HACCP Cases

RI = Risk identification / NC = non compliance / PRP = pre- requisite program / CB = certifying body / Standard § = audit standard clause.

Year	standard §	Case	CONSENSUS
2015-1		**Target values, action limit and critical limits** For CCP 2 metal detection, the standard values are: Fe 9.0 mm, non-Fe 7.1 mm and stainless steel 316 8.0 mm. Note: This standard is above the value of 7.0 mm which is regarded by the Dutch Food Authorities (NVWA) as an acceptable risk. In ch 4.3 Overview of CCPs the values of 6 mm for Fe, non-Fe and stainless steel are quoted. SBM 3 Procedures Metal detection has been updated. Customers are not yet informed about the revision of the standard for metal detection. In the specification the old standards of 6 mm (Fe, non-FE and RVS) are quoted whilst the current values are Fe 9.0 mm, non-Fe 7.1 mm and stainless steel 316 8.0 mm..	5.7.2 Major The company has determined that it is a CCP. The values are not consistent with accepted limits of 7mm.
2015-2		**Misleading** During the audit it appears that the ingredient declaration drawn up by the company, as shown on the product specification (it is a semi-finished product B2B) is not correct. The order is not correct and glucose syrup is not mentioned while this is the main component of one of the raw materials used.	The specification is not correct. Not all ingredients listed and not in the correct order. 5.2.1 Minor
2015-3		**Reliability research** Company specializes in processing of soy and Lupine into ingredients for the bakery sector. They buy their raw materials themselves, the soy mainly from Canada and the lupine from Australia. When processing lupine specific dangers play (Phomopsine and Lupine quinalizidine alkaloids) which also are listed in Risk Plaza. During the audit it appears: 1. The company processes soy and sunflower lecithin. For the analysis of heavy metals by a laboratory, an extraction has to be made. Lecithin is a small market, the company failed to find an accredited laboratory able to perform these analyses. Analyses are now performed by reputable laboratories. During the audit, no abnormal results found . 2. Analysis on Phomopsine: These are carried out in Australia in order to have insights to the results for offloading. In Australia no accredited laboratory is available for this analysis. The company collaborates with a Dutch laboratory in order to get insights to risk areas for this danger through the additional analyses. This laboratory is not accredited for the analysis. The realisation of ring testing is not possible, since these analyses are hardly carried out on this item in NL, IE there is no frame of reference for a statistically-based ring	Correct assessment has been carried out and the right conclusions are drawn. There are a couple of footnotes. In case there is no accredited lab to find for a given matrix, this does not mean that the analysis results can't be used. An analysis result of a non-accredited lab for that analysis could be acceptable. Possibly the lab is accredited to perform analyses on food in a broader sense ("scope accredited") and is the method "in house" validated. As a result, it seems unlikely that there is no accredited result for heavy metals. There are labs that can analyze on heavy metals under a flexible accreditation, so including lecithin. In the Regulation (EC) 882, currently under revision, this will be covered. For new risks/incidents the lab doesn't need to be accredited (yet) for the method. It is therefore also a matter of justification of the reasons that lead the company to the choice of a lab

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		test. The company applies for the interpretation of the results the legal claim, which in Australia is used (max 5 ppb). During the audit, no abnormal results found. 3. Analysis on Lupine quinalizidine alkaloids. Also for these analyses there are no accredited laboratories and methods available. There is an official EU protocol for these analyses (VDUFA M 16.2.1.); However, this is not suitable for values < 1000 ppm. For this danger is, however, a standard of 200 ppm, so this protocol is not suitable. Appropriate method is the method of the University of Heidelberg/Prof. Wink using a HPLC. However, this is not an accredited method and therefore no ring tests are carried out (see note at point 2). Regarding this specific risk, company uses a danger associated with provenance of the lupine. During the audit, no abnormal results ofund. In summary: 3 significant risks that are governed by means of analysis, for which no accredited laboratory and/or method are available. Formally this is not in line with the requirements from info sheet 64 regarding the use of accredited analytical methods.	and/or method. Then a result, despite the matrix is not accredited, can be seen as reliable.
2015-4		**Scope 1** Company produces cheese and has outsourced transport and storage. This outsourcing is under the responsibility of this producer. This means that finished product at this producer is retrieved and interim stored externally. Transport and storage are included in the HACCP analysis and is included in the system of vendor evaluation and audits, etc. Transport and storage are not part of the scope on the certificate. Can transport and storage be part of the scope if the company if the CB verifies the outsourced service during the audit. What are the conditions for such an assessment? What are the consequences for the time allocation? The HACCP standard states in 5.1.2 that all outsourced activities should be properly included. How should the auditor verify this?	Transport and storage may not be included in the scope. It does not affect the time allocation. The auditor should verify that the outsourced processes are included in the hazards and risk analysis. Furthermore, the outsourced processes should be controlled.
2015-5		**Zoning** During Stage 1 audit it is assessed that a producer of microbiological vulnerable products (wet cakes) hasn't implemented sufficient zones Examples • No demarcation applied for clothing area's/colour visibility of hairnets/shoe changing cleaning • No additional requirements regarding cleaning and disinfection of hands • No physical separation between area's for cold cooked products and other	The company must examine to what extent the risks are secured and validated. In the HACCP standard there are no zoning requirements, however there are requirements regarding personal hygiene, air etc. that on the basis of risk analysis could lead to a zoning plan. In this particular case the auditor would have to look for the right balance between the hazards and risk analysis. PRP: such as. 3.2.4./2.4.6.2.)

