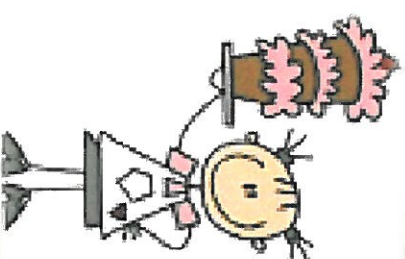


# The ZA CTD It's a piece of cake



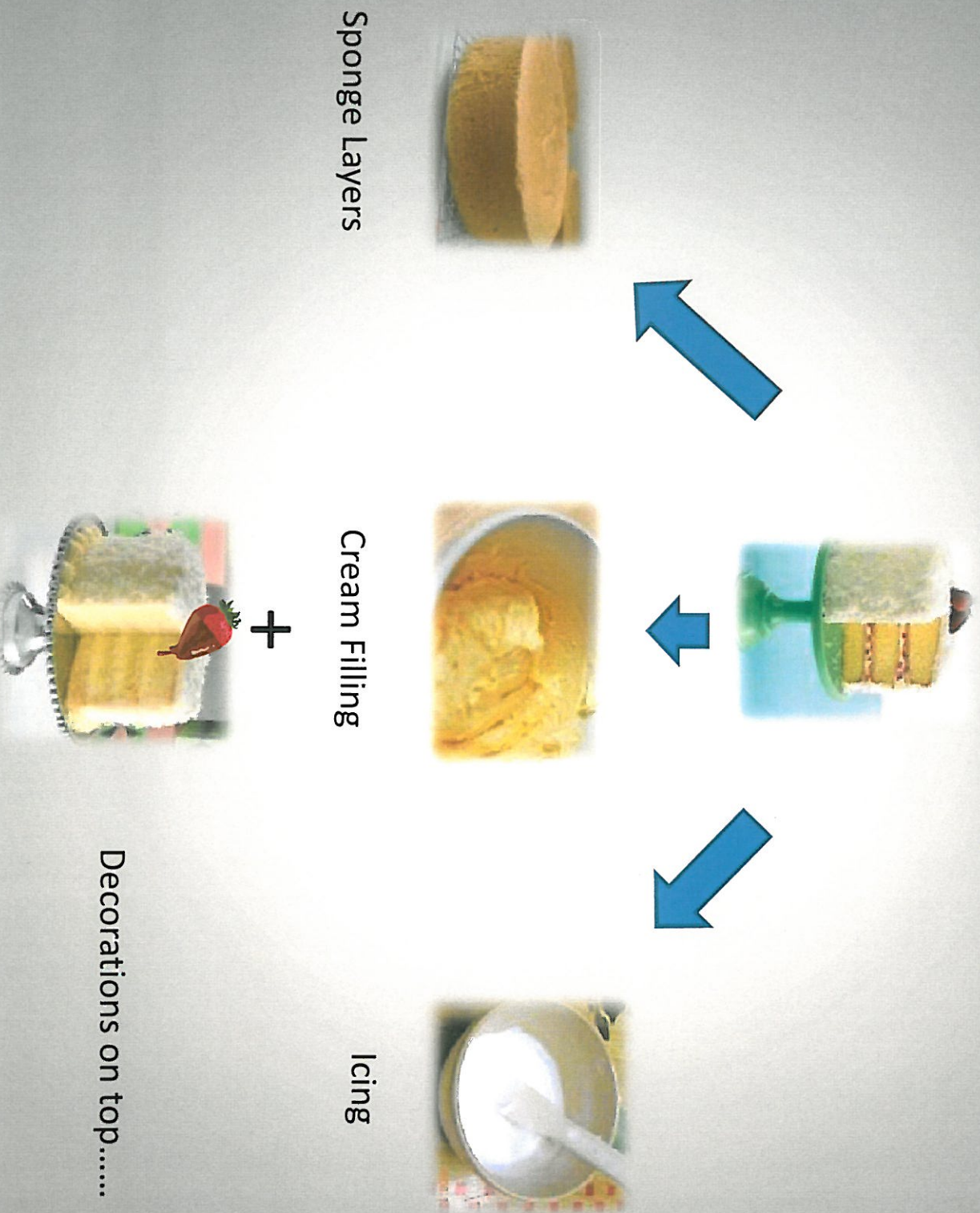
SAPRAA – 15 September 2010  
Hilde Rodseth

# INTRODUCTION

The CTD is a dossier format:



# Dossier Format + Requirements = ZA CTD



## Local ZA Company

Has to bake the cake from scratch

## Multi-national Company

Gets basic cake from overseas

Just need to add:



Cream filling



Icing



Decorations



Recipe – in the MCC's ZA CTD  
Guidelines

BIZA document created for decorating an EU CTD into a ZA CTD cake.



**Purpose:**

- Highlight areas where ZA application goes beyond EU CTD [= need for fillers]
- Guide an EU regulatory partner regarding the recipes [= source in ZA guidelines]

This document is **not** a comprehensive overview of all information required for a ZA CTD

# ZA CTD vs EU CTD

## Modules 2, 3, 4 and 5



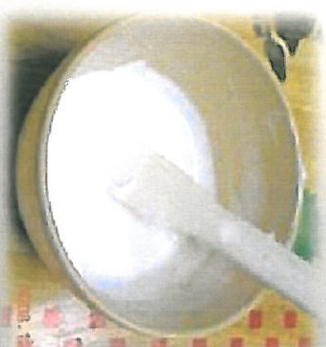
Layers



Cream Filling

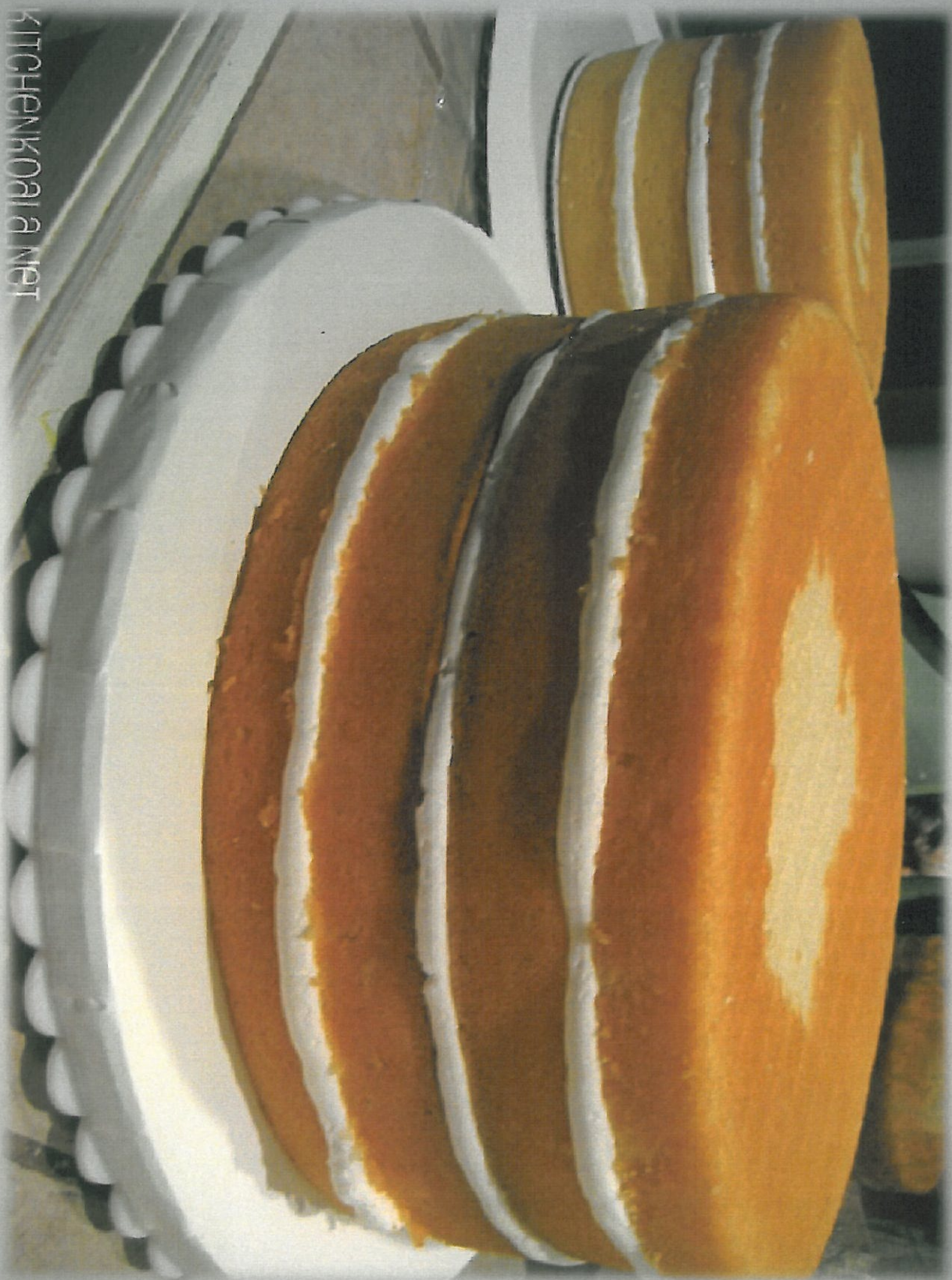


Microsoft Office  
Word Document



Icing

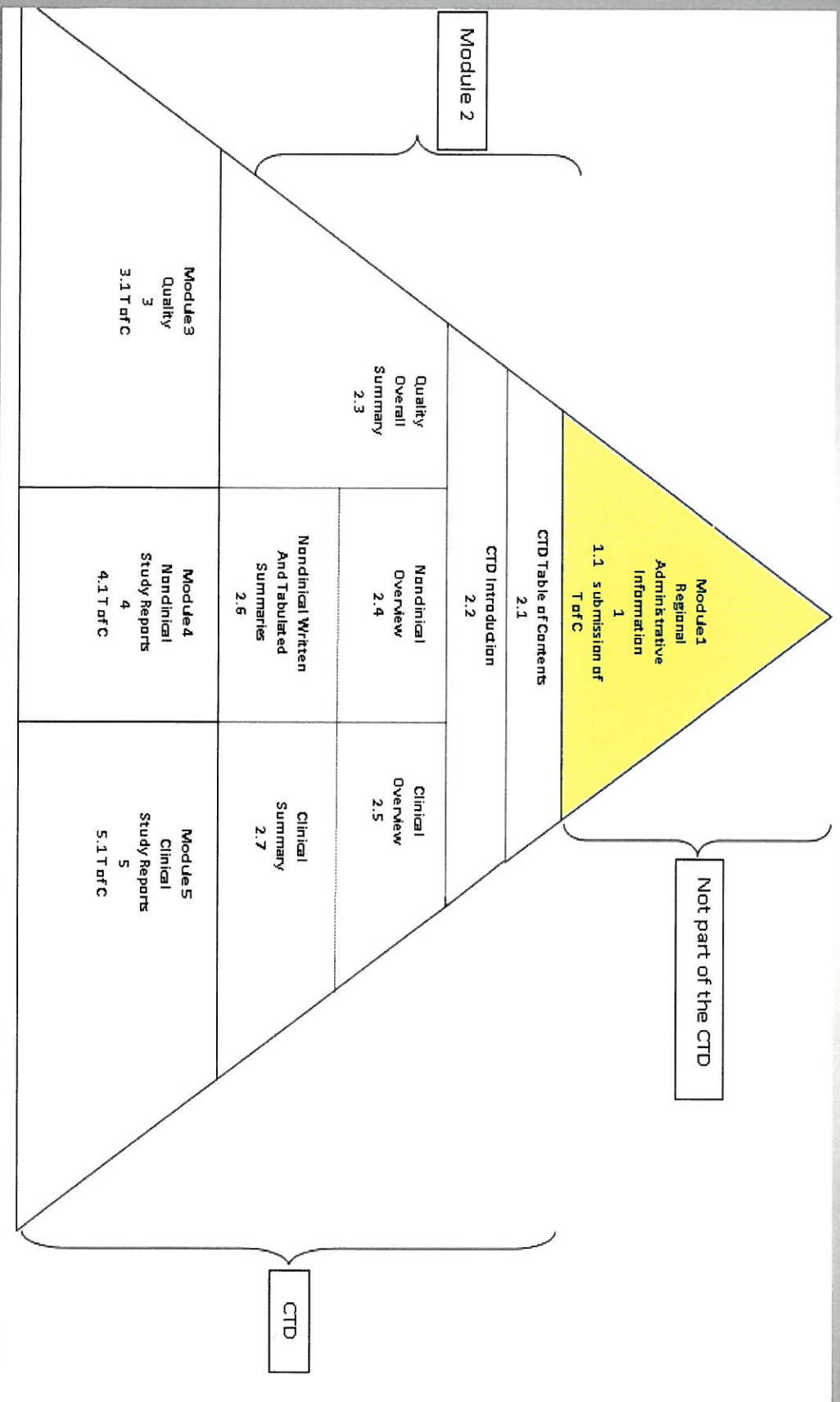
KITCHENROAI A NET



# MODULE 1



Microsoft Office  
Word Document







The  
Final  
ZA CTD  
Is Ready  
to  
be  
Served

# Conclusion

- The ZA CTD is a very rich cake
- The EU CTD needs a lot of 'decorating' to make a ZA CTD
- Question – is this really necessary in all cases, or is there opportunity to reduce our regulatory indigestion?





АТһу әруік сыноһд?