











**Regulations &** 



### **Applications**







# **AGENDA**

- 1. Regulations
- 2. Applications
- 3. Examples





#### **EN ISO 22000**

"Management system for food safety"



The ISO 22000 is a world-wide accepted and harmonised safety standard and stands for:

- fulfil the world-wide standards of the food safety
- a management system along the entire food chain up to the end user



#### **EN ISO 22000**

# Stality Star

#### **Targets:**

- Supply of interactive communication
- Compliance with HACCP-requirements
- Harmonisation of the existing standards
- Formulation of a structure based on ISO 9001:2000
- Process control



#### **Pharmaceutical industry**



Currently there are no laws or regulations regarding the water activity (a<sub>w</sub>-value) for pharmaceutical or cosmetic products.

However there is a **USP** (United States Pharmacopeia) Method for non-sterile pharmaceutical products, wherein guidelines are described about the influence of the water activity of a product regarding the sensibility on microbial contamination

USP Method <1112>



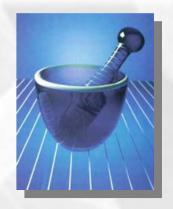
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#### **Development - Shelf life**



Customer demands and the continuous broadening of distribution channels require from the food manufacturer to find new ways to assures product stability by increasing the shelf life.

Stability and shelf life tests become consequently a relevant tool. However the manufacturers and suppliers starts more often to perform test series early during development. Hence factors and influences which will affect the product can be predicted and warded.



#### **Research & Development**

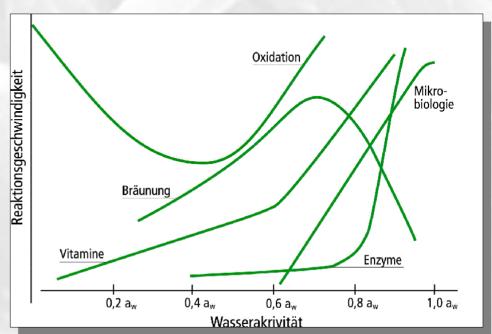
The water activity concept should be incorporated from the beginning

If start with a<sub>W</sub> concept than new products will be safe, have a maximised shelf life and the highest quality

Water activity data's can be used to predict potential hazards for new

products

Water activity should be used as a stability map to predict potential changes, reactions and hazards for new products!





#### **Additives**

#### Ingredients which bind water:

- Humectants
- Salt (NaCl)
- Sugar (Glucose, Fructose, Saccharose, Syrup)
- Glycol (Glycerine, PEG, Propylene Glycol)
- Amino acids (Glycin, Alanin)
- Polymers (Starch, Gum)
- Acids (citric acid, milk acid)
- Anti-caking additives





#### **Additives**

#### Limitations of aw-lowering

- Solubility
- Molecular weight
- Organoleptic
- crystallisation during storage
- Reactivity e.g. browning reactions
- Toxicity





#### **Raw Material Testing**

The knowledge of the water activity of raw materials assists the manufacturer for the estimation which ingredient is relatively safe and which substances would have to be treated carefully during the subsequent processing

Hence water activity measurement of raw material with a lower  $a_W$ - value could replace (or complement) extensive microbial routine tests



#### **Incoming inspection – raw material**



- Many companies are requiring their suppliers to meet water activity specifications on the products or ingredients
- The specification of the water activity of raw material insures a constant product quality
- When the water activity of a product changes, problems can be traced either during processing or due to ingredients



#### Water activity of dehydrated products

Advantages of powders and dehydrated products:

- increasing of the shelf life of the product by lowering the water content and water activity (a<sub>W</sub>)
- manufacturing of "convenient food"
- reduction of weight what enables a better transport and storage
- necessary step during production

The control of the water activity in dry and dehydrated products preserves its structure, texture, stability, density and the possibility of reconstitution.



#### Caking

Caking is the phenomenon where an arid, free flowing powder is transformed to clumps or agglomerates.

This is an omnipresent problem within the food and pharmaceutical industry and depends on the water activity, time and temperature

To preserve the good free flowing property of a powder and to prevent the caking of a powder the following methods can be applied:

- dehydration on a low water content
- conditioning at low air humidity and packaging in airtight packing
- storage at low temperature
- agglomeration
- additives and anti-caking-substances





#### **Advantages of Water Activity Measurement**



- a<sub>W</sub> measurement is almost always faster than any moisture content method
- a<sub>W</sub> measurement is more accurate compared to the range of measurement values
- a<sub>W</sub> measurement is easier in setup, performance and has a direct readout
- a<sub>W</sub> measurement takes less time and material to perform calibration and validation
- a<sub>W</sub> measurement is often less expensive compared to Karl Fischer, loss-on-drying or NIR measurement



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#### Shelf life of long-life bakery products

Long-life bakery products such as sponge cake are good examples of food where the water activity is one of the main preservation factor. These bakery products have a durability of approximately 6 months in spite of a water content between 15 to 27%. The filling of these products consists of a variety of different sugars, jams or chocolates.

Example of a sponge cake with chocolate filling:

|                         | Water activity (aw) | Moisture content (%) |
|-------------------------|---------------------|----------------------|
| Dough                   | 0.755               | 23.2                 |
| Milk-caramel-<br>mousse | 0.785               | 15.4                 |



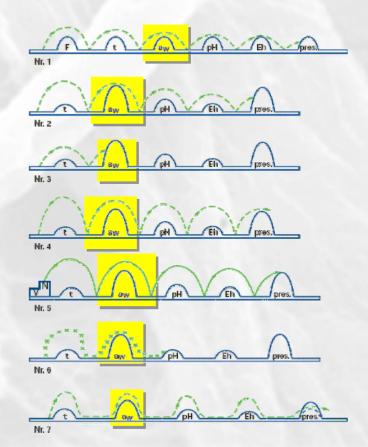


#### Shelf life of long-life bakery products

The main preservation factor is the  $a_w$ -value which is set in a range between 0.7 and 0.8  $a_w$ . This may be achieved by the help of different sugars (glucose,

saccharose) or polyol (sorbitol).

But also to spray the surface of a product with ethanol helps to control the growth of xerophilous molds. These steps, together with a packaging under controlled atmosphere build a hurdle technology which assures the microbial stability.





# **Example: Influence of the sample preparation for pancakes**



Product was pressed into the sample dish:

- stable result after 34 minutes (1 minute stab. time) 0,875aw
- aw-value after 3 hours 0,935aw

Product was pressed into the sample dish and the surface was carved with a knife:

- stable result after 4 minutes (1 minute stab. time) **0,941aw**
- aw value after 40 minutes 0,941aw



#### **Cosmetic Industry**

Example: lip balm

- low moisture content, approx. 1% to 2%
- but the water activity was 0.8aw



#### Solution:

- Addition of further ingredients to the aqueous solution during formulation
  - lowering of the water activity
  - "natural" conservation