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		ingredients in cooking and packing department • No positive release on products/intensive monitoring on microorganisms like enterobacteriacea • No frequent monitoring of air quality/pressure systems How to handle zoning? When should requirements be set on pressure systems, air quality monitoring, additional clothing requirements for personnel, environmental investigations on microbes (Listeria) etc	
2015-6		**Purchasing** A company buys fish around from suppliers all over the world and processes and sells the fish. The suppliers are used regularly. The hazard analysis on Purchasing mentions several significant risks, such as heavy metals (Hg tropical fish), histamine (tuna, mackerel) and bact. risks (eg. Listeria processed fish). The annual suppliers rating consists of assessment of complaints, quality, service, etc., also the supplier must have a certificate from a recognized food safety system (GFSI certificates, RVA-HACCP). The analysis plan mentions analysis of heavy metals or histamine. Although there is an odd analysis result to be showed, often sent by the supplier, it appears that the frequency of the analyses varies and, in all cases, is lower than the square root of the number of deliveries. The analysis plan deals with the monthly monitoring of bact. Risks including pathogens such as Listeria.	Info sheet 64 states that analysis of each delivery may be reduced to at least √ N in case of good results. Minor NC (5.4) based on legal requirements. 5.8.1 is not applicable as this is not a CCP
2015-7		**Traceability** A company manufactures an ingredient with a broad application field in food, pharma and chemical industry. There are several prod. lines for different levels of this ingredient (20% up to 99% and everything in between), forms (liquid, dried) and packaging (drums, IBC, cans, boxes, bulk etc.). It occurs frequently that certain semi-finished and finished products are added back into the process, usually to another line, whereby new (semi-finished and) end products are made. Although traceability is well arranged it is, according to the company, not do-able to trace back the raw material by end product batch, this can only be determined on ' head lines'. The mass balance of the traceability test does not take into account the reprocessing and relocation of semi-finished and finished products and 'end' as soon as semi-finished and finished products are fed back into the process. As a result, the new products don't appear in the mass balance anymore. By executing an extensive QC test program of purchased materials (oa contaminants like heavy metals) 'surprises' and thus recalls are prevented.	The Organization should take care of an effective track and trace system, in such a way that the company is able to recall the product in case of emergencies in time (5.9.3) In this case they can't. Conclusion: Major NC
2015-8		**Management of complaints** During an HACCP audit at a manufacturing company, the auditor sees a complaint related	During the audit at the production company the auditor should have raised a finding as the authorities NVWA and CB were not informed. Auditor should

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		to food safety, regarding a supplier. A few weeks later the same auditor conducts an HACCP audit with this supplier. The supplier had not registered this complaint, so it seemed it didn't exist. How should the auditor act? MAY/must he report this to this company or is confidentiality at stake?	discuss with the supplier the management of complaints. If the complaint was not registered, the auditor must raise a major finding. The relevance of food safety/health of the consumer has priority over confidentiality of the auditor.
2015-9		**Product specification** Bakery uses liquid egg as raw material. It is indicated by the supplier that at a storage temperature < 4 Gr. C a THT is guaranteed of 3 weeks. However, this raw material is stored by the bakery at 7 Gr. C and processed within 1 week. Bakery has carried out microbiological studies which show that the quality/microbiological results are within limits. Is this allowed?	For raw egg the legal requirement of storage is < 4 C. In this case it concerns pasteurized egg, so the law is not exceeded. If there is a validation report of the company with tests performed by an accredited lab (or equivalent) this approach should be approved. Conclusion: No finding.