliness were issues at some of the firms.
- 87% of seed storage areas were described as dry, but 30% did not appear clean.

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California Sprout Industry Inspection Report 2004 - Discussion

Seed Storage Areas

- Almost one-third of the firms did not have a contract pest control program.
- Inspection at 8 facilities revealed evidence of rodents, insects, and/or birds.

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California Sprout Industry Inspection Report 2004 - Discussion

Sanitation

- **50% of the firms were described as having deficiencies in sprout production including unsanitary food contact surfaces (38%), evidence of pests (33%), lack of personnel cleanliness (25%), and water quality problems (8%).**

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California Sprout Industry Inspection Report 2004 - Discussion

Seed Treatment

- FDA guidelines state that at least one approved antimicrobial treatment should be applied immediately before sprouting.
- Calcium hypochlorite at 20,000 ppm for 15 minutes with agitation is the preferred method.
- Significant deficiencies in seed treatment protocols existed for all types of sprouts examined.

California Sprout Industry Inspection Report 2004 - Discussion

Seed Treatment

- Overall, 12 of the 24 firms applied at least one antimicrobial treatment immediately before sprouting
- One-half pre-rinsed the seeds before treating.
- 75% kept seed treatment records.

California Sprout Industry Inspection Report 2004 - Discussion

Seed Treatment

- 70% of sprouts were treated with $Ca(OCl)_2$, as recommended, but only 2 treatment protocols used the correct concentration, duration, and method.
- The next most common biocide was sodium hypochlorite (25%). Ozone and peroxyacetic acid were also used.

California Sprout Industry Inspection Report 2004 - Discussion

Seed Treatment

- Many firms used the correct concentration of $Ca(OCl)_2$, but a number of them failed to agitate or rotate while soaking (one just poured biocide over mung bean seeds).
- The duration of treatment was also quite variable ranging from 30 seconds (pour over) to 8 hours. The average was 26 minutes.

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California Sprout Industry Inspection Report 2004 - Discussion

Seed Treatment

- Approximately half of the firms verified the concentration of the antimicrobial solution used to treat their sprouts; however, the frequency of testing for verification was variable.
- The majority of firms used various commercial test kits, and all but one of those surveyed were able to correctly conduct the test (3 firms were not evaluated).

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California Sprout Industry Inspection Report 2004 - Discussion

Sampling and Microbial Testing of Spent Irrigation Water

- **71% of firms collected spent irrigation water for microbial testing, and 82% of these were obtained within 48 hours after initiation of seed disinfection.**
- **Almost all firms tested for *Salmonella* spp. and *E. coli* O157:H7 but the testing method varied greatly.**

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California Sprout Industry Inspection Report 2004 - Discussion

Sampling and Microbial Testing of Spent Irrigation Water

- Two-thirds conduct confirmatory testing following a positive initial test.
- 38% use enrichment media for confirmatory testing
- Of the firms that conduct confirmatory testing, almost half wait to ship until the results have been received.

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California Sprout Industry Inspection Report 2004 - Discussion

Sampling and Microbial Testing of Spent Irrigation Water

- A majority that conduct testing maintain records of 48 hour spent irrigation water samples.
- Less than 20% that conduct confirmatory testing maintain records of the positive results.
- A majority of firms (92%) do not maintain records of the disposition of the product where confirmed positive irrigation water is detected.

Recommendations

1. Given the high number of outbreaks and the vast deficiencies in sprout growing and processing, Hazard Analysis Critical Control Point requirements should be enacted for the sprout industry.

Recommendations

2. Sprouts are a potentially hazardous food. Individuals at the highest risk of severe morbidity should not consume sprouts. Sprouts should not be served to patients in hospitals, children (daycares, schools) or the elderly (skilled nursing facilities, residential care facilities).

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Recommendations

3. Deficiencies in cleanliness and pest control still exist in sprout production areas at some firms. Sprout growers generally need to increase their compliance with GAPs and GMPs. A number of growers also still need to develop written SSOPs.

Recommendations

4. Industry, academia, and regulators should increase efforts to provide outreach and training activities to assist in implementing antimicrobial treatment protocols for seeds using the correct biocide, concentration, duration, and method. There appeared to be a widespread lack of knowledge on this area of the survey.

Recommendations

5. The expertise and knowledge of microbial testing methods varied. Sprout growers should consider using well-qualified laboratories for testing.

Recommendations

6. Record keeping was a problem for many of the firms. Sprout growers need to improve record keeping throughout production from seed purchase to distribution. They also need to maintain better records of seed treatment and microbial testing results for spent irrigation water.

Recommendations

7. Most of the sprout firms must improve their record keeping systems to be in compliance with the traceback capability requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

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Recommendations

8. The sprout industry should be encouraged to evaluate their recall and traceback capabilities through more drills and exercises.

Recommendations

9. Opportunities for applied research should include development of improved techniques to easily and adequately disinfect sprout seeds.

Acknowledgements

•US Food and Drug Administration

•CA Department of Health Services Food and Drug Branch

•Western Institute for Food Safety and Security