Principles of HACCP on oil refining

article 5 Reg. (EC) No. 852/2004
How could THIS go THAT wrong...?
Contents

- Relevant legislation
- Refining edible fats and oils
- The 7 (or maybe 12...?) HACCP-principles
- Article 5 Reg. (EC) No. 852/2004
- Casus
Relevant legislation

- **Reg. (EC) 178/2002**
  Safety, responsibility, traceability, information of the CA

- **Reg. (EC) 852/2004 (Food) and 183/2005 (Feed)**
  Pre-requisites program (annex II), HACCP (article 5 or 6)

- **Reg. (EC) 1069/2009**
  Animal by-products

  Legal limits on contaminants and pesticides

  Analysis and identification of Feed (by)products
Scheme of the refining process
Example of a refining plant

1. Neutralizer
2. Neutralizer
3. Bleacher
4. Deodourizer
5. Cooler
6. Thermic Fluid Boiler
7. Filter Press
8. Filter Press
9. Raw Oil Tank
10. Bleach Oil Tank
11. Soap Pan
12. Soap Pan
Basic documents HACCP

Codex Alimentarius (basics of HACCP)

Article 5 Reg. (EC) no. 852/2004 or 6 Reg. (EC) 183/2005

SANCO/1955/2005 (guidance document for implementation of HACCP)
12 steps for the application of HACCP

Obtain management commitment

Define terms of reference

Select the team

Describe the product

Identify intended use

Flow diagram / define process

Confirm flow diagram
Application of the 7 HACCP principles

- Identify potential hazards
- Conduct a hazard analysis
- Specify control measures
- Determine CCPs
- Establish critical limits
- Establish monitoring system
- Establish corrective action plan
- Verification & review
- Establish documentation and records
Article 5 Reg. (EC) No. 852/2004 – principle 1

- (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
Hazard Analysis

At each process step consider!

- Presence of hazards e.g. associated with ingredients or raw materials.
- Introduction of hazards e.g. from environment, equipment or personnel.
- Changing on existing hazards e.g. growth or survival of microorganisms, toxin production, chemical reactions...
- Include the causes of the hazard.

Examples of hazard definition:

- “Presence of too high levels of residues of pesticides on oil due to poor instructions in the plantation.”
- “Presence of too high levels of PAH in oil due to inappropriate drying of the tanks after coating.”
Hazards (1)

- Pesticides
- GMO’s
- Solvents
- Mycotoxins
- PAH’s
- Hydraulic oil
- Heavy metals
- Dioxins
- PAH’s
- Pesticides
- Water
- Mycotoxins
- PAH’s
- Dioxins
Hazards during transportation (2)

- Contamination by previous cargo.
- Contamination by cleaning agents.
- Contamination by containers/materials.
- Contamination with thermal oil.
- Cross-contamination: poor segregation during storage, transport or (un)loading.
Article 5 Reg. (EC) No. 852/2004 – principle 2

(b) **identifying the critical control points** at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

**Example of CCP:**
“Step: purchasing - Residues of aflatoxins in organic coconut oil, within the legal limits”
Generally

Specifically

Controlling + Place

“Probability x Effect”

Controlling measures

“Decision tree”

Hazards

Risks

CCP’s
Article 5 Reg. (EC) No. 852/2004 – principle 3

• (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
Article 5 Reg. (EC) No. 852/2004 – principle 3

- **Critical limit**: A criterion which separates acceptability from unacceptability.
- **Target level**: A predetermined value for the control measure which has been shown to eliminate a hazard at a CCP.
- **Tolerance**: The values between the target level and the critical limit.
- **Deviation**: Failure to meet a critical limit.

*Example of critical limit:*

**CCP 1: PAH in cocoa butter**

- **Legal limit**: $< 5 \mu g/kg$ PAH in cocoa butter
- **Critical limit**: $< 4,0 \mu g/kg$ PAH in cocoa butter
- **Target**: $< 2,0 \mu g/kg$ PAH in cocoa butter
Article 5 Reg. (EC) No. 852/2004 – principle 4

• (d) establishing and implementing effective monitoring procedures at critical control points;

Example of monitoring procedures:
“CCP 1: too high content of pesticides in sunflower seed
For every crop a lab analysis will be conducted. Positive release will be applied to every consignment within legal limits.”
Article 5 Reg. (EC) No. 852/2004 – principle 5

• (e) establishing **corrective actions** when monitoring indicates that a critical control point is not under control;

Example of corrective actions:
“CCP 3: pesticides above legal limits in final product
   Aiming product: product recall, inform CA and customers.
   Aiming process: contact with the growers, GMP, improving instructions to staff, purchase from Global GAP certified growers”
Article 5 Reg. (EC) No. 852/2004- principle 6

• (f) establishing procedures, which shall be carried out regularly, to **verify** that the measures outlined in subparagraphs (a) to (e) are working effectively;

**Example of verifying procedures:**
• Verify your CCP’s and your entire HACCP handbook
• Review complains
• Internal and external audit, certification
• HACCP-team meetings
• *Stay up-to-date on literature, RASFF’s, EWRS, alerts, changes in legislation... and implement this into your HACCP-plan!*
• Follow a course of the MVO.
Article 5 Reg. (EC) No. 852/2004 – principle 7

• (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).
Article 5 Reg. (EC) No. 852/2004

When any modification is made in the product, process, or any step, food business operators shall **review the procedure** and make the necessary changes to it.
• Let’s work together!
A HACCP case

- Why HACCP didn’t work
- Legislation in breach
- Corrective measures
- Lessons for the future
- Discussion
Description of the case (1)

- On the evening of Wednesday, December 24th 2012, the refining company “The Sunny Plantation” (TSP) were informed by their Serbian customer “All Fried” so that during a routine check they found 4,0 µg/kg BaP in a frying fat they produce for the local market.

