



# Proposed amendment of the Harmful Substances in Food Regulations (Cap. 132AF)

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Centre for Food Safety  
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# Proposal

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- To amend the Harmful Substances in Food Regulations (Cap. 132AF) so that the restriction of prohibited substances in Schedule 2 will be extended to cover dried milk, condensed milk and reconstituted milk



# Background

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- Food incidents involving infant formulas in recent years
- E.g. the detection of melamine in 2008 and suspected presence of estrogen in 2010
- Concern about the spillover of problem infant formulas into Hong Kong
- Whether the current regulatory regime in Hong Kong has provided sufficient control over this food item



# Regulation of Public Health and Municipal Ordinance (Cap. 132)

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- Section 54 of the Public Health and Municipal Service Ordinance (Cap. 132) stipulates that all food on sale must be fit for human consumption
- The safety of infant formulas (as food) is regulated through section 54
- Prosecution actions will be taken if it is found to be unfit for human consumption



# Presence of exogenous hormones in milk powder

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- Public concern over the suspected presence of estrogens in some infant formula which led to suspected cases of precocious puberty in some children in the Mainland in August 2010
- We have reviewed whether there is any specific statutory control governing the presence of hormones of exogenous origin in milk powder



# Review of relevant legislation – food traceability

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- Under Food Safety Ordinance (Cap. 612), importers of food (including dried milk, condensed milk and reconstituted milk) are required to register with the Director of Food and Environmental Hygiene and to keep import and supply record of the food
  - already enhanced traceability in case of a food incident involving infant formula in Hong Kong
  - introduction of a new import control on these items is not necessary



# Review of relevant legislation – food standards

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- Colouring Matter in Food Regulations (Cap. 132H)
- Sweeteners in Food Regulations (Cap. 132U)
- Food Adulteration (Metallic Contamination) Regulations (Cap. 132V)
- Mineral Oil in Food Regulations (Cap. 132AR)
- Preservatives in Food Regulation (Cap. 132BD)



# Review of the relevant legislation

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- Conclusion –

Except for the Harmful Substances in Food Regulations (Cap. 132AF), no amendment to other legislations is necessary as they provided sufficient food safety control on food and the broad definition of food already covers dried milk, condensed milk and reconstituted milk





# Harmful Substances in Food Regulations (Cap. 132AF)

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- The Harmful Substances in Food Regulations (Cap. 132AF) governs the import and sale of food containing harmful substances
  - Schedule 1 –
    - sets out the maximum concentration of certain substances present in specified food
    - under Regulation 3, no person shall import, consign, deliver, manufacture or sell, for human consumption, any specified food which contains any substance in greater concentration than is specified in Schedule 1



# Harmful Substances in Food Regulations (Cap. 132AF)

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- Schedule 2 –
  - sets out the prohibited substances not allowed in any fish, meat or **milk**
  - under Regulation 3A, no person shall import, sell or consign or deliver for sale for human consumption, any fish, meat or **milk** which contains any substance specified in Schedule 2
- As the definition of “milk” in Cap. 132AF excludes dried milk, condensed milk and reconstituted milk, the concentration limits in Schedule 1 or prohibition of prohibited substances in Schedule 2 do not apply to dried milk, condensed milk and reconstituted milk (except melamine)



## Expansion of scope of concentration limits in Schedule 1 of Cap. 132AF

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- The Working Group on Standard Setting for Veterinary Drug Residues in Food advised that it would be very difficult to establish maximum residue limits (MRLs) in milk powder because the manufacturing process may change the veterinary drug residues in many ways
- For example, the dehydration process may either increase or decrease the residue level depending on the solubility of the veterinary drug
- The same applies to condensed milk and reconstituted milk
- Based on the experts' advice, we have therefore decided not to extend the MRLs for milk in Schedule 1 to cover dried milk

# Expansion of the scope of prohibition of prohibited Substances in Schedule 2 of Cap. 132AF

- From a risk assessment point of view, it is unacceptable to find the presence of the prohibited veterinary drugs in dried milk, condensed milk and reconstituted milk
- In view of the exclusion of “dried milk” in the definition of “milk”, the presence of the exogenous estrogens on Schedule 2, namely Dienoestrol, Diethylstilboestrol and Hexoestrol, in infant formulas are not prohibited by Cap. 132AF
- Hence, expanding the scope of the prohibition of prohibited substances in Schedule 2 of Cap. 132AF by amending Regulation 3A will address the issue



# Risk Assessment

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- CFS collects samples of milk powder for both chemical and microbiological testing every year. **ALL** testing results in the past 4 years are satisfactory
  - **Chemical testing:** Antibiotics, Anti-oxidants, Colouring matter, Metallic contamination, Composition, Radioactive contaminants, Mineral oil, Pesticides, Preservatives, Sweeteners, Toxins, Dioxins, Melamine, Food spoilage, Foreign matter, Allergen, Hormones
  - **Microbiological testing:** Indicator organisms, Pathogens, Enterobacter sakazakii



# Risk Assessment

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- Dried milk not as perishable as milk
- Presence of pathogens in dried milk reduced by the manufacturing process, hence risk of having pathogens is low
- Possible that it may contain prohibited veterinary drugs as prescribed in Schedule 2 of the Harmful Substances in Food Regulations (Cap. 132AF)



# Risk Assessment

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- As infant formula is the main food item for babies, the public would expect a stringent control by the Government given babies' vulnerability
- From a risk assessment point of view, it is unacceptable to find the presence of the prohibited veterinary drugs in dried milk, condensed milk and reconstituted milk



# Proposed Legislative Amendments

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- To expand the scope of the restriction of prohibited substances in Schedule 2 of Cap. 132AF to cover dried milk, condensed milk and reconstituted milk
- To define the term “dried milk”, “condensed milk” and “reconstituted milk” for clarity. We will define “dried milk” wide enough to cover not just infant formulas but other milk powders for all age groups





# Proposed definitions

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- “Dried milk” (奶粉) means milk, skimmed milk or partly skimmed milk which has been concentrated in the form of solid or powder by removal of water, and includes any such milk which has been sweetened, modified or compounded intended for human consumption by all age groups



## Proposed definitions

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- “Condensed milk” (煉奶) means milk, skimmed milk or partly skimmed milk which has been condensed by the evaporation of a portion of its water content, whether or not sugar has been added, and includes evaporated milk (淡奶)



# Proposed definitions

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- “Skimmed milk”（脫脂奶） includes separated or machine skimmed milk
- “Reconstituted milk”（再造奶） means products resulting from the recombining with water of milk constituents, namely, milk fat and other solids derived from milk exclusive of any other substance, and includes the products resulting from the melting of frozen concentrated milk



# Outcome

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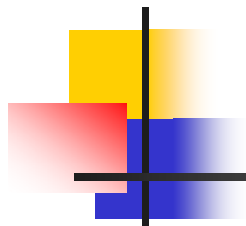
- When the amendments are passed by LegCo, the three exogenous estrogens on Schedule 2 would be prohibited in infant formula
- The potential problem highlighted by the suspected contaminated infant formula in the Mainland in last August would have been tackled



# Timetable

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- Consult the Food Safety and Environmental Hygiene Panel of the Legislative Council (LegCo) on 14 June 2011
- Aim to table the amendment regulation at LegCo in end 2011



# Q&As