

Cases Harmonization Days HACCP auditors.

RI = Risico-inventarisatie – TKK = tekortkoming – BVP = basisvoorwaardenprogramma – CI = certificerende instantie - Norm §. Dit is het nummer van de norm.

YEAR	NORM §	CASUS	nr	SETTING / QUESTION	CONSENSUS
2010 CUC	5.5.2	A company produces canned cherries (5 L) for the bakery industry. The only ingredients are cherries and water. The closed cans are pasteurized for prevention of the growth of yeasts and fungi, which can cause bombage (which increases the volume of the container) during storage. The risk analysis shows that if bombage occurs within 6 weeks after production, the pasteurization should be recognized as PVA bombage. The control after 6 weeks is not considered critical, and there are no further management mentioned in this part of HACCP analysis. In practice, the cans are actually held six weeks in storage (quarantined). After 6 weeks (or longer) the cans are given the desired final private label. This will be checked before released and delivered for customers. A data logger checks the pasteurization process every two hours by measuring the process in the middle of the cans. The pasteurization time and temperature and the bombage test after 6 weeks is validated by the company as well as being tested on shelf life.	1	Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns.	This is not a shortcoming: the company has a proper risk assessment and validation. Additionally, this risk is well managed by, 1) the reading of the data logger every 2 hours; 2) conducting durability test and 3) the visual inspection of the cans at least 6 weeks after the closing and pasteurization of the cans.
2010 ISACert	5.8.1/ BVP3.2.1/ 5.9.1	A poultry processing company adds a salt solution to fresh chicken (tumble). After that the product is stored in a freezer and shipped as frozen product. At the reception, during storage and the departure of the product, temperature of the chicken fillet is a CCP (respective $\leq 4^{\circ}\text{C}$ and $\leq -18^{\circ}\text{C}$). The company is demonstrable in control of these CCP's.	2	Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns.	This is not a NC. Regulation (EG) 853/2004, Annex III, Section II, Chapter V, Article 1 sub b says about meat cutting plants: "during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4°C by means of an ambient temperature of 12°C or an

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		During the audit is determined that the temperature of the chicken fillet, directly after tumbling, exceed the legal limit of 4°C in a limited way (1 or 2°C). According to the HACCP study the temperature is measured 3 times a day (after each break). The limit is determined on 5°C maximum in relation to the maximum stay of half a hour in the tumbling department (process control, no CCP). There are no complaints about this products and microbiological examinations at date of expiration show no exceeding of the legal limits of the chicken fillet. The temperature of the room with the tumbling equipment is demonstrable always ≤ 12°C.			alternative system having an equivalent effect” This is only for a meat cutting plant and not for a plant for the production of meat products. The regulations for this kind of food business operators are mentioned in Section VI of this Regulation.
2010 ISACert	BVP 2.3.2./ 5.8.1/5.10	A fishing company that processes herring products (chilled, frozen) as determined CCP, refrigerating temperature, freezer, ripening store, temperature store and production space. The temperature in these areas is normally measured by a continuous system logger in the computer with SMS services to the main production if temperature is exceeded. Production controls a list of the temperature that is checked three times per day manually (by means of a calibrated hand thermometer), this due to the not functioning of the computer system for the past couple of months. The manager indicates that there is no budget in the foreseen future in order to restore the computer. The alarm on the log system of the SMS service still works, but registration of alarms in the computer no longer takes place. (Temperature) anomalies are consistently recorded	3	Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns.	This is not a shortcoming. When using a validation study is demonstrated that a frequency of 3 times a day is representative of the temperature of the stored product, also that the alarm system functions. A condition is that the validation under worst-case conditions is fully and properly implemented. (Worst Case = maximum permissible temperature of the refrigerator below warning level in relation to a minimum "utilization" of the warehouse, maximum ambient temperature, etc.

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		manually and arguably succeeded. Apart from the SMS alert system, there is no illuminated or audible signal to alert the refrigerator of the (temporary) temperature overrun. The months before the 'crash' of the system, the records are still intact and beyond the normal defrosting curves shows no abnormalities in temperature.			
2010 ISACert	BVP 2.4.5/ 5.9.1/5.11/5.1.6	A logistics service provider specializing in the transportation and storage of chilled and frozen foods, has a contract with a major customer for the transport and storage of frozen potato products. Data shows that a majority of the receiving temperature of delivered parties is > -15 °C (standard) This is identified as a CCP. There are recorded values to -5 °C. In accordance with internal procedures the action is consistently a complaint to the supplying party (large contractor). The supplier responds structurally not. The company takes no further action. In the internal audit reports, management review or verification is nothing mentioned about. This. The parties are stored in the freezer immediately after delivery. If the party is measured before loading (within 24 hours of receiving) in some case the minimum temperature of -15 °C (standard) is still not reached. In some cases the measure temperature is -12 °C. There are a limited number of complaints from a DC of a supermarket about to high temperatures of receipt.(> -15 °C)	4	Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns.	This is a major shortcoming. This is a breaking the rules of the law. The CCP standard -15 °C is also questionable. (Commodities Scheme frozen food article 4, normally -18 °C, during transport: a maximum tolerance of 3 °C during local distribution and retail display cabinets). If the company can prove (properly supported through validation) that by the internal standard (-15 °C) there is no risk for food safety, it will be a minor shortcoming. But given the fact the large excess and there are no structural corrective / preventive actions taken. It is a major shortcoming on preventive / corrective measures; in food safety hazard even a critical shortcoming. Expected that this "problem" by the company is recognized and by the HACCP team is analyzed. Also on a major shortcoming because there is not in the internal audit, not in the HACCP team and not in the management review and verification attention has been paid and because there are complaints. The management does not take their

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					responsibility with regard to a potential food safety problem (not control CCP).
2010 Qlip	5.4	A cheese production company produces various types of cheese. In some cheeses are processed spice mixes. These spice mixes consist of a blend of many spices. During the audit the specifications are assed by the auditor. The spices are all listed separately, in the specification is listed under "source": India / China. The spices are purchased through a wholesaler, which is HACCP certified. The potential risks of these spices are mentioned in the HACCP study of the cheese company. The potential hazards are for instance contamination by pesticides, heavy metals and other contaminants (such as PCBs and dioxins). The risk is seriously and the possibility "average" (can happen) It is indicated as a general control measures (HACCP purchases from certified suppliers). Reference is made to the importer who is HACCP certified. The cheese company does no do further analysis. On inquiry it appeared that the importer does no do analysis. According to the importer this not necessary, because the Chinese and Indian exporters are only allowed to export spices to the EU if they comply with EU legislation. They have performed analysis, but these data are no more available.	5	Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns.	This is a minor shortcoming. There is insufficient evidence that the spices meet requirements on listed items. The fact that the importers are HACCP certified is on itself an insufficient guarantee. There are insufficient data to provide a risk analysis in relation to their own process. It's a small shortcoming, because quite a "dilution effect" and the risk of food safety hazards therefore very limited. Point is how the deficiency within the prescribed period for a 'small' shortcoming can be remedied: the minimal availability of a plan of how data generated will be submitted to the CB Minimum requirements: Company must at random analysis product, or have data available showing that the requirements are met (eg, by monitoring such a central organization). This would be through a final inspection taking into account the dilution effect. Analyze (sampling) should be risk-oriented and not volume-oriented. Additional comment; Dilution Effect: This should not abuse by "cutting" of parties with an initial (known) party contains excessive levels of harmful substances (see EC Regulation 1881/2006 Art. March).
2010 Qlip	5.4	Company mix and packages powdered products (food only) by order of client. The powders are continuously owned by	6	Is this a shortcoming? If yes, please specify at what point standard and whether	Major shortcoming, it is not proven that the company has done own research based on knowledge in