- “All Fried” had verified all ingredients and concluded that the contamination in the frying fat could only come from the sunflower oil (SFO, 25% w/w in the final product), that had been delivered by TSP 4 months earlier. The entire production of frying fat had already been placed on the market, but after consultation with the Serbian authorities, they considered that the product was not unsafe, because fried food only absorbs up to 10% fat. In the worst-case scenario the final product would contain up to 0,4 µg/kg BaP, so they don’t take any further actions.
Description of the case (2)

- The QA-manager of TSP traces back the SFO sent to “All Fried” to come from batch SFO/1234/9 that had been delivered by Girasol Trade Ltd. (GTL), a Buenos Aires based broker, that usually delivers SFO from Argentina. TSP had refined the crude SFO accordingly to the following procedure:
  - Degumming
  - Dosage of carbon (method 1, CP-1) No analysis
  - Deodorization

TSP delivered the refined SFO to 10 other customers in EU-countries. There is no more stock, and the reference samples can’t be analyzed before the Christmas-weekend, because the laboratory and the entire refinery are closed for 4 days for big-maintenance.
Description of the case (3)

- The QAM is pretty sure that all other customers of TSP use the SFO in multi-ingredient food products, all of them containing less than 10% SFO (w/w), so they should be safe. Just to be completely sure, he asks a junior-colleague to check this and to report to him on Monday 29th, after the Christmas-weekend. He asks not to contact the customers and to perform a risk-assessment, based on the expected BaP-amount in the final products using the specs of these final products that TSP keeps from all her customers.
Description of the case (4)

- On Monday 29th the report is finished and concludes that, based on the available specs, only 2 mayonnaise products from a German producer containing 15% SFO (w/w) could contain up to 2.4 µg/kg BaP. All other products are expected to contain less than 2 µg/kg. The QAM decides to analyze the reference sample of SFO/1234/9 before informing the customer.
- On the evening of Tuesday 30th the lab of TSP comes with the result of the analysis on SFO/1234/9: 13 µg/kg BaP. This means that the BaP in the mayonnaise just sticks under the 2 µg/kg.
- The QAM and the direction of TSP decide not to inform the customers or to undertake any other corrective measures. They plan a meeting of the HACCP-team for January 2nd to verify the HACCP-analysis and the internal procedures concerning the import and processing of SFO.
You are provided the following relevant documents:

- The case and the questions.
- Specification of the crude SFO provided by the broker in Argentina.
- Hazard analysis on PAH.
- Work instruction CP1: dosage of active carbon (for this case we’ll assume that TSP correctly followed the instruction)
- Recall procedure.
Question 1

Do you think that TSP took the appropriate measures? What had you done different? Think about:

• Legislation in breach.

• Appropriate corrective actions (Recall procedure)

• Information to third parties.
Question 2

What you think about the hazard analysis and the CP1-instruction of TSP? Would you make some changes? Think about:

- Properly conducted hazard analysis.
- Effectiveness of the monitoring procedure (CCP1)
Question 3

The by-products after the refining are collected and delivered to the following customers with no further analysis:
- Water from degumming and neutralization: extraction of lecithins and FFA, delivered to a Food customer.
- Bleaching earth + active carbon: delivered to a power plant.
- Distillate: delivered to a Feed-producer.

• Do you have any concerns about the hazards in these by-products, taking into account the intended use? What would you do different?
You have 30 minutes to answer the questions in 2 separate groups.

A short presentation on the view of the NVWA will follow.

Good luck!
Question 1: NVWA approach

Do you think that TSP took the appropriate measures? What had you done different? Think about:

- Legislation in breach.
  - Reg. (EC) 1881/2006 art. 1 and 3: applies to raw materials. Dilution is not allowed. Limit for BaP and sum-PAH.

- Appropriate corrective actions (Recall procedure)
  - The whole procedure is unspecific. No names!
  - All unsafe products must be withdrawn from the market.
  - All measures based on assumptions, not on data.

- Information to third parties.
  - Supplier of the crude SFO, CA and customers should have been informed immediately of injurious food.
Question 2: NVWA approach

What you think about the hazard analysis and the CP1-instruction of TSP? Would you make some changes? Think about:

• Properly conducted hazard analysis.
• Probability of hazards should not be influenced by already implemented control measures.
• PAH in crude SFO from all countries should be better monitored.
• Motivation: no scientific arguments, cross-references.

• Effectiveness of the monitoring procedure (CP1)
  • Dosage of active carbon should have been a CCP based on a PAH-analysis of the crude SFO prior to refining.
  • Critical limits are not clearly defined.
  • Verification 1/3 could be sufficient if carbon properly dosed CCP.
  • Corrective actions are insufficient (product + process)
Question 3: NVWA approach

The by-products after the refining are collected and delivered to the following customers with no further analysis:

- Water from degumming and neutralization: extraction of lecithins and FFA, delivered to a Food customer.
- Bleaching earth + active carbon: delivered to a power plant.
- Distillate: delivered to a Feed-producer.

Do you have any concerns about the hazards in these by-products, taking into account the intended use? What would you do different?

- Materials from water to be subjected to risk analysis.
- Any materials intended for Feed to be analyzed and to comply with Reg. (EC) 152/2009 and identified acc. to Reg. (EG) 767/2009
Thank you for your attention!

Do you have any questions