

Case Study Harmonisation Meeting CB's HACCP RVA

RI = Risk identification / NC = non compliance / PRP = pre- requisite program / CB = certifying body / Standard § = . Dit is het nummer van de norm.

Year	standard §	case	nr	Statement	CONSENSUS	Standard § sufficient?
2011-1		<p>A company that produces food supplements was reported by the food safety authorities after accepting raw materials with high benzopyrene content: legal limit is exceeded.</p> <p>The company runs an ingredient analyses program that has concluded that after using the raw material as an ingredient in a spice & season mix, the benzopyrene content is below the maximum legal value. Therefore the raw material was accepted.</p>		Is there a non conformity and if so which grade (serious/minor or less serious/major)?	According to VWA guide 64 dated 1 Sep 2009 (Dutch food safety authorities) this is a nonconformity.as "it is not allowed to dilute unsafe raw materials"	Yes
2011-2		<p>A company that produces food supplements (like vitamin A with a maximal daily intake) runs a validated automated weighing system. The program guarantees the right weight and identity of weight ingredients. If more than 2% deviation from the recipe occurs, the system is blocked. The auditor confirms the system to be effective. Also every change is being recorded on the 'change control form'.</p> <p>In the risk analyses the risk for 'overweight' and 'incorrect ingredients' is estimated based on effective control measures (the validated weighing system) and therefore graded as 'low'. Therefore, the weighing control system is not regarded a CCP.</p>		Is there a non conformity and if so which grade?	<p>Process was designed by the company in order to eliminate the chance regarding overdosing and therefore the food safety risk is not relevant.</p> <p>Note. This does not dismiss the company from executing a sufficient analytical program for finished products.</p>	Yes
2011-3		In the finished product warehouse (boxes with dried products) you see that some pallets are stored right along the wall. This prevents you from walking between the wall and the pallet and also prevents wall inspection. The same has been identified by the pest controller repeatedly ('bates nr. 13 and 14 can't be inspected'). The pest control inspector however has not found any pest traces or sign in the warehouse.	3	Is there a non conformity and if so which grade (serious/major or less serious/minor)?	<p>Minor NC (5.4) No corrective action taken to control PRP. It cannot be shown whether bates nr. 13 and 14 were gnawed or not.</p> <p>Auditor is urged to do further auditing/investigation. E.g. were these traces incidents? If more</p>	Yes

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					were found and also insufficient action has been taken major may be indentified.	
2011-4		The personnel on the bottling line for vegetable oil wear a uniform but no hair net. The quality manager explains that the employees are not indirect contact with the product as the oil is closed circuit and the filler is protected. Indeed, the filler is protected and bottles are capped right after filling.	4	Is there a non conformity and if so which grade (serious/major or less serious/minor)?	No NC. However the auditor has to investigate if there are	Yes
2011-5		The hazard analysis of an industrial bakery is not formally addressing bio-terrorism or sabotage. However some satisfactory control measures regarding this issue are implemented (e.g. site enclosed, locked silos).	5	Is there a non conformity and if so which grade (serious/major or less serious/minor)?	No NC. Terrorism is not documented in the standard.	Yes
2011-6		The QA/FS responsible employee has no background in HACCP and food safety. This requirement however is mentioned in his job description. Also other HACCP team members have process and product related knowledge, but no knowledge concerning HACCP methods. They have limited food safety knowledge. The QA/FS responsible employee explains that the HACCP expertise is outsourced to the (external) advisor. The advisor has implemented and maintained the HACCP system and visits the company appr. 2 days per year. He is using 'input' from the HACCP team members for the implementation and maintenance of the system. Also, during those visits, he conducts internal audits, collects information for the yearly verification reports and validation reports (if applicable) and he gives a short hygiene training for the employees.	6	Is there a non conformity and if so which grade (serious/major or less serious/minor)?	It cannot be concluded that the HACCP teams' expertise and knowledge is insufficient. Only if audit findings show that e.g. hazard analyses is incomplete or no validation took place at changes, a NC can be identified. A minor NC shall be identified based on the fact that the internal audit was not independent (5.11) <i>Note:</i> <i>The external advisor <u>can</u> audit things like:</i> <i>- Actual status (implementation)of the PRP</i> <i>- Implementation of control measures;</i> <i>As long as he does not carry out activities that are clearly related (e.g. supplier selection, defining</i>	Yes

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					<p><i>label information & specifications, carrying out routine hygiene control audits, etc...),</i></p> <p><i>Possible conflict might arise in sections like:</i></p> <ul style="list-style-type: none"> - <i>Judging the actuality of the HACCP system;</i> - <i>Maintenance of the HACCP documentation, in which case the internal audit shall be carried out by someone impartial.</i> 	
2011-7		<p>Case 1: For a lid placed on top of a peanut butter jar with food contact, the (lid) supplier has forwarded a food safety statement: the lid complies with relevant legislation regarding to migration of toxins when in contact with food contact ("film approved according EC 1935/2004"). However no validation is known related to the use of this packaging in peanut butter.</p> <p>Case 2: Same situation for a company that packs bread.</p> <p>Case 3: Same for company that produces heat&steam microwave meals.</p>	7	<p>Are the HACCP requirements fulfilled or should a NC being identified?</p> <p>For all three cases.</p>	<p>Case 1: NC (less serious) 5.10. No complete validation of use of packaging (high oil content)</p> <p>Case 2: No NC. No 'worst case simulant' according EC 82/711</p> <p>Case 3: NC (less serious) 5.10. No complete validation of use of packaging (in microwave oven)</p>	Yes
2011-8		<p>a. The external calibration of the temperature probe does not occur in the monitoring area (appr. 75°C), but at 10°C and 100°C. The documented tolerance is max 0.5°C.</p> <p>At 10°0.2°C deviation is measured, at 100°C 0,5°C.</p> <p>According to the company's representative the calibration company says that the deviation at 100°C is always more than in the monitoring area of appr. 75 °C.</p>	8	<p>Is there a non conformity and if so which grade (serious/major or less serious/minor)?</p> <p>Both a and b.</p>	<p>a. No NC. No reason to doubt the calibration company's statement.</p> <p>b. No tolerance documented: Minor NC. In case of CCP monitoring a major NC should be raised if the process parameter is lower than the critical limit (based on the 1.2°C deviation).</p>	Yes

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		b. The calibration is conducted at 0°C (with melting water) and at 100°C (boiling water). No reference temperature probe is used. No tolerance is documented. The results are: at 0°C deviation of 0.4°C en at 100°C deviation of 1.2°C. The monitoring area is appr. 75°C.				
2011-9		A complaint analysis is not demonstrable. Three complaints of three different consumers were identified regarding the same product. The complaints concern plastic in the product. The individual complaints were dealt with.	9	Is there a non conformity and if so which grade (serious/major or less serious/minor)? If so, what corrective action is expected?	Minor NC (5.11). No analyses of possible food safety risks. Expected corrective action is that a food safety evaluation for complaints of a certain period (e.g. a year) is included in the complaint or verification procedure.	Yes
2011-10		a. HACCP-audit was conducted 1 March 2011. Management review was planned 31 January 2011 but conducted 13 February 2011. Last management review was conducted 12 January 2010. b. What if the management review was conducted 11 Feb. 2011	10	Is there a non conformity and if so which grade (serious/major or less serious/minor)? If so, what corrective action is expected?	a. Minor NC (5.11). Management review was late (more than 13 months). Corrective action: Adapt procedure management review and plan within 12 months. If planning is not followed next year -> Major NC. b. No NC	Yes