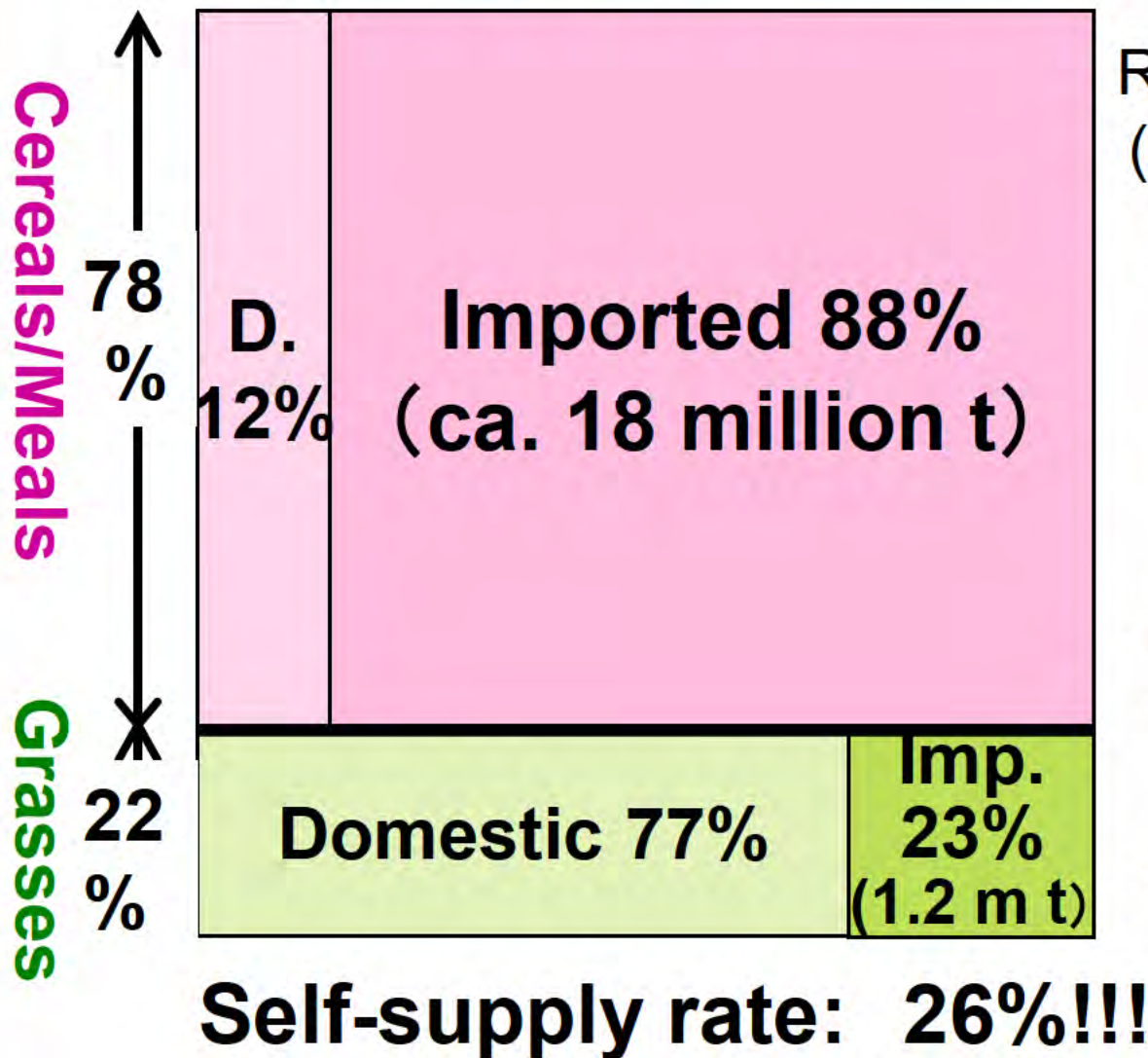


Chemical Safety of Feed - Japan -

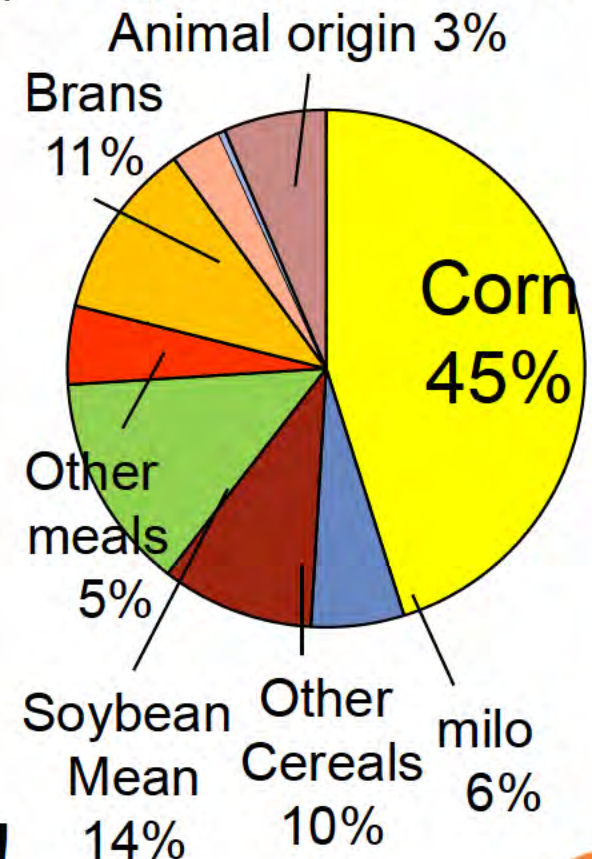


Yukiko Yamada, Ph.D.

SUPPLY OF FEED IN JAPAN (TDN BASIS, 2011)



Raw Ingredients of Feed
(2011, Total 24 million t)



IMPORTATION OF CEREAL GRAINS FOR FEED

Importation of Cereal Grains for Feed in Japan (2011)

Corn: 10.6 Milo: 1.3
Barley: 1.1 Others: 0.5
(in million tons)

Canada

Wheat (30%)
Barley (47%)

Corn in the USA (2011-12)
Production: 314
Export: 39
(in million tons)

USA

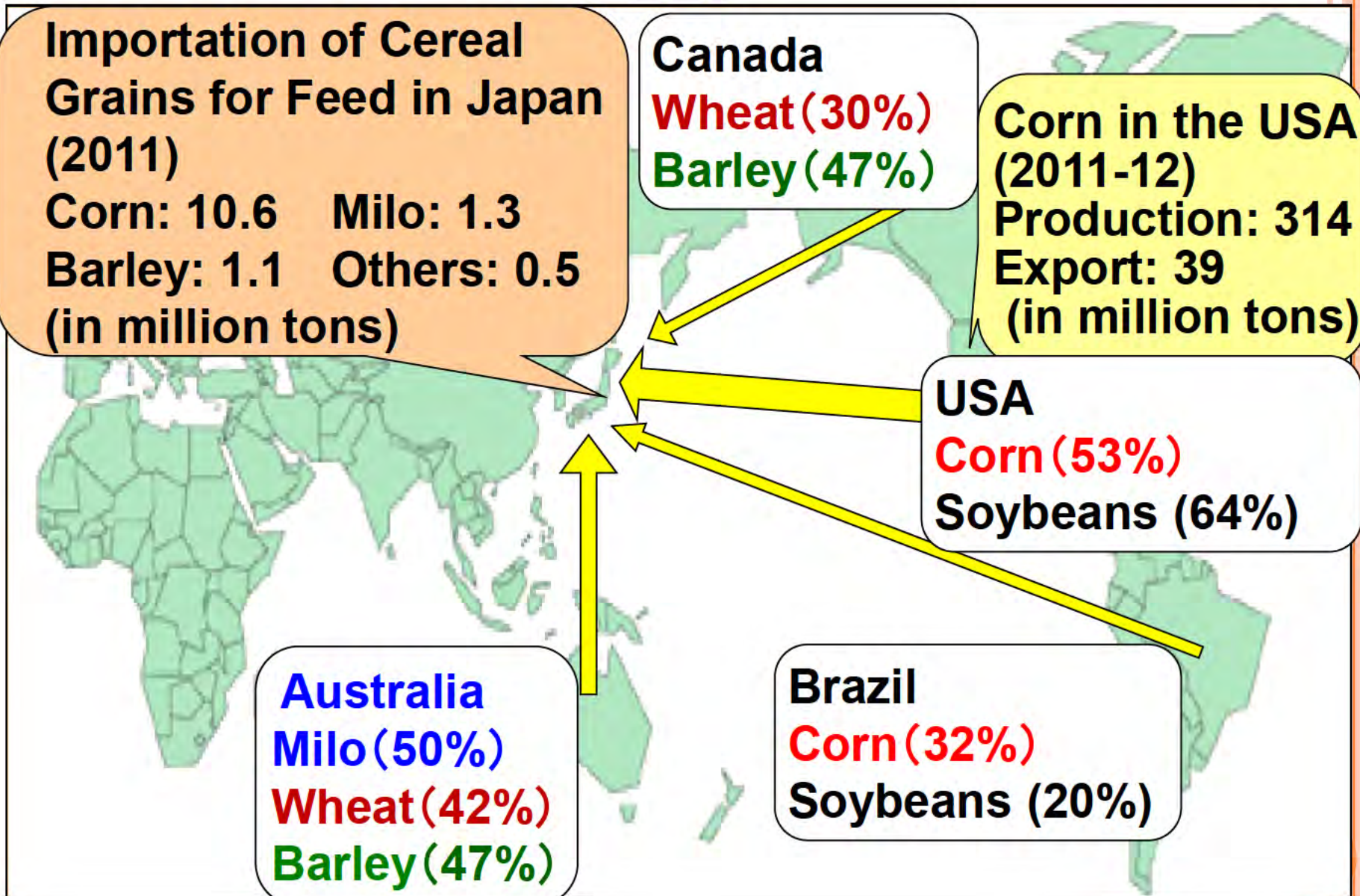
Corn (53%)
Soybeans (64%)

Australia

Milo (50%)
Wheat (42%)
Barley (47%)

Brazil

Corn (32%)
Soybeans (20%)



CHEMICALS CONTROLLED

- Unintended presence – Difficult to control
 - Natural toxins, such as aflatoxins, ochratoxin A, phytotoxins, etc.
 - Environmental contaminants, such as heavy metals, arsenic & radionuclides
- Resulting from intentional use – Easier to control
 - Pesticide Residues
 - Feed additives
 - Nutrients
 - Pharmaceuticals
 - Additives for maintaining the quality of feeds, such as antioxidants




DIVISION OF RESPONSIBILITIES

- Food Safety Commission
 - Risk assessment: Safety of foods of livestock origin to **humans**
 - Ministry of Agriculture, Forestry and Fisheries
 - Risk assessment: Safety of feed to **livestock** (including fish in aquaculture)
 - Risk management and exposure assessment (Feed Safety Law):
 - Setting maximum residue levels/maximum levels for pesticides and contaminants
 - Establishing quality and safety standards for feed additives
 - Inspection of manufactures (factories)
 - Others (GM feeds, prion, endophytes, etc.)
- 

Selection of Chemicals to Be Regulated



SELECTION OF CONTAMINANTS

- Literature search → Risk profiles → Published
Consideration of the growing conditions
→ High probability of occurring in raw materials
of feed and/or foods of livestock origin
→ Potential to affect the health of humans
and/or livestock
- Mycotoxins (aflatoxins, DON, zearalenone)
Potential for adversely affect the health of
livestock (acute or chronic effect)
 - Heavy metals (Pb, Cd, As, Hg)
Potential for accumulation in animal organs
 - Radionuclides (immediately after the
accident)
- 

SELECTION OF TARGET FEED ITEMS

Controllable through risk management measures

- Mycotoxins in composite feed
Mycotoxin concentrations can be reduced by removing dusts and broken grains, or by changing ratio of the raw material
- Heavy metals in:
 1. Hay/Fodder and fish meal
 - High heavy metal concentrations
 - Farmers buy these raw materials
 2. Composite feed
 - Extraneous materials, such as paint and metal fragments found in the past



SELECTION OF PESTICIDES

Pesticides used to protect those crops fed to livestock:

- Pesticides authorized in Japan for application on those crops used as feed or raw material of feed
 - New pesticides developed and registered or in the process of registration in feed exporting countries
 - Pesticides detected frequently in feed in surveillance/monitoring by the Government
- Data from supervised residue trials were taken into consideration.



SELECTION OF TARGET FEED

Raw materials used in feed and fed to livestock in a large amount

- Cereal grains (mostly imported)
 - Corn, milo, barley, wheat, rye, oat
- Grasses (mostly imported)
 - Residues on/in alfalfa, timothy grass and other imported grasses from residue trials conducted in exporting countries
 - Establish an **MRL** for “hay/fodder” (adjusted to 90% DM) (also **import tolerance** upon request)
- **Rice** straw, rice whole crop silage, rice grown for feed (mostly domestic production)



Studies using livestock



FEEDING AND METABOLISM STUDIES

Feeding study

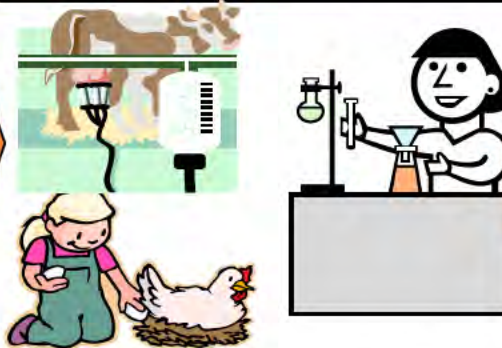


Continuous feeding
at Low-high doses

Metabolism or
toxicological studies
on lab. animals or
livestock



Analysis of
Tissues



Determination of
chemicals

Analysis of
tissues

Effect on health

Concentration
of chemicals in
feed not
resulting in
accumulation
in tissues


AND

Concentration
of chemicals
in feed without
adverse
health effect
on livestock

EFFECT ON THE HEALTH OF LIVESTOCK

Regular literature search plus:

During feeding studies, collect data on:

- Health conditions, such as diarrhea, sialorrhea or any other abnormal symptoms
 - Intake of feed
 - Weight gain
 - Milk production (cattle) or egg production (hens)
 - Hematologic examination
 - Red blood cell count
 - White blood cell count
 - Hematocrit
 - Hemoglobin
- 

EFFECT ON THE HEALTH OF LIVESTOCK

- Biochemical examination of blood
 - Enzymes: GOT, GPT, ALP and LDH
 - Blood urea nitrogen
 - Total bilirubin
 - Total cholesterol
 - Triglycerides
 - Glucose
 - Total protein
 - Albumin

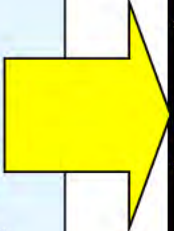
At the end of feeding studies → sacrifice

- Any lesions in tissues and organs
- Weight of organs



EXAMPLE: AFLATOXIN B1

Continuous administration of Aflatoxin B1 to lactating cows at 0.01, 0.03 and 0.1 mg/kg in feed for 28 days



Conc. in Feed (mg/kg)	Aflatoxin M1 in Milk ($\mu\text{g/kg}$)
0.01	0.05-0.24
0.03	0.25-0.48
0.1	1.1-1.7

At the highest dose (10 times the ML in feed), no abnormalities were observed in milk production, feed intake and health conditions. No lesions of tissues or organ weight changes were observed after the 28-day feeding period.

RISK ASSESSMENT FOR HUMANS

- Requesting risk assessment by the FSC is mandatory by the Food Safety Basic Law
- Conducted by the Food Safety Commission
- In the same manner as contaminants/pesticides in human foods
- Toxicological evaluation of data
- Resulting in TDI/ADI
- In some cases such as mycotoxins, exposure assessment is conducted



Setting MLs/MRLs



SETTING MLS FOR CONTAMINANTS

- In principle, follow the process described in the Codex General Standard for Contaminants and Toxins in Food and Feed
 1. Collect **occurrence data** through surveillance/monitoring
 2. Draw a distribution curve
 3. Apply the **ALARA principle**
 4. Prepare a proposal for ML
 5. Calculate potential highest total intake from feed (worst case scenario) using the table of feed rations in Japan



SETTING MLs FOR CONTAMINANTS 2

7. If necessary, conduct an animal feeding study (1x, 3x and 10x)
8. Estimate the concentration in edible tissues of livestock/milk/eggs using the result of feeding study (can be from literature or outside sources)
9. Estimate exposure from foods
10. Request the Food Safety Commission to conduct risk assessment for humans (mostly hazard characterization)
11. Final proposal for ML



SETTING MRLS FOR PESTICIDES

- In principle, follow the process used by JMPR
 1. Obtain **residue data from supervised trials** on feed crops or crops whose byproducts may be fed to animals (pesticide registered in Japan or pesticides for which import tolerance is requested)
 2. Review residue data
 3. Prepare a proposal for MRL
 4. Calculate potential highest total intake from feed (worst case scenario) using the table of feed rations in Japan



SETTING MRLs FOR PESTICIDES 2

7. Estimate the concentration in edible tissues of livestock/milk/eggs using the result of feeding study (manufacturer's submission, or can be from literature)
8. Estimate exposure from foods
9. Request the Food Safety Commission to conduct risk assessment for humans (mostly hazard characterization)
10. Final proposal for MRL for feed
11. If necessary, request MHLW to amend the MRLs for foods of livestock origin



ADDITIONAL GUIDANCE ON CONTAMINANTS

- If necessary,
 - Provide guidance on the preparation of raw materials or feed to reduce the concentration of contaminants of concern
- As Japan is importing a large amount of feed, establish a time-limited MLs for certain natural toxins as necessary as long as the health of humans and livestock is not adversely affected.
- Regular inspection of manufacturing sites and provide guidance on corrective action as necessary.



THANK YOU FOR YOUR ATTENTION!

**FOR SAFE FOODS OF ANIMAL ORIGIN, THE
SAFETY OF FEED IS OF EXTREME
IMPORTANCE**

