

Positive list system and MRLs in Japan

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Department of Food Safety

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What is the Positive List System?

In general,

○ Negative List

In the situation where there is no general regulations, make a list of substances to be regulated

○ Positive List

In the situation where all the substances are regulated (banned) in principle, make a list for those that are approved exceptionally (to be used or to be remained)

Positive List System for Agricultural Chemical Residues

【 Previous Regulation 】

Pesticides, Feed Additives,
and Veterinary Drugs

Chemicals for which
MRLs are established

283 substances

MRLs for 250 Pesticides and
33 Veterinary Drugs



Foods containing chemicals
above the MRLs are enjoined
from domestic distribution

Chemicals for which MRLs
are not established



Basically, even foods found
to contain chemicals are not
enjoined from distribution.

【 Enforcement of Positive List System 】 May 29 2006~

Pesticides, Feed Additives and Veterinary Drugs

Chemicals for which
MRLs are established

799 substances

Establishment of
provisional MRLs for
agricultural chemicals,
considering Codex
standards, Japanese
registration withholding
limits, and other standards
established based upon
scientific evaluation

758 substances

Acceleration of the
establishment of MRLs

Foods containing chemicals
above the MRLs are
enjoined from domestic
distribution.

Chemicals for
which MRLs are not
established

Establishment of a
certain level that is
determined to
pose no adverse
health effects

0.01 ppm

Foods found to
contain chemicals
above the level are
enjoined from
domestic distribution.

Chemicals
designated by
MHLW

Chemicals that
do not pose
adverse health
effects

65 substances

Not subject to the
positive list
system

Basic Idea of Establishing the Uniform Limit

○ Study of Acceptable Amount

- “Acceptable Exposure Amount” based on the international assessment
 - Evaluations of flavoring agents by JECFA
 - Evaluations of indirect additives by the US FDA
- ADIs that had been already evaluated in Japan or by JMPR or JECFA
 - It is appropriate to use an amount of 1.5 μg/day as a reference acceptable amount

○ Study of exposure assessment

In the light of the nation's amount of intake, an Uniform Limit of 0.01 ppm is established so that the amount of intake regulated by the Uniform Limit should not exceed 1.5 μg/day.

Area in which positive list system is adopted and their uniform criteria

- EU: 0.01 ppm
- Germany: 0.01 ppm
- New Zealand, Canada: 0.1 ppm
- USA: Uniform criteria is not set. However, 0.01 ~ 0.1 ppm is virtually used.

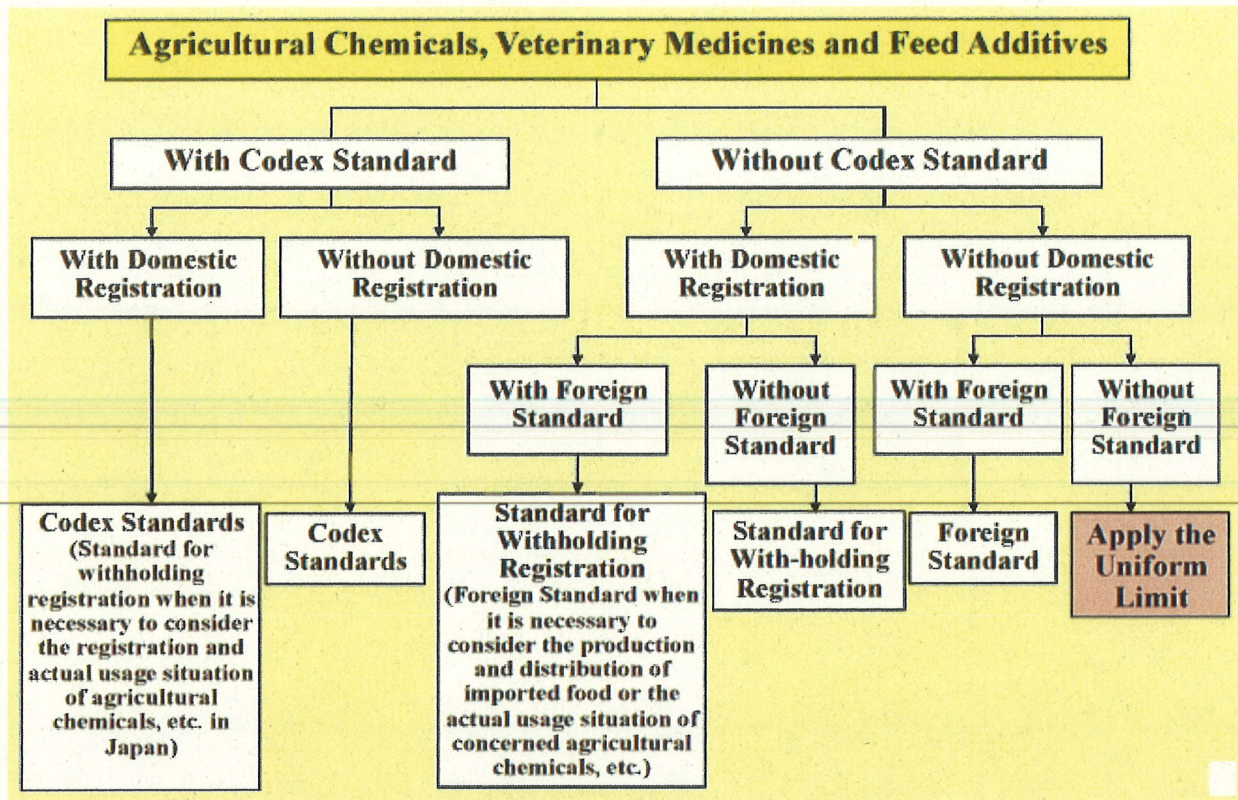
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Basic Idea for Exempted Substances

○65* substances are selected as Exempted Substances

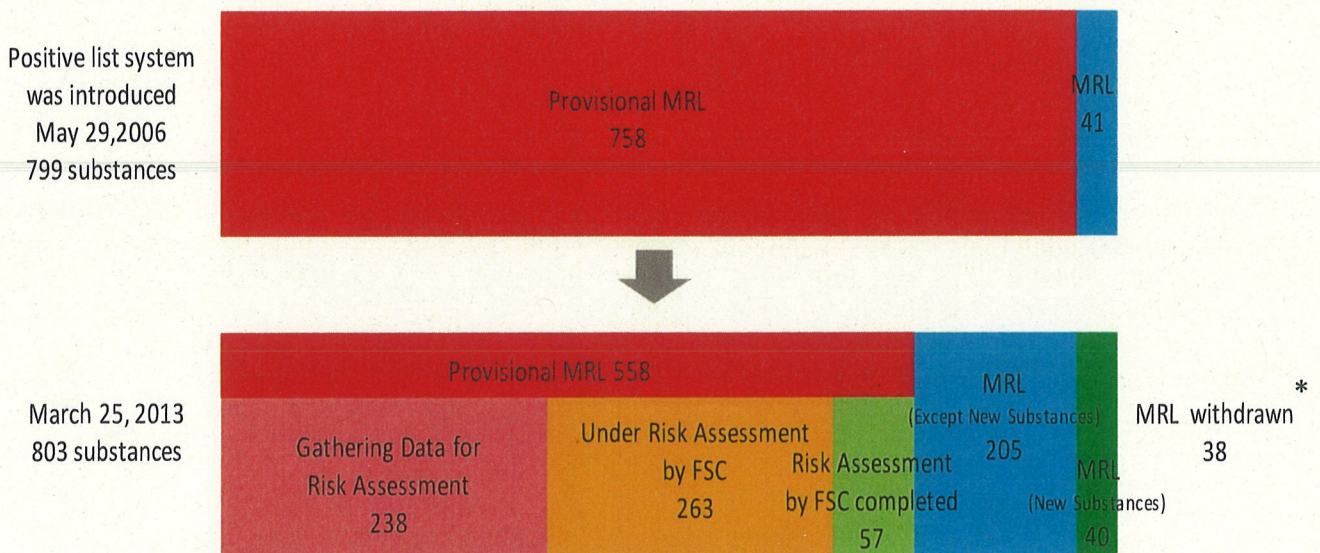
- Agricultural chemicals and their decomposition products which are determined to have no potential to cause damage to human health, even if they remain in food to a certain level.
- Specified agricultural chemicals provided in the Agricultural Chemical Regulation Law.
- Agricultural chemicals which are determined not to have to set the residue standards in foreign countries and whose usage is not restricted.
(* :66 substances, as of August 2009)

Establishing Provisional MRLs



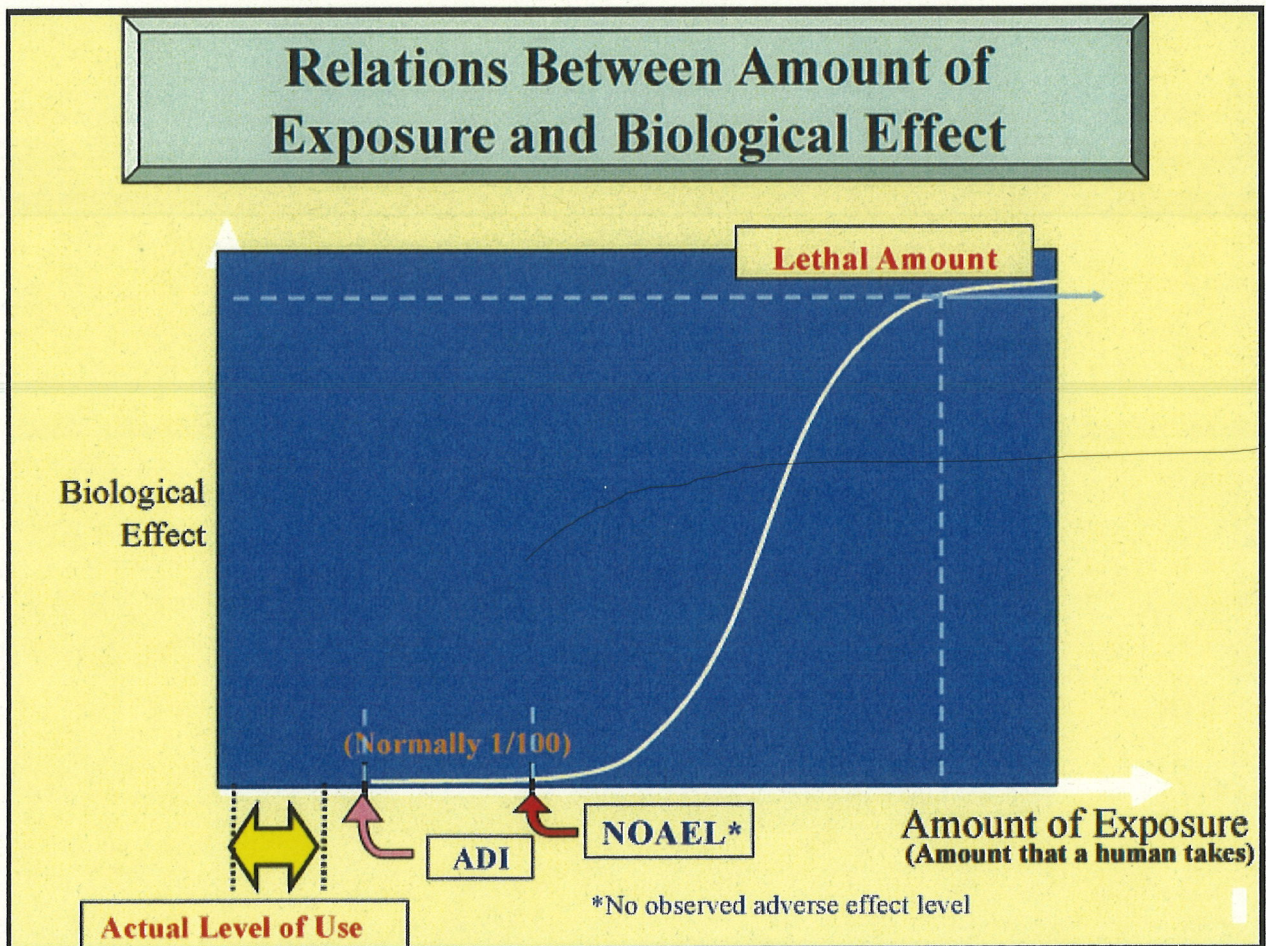