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		the client. The mix company is not in possession of specifications of the powders. However, the client has provided data, what in his view may be relevant to the process (eg allergens). The company itself has no risk analysis related to cleaning between two runs or in order production. There are agreements that suppliers and clients will notify changes.		a minor or major shortcoming concerns.	relation to their own processes. Obviously, this study must be evidently and be founded. Explanation: the general view of certified companies is that the responsibility by "subcontracting" lies with the client and not the processor. This is wrong when it is related by process. To analyze the risks in the mixing process, the company must take in addition the process hazards (eg metal particles due damage mixing equipment, lubricants through leaking bearings, etc.), and also the product hazards in the form of cross-contamination in HACCP study. This is information about the products needed. Additional note: It is no shortcoming if after each product change, there is performed a validated cleaning.
2010 BV	5.5.1/5.6.2	In the corner, in the production department of a fruit and vegetable cutter, there are two speakers, hanging from the ceiling, not directly above product, The metal brackets showed rust spots and the (wooden) walls of the speakers showed mould. The company has a cleaning plan with detailing of all cleaning items The speakers were not included herein. Furthermore, there are in the production no facts found Attn poor maintenance / cleaning.	8	Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns.	There is a minor shortcoming in the General Management measures. Deficiency in one omission in the cleaning plan (the speakers are not included in the cleaning plan) related to an incomplete hazard identification. Given that it is not above the product this is regarded as a minor shortcoming.
2010 BV	5.4/5.6 + 5.12.1/BVP 4.1.1.4	In a cabinet in the room of the Technical Department of a bread and pastry factory are the lubricants stored. In the cabinet is a rich assortment of oils and fats. There is a shelf for food grade lubricants and a shelf for non-food grade lubricants. The	9	Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns	The fact mentioned under 1) can lead to use of lubricants which are thought to be suitable for the purpose for which they are applied, in fact they are unfit. If it appeared that non-food grade lubricants used

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		<p>shelves are not identified.</p> <p>Also, the TD chief holds a list in which the lubricant in use is specified in relation to the object. The list is split between food grade and non-food grade lubricants. The auditor noted in several situations:</p> <p>1) In the cabinet there are non-food grade lubricants which are not on the list. Enquiries revealed that these lubricants are used. No clearly by which objects.</p> <p>2) In the cabinet are lubricants which not used anymore. They are on the list.</p> <p>3) On the shelf between all food grade lubricants, there are some non-food grade lubricants.</p>			<p>for "sensitive" items, significant risk that food contaminated by grease boards, than there is one major shortcoming .By 2) and 3) that fact will not directly lead to food safety hazards if the mechanics are complying with instructions and read and apply the labels on the lubricant. There has in fact been sloppy documentation and warehouse. This justifies a minor shortcoming respectively for document management and facility maintenance and care.</p>
2010 BV 1	5.11/5.12	<p>Given a document based on Annex 1 of the standard, basic program. In a company document the table is taken on and it has added a column indicating how it is regulated within the company, sometimes a referral. Date is mention on the top of this extra column. The quality manager mentions that this is the verification document and also internal audit document. The date on top of the column is adjusted annually. The latest changes in the last column and what the changes were substantive is not to trace. The document is actually two goals, namely, the description of the fundamentals of this company and it is also the annual internal audit / verification report. During the audit there is no evidence that the above process is reviewed.</p>	10	<p>Is this a shortcoming? If yes, please specify at what point standard and whether a minor or major shortcoming concerns.</p>	<p>The document has two objectives: the description is the fundamentals of this company and also audit / verification report;</p> <p>1) If the date above the additional column indicating the date when the basic program last reviewed and possibly adapted, the basic program adequately considered. It is necessary that the latest changes are visible in the document (or elsewhere). This is rated as a minor shortcoming.</p> <p>2) The document is apparently intended as an internal audit report. The document is also considered by the Quality Manager as the verification report. Then shoot the document briefly. Internal audit and verification will involve far more than just assessment of the basic program. See paragraph 5.11 of the</p>

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					standard. If this is the only document that refers to verification / internal audit, it is a major shortcoming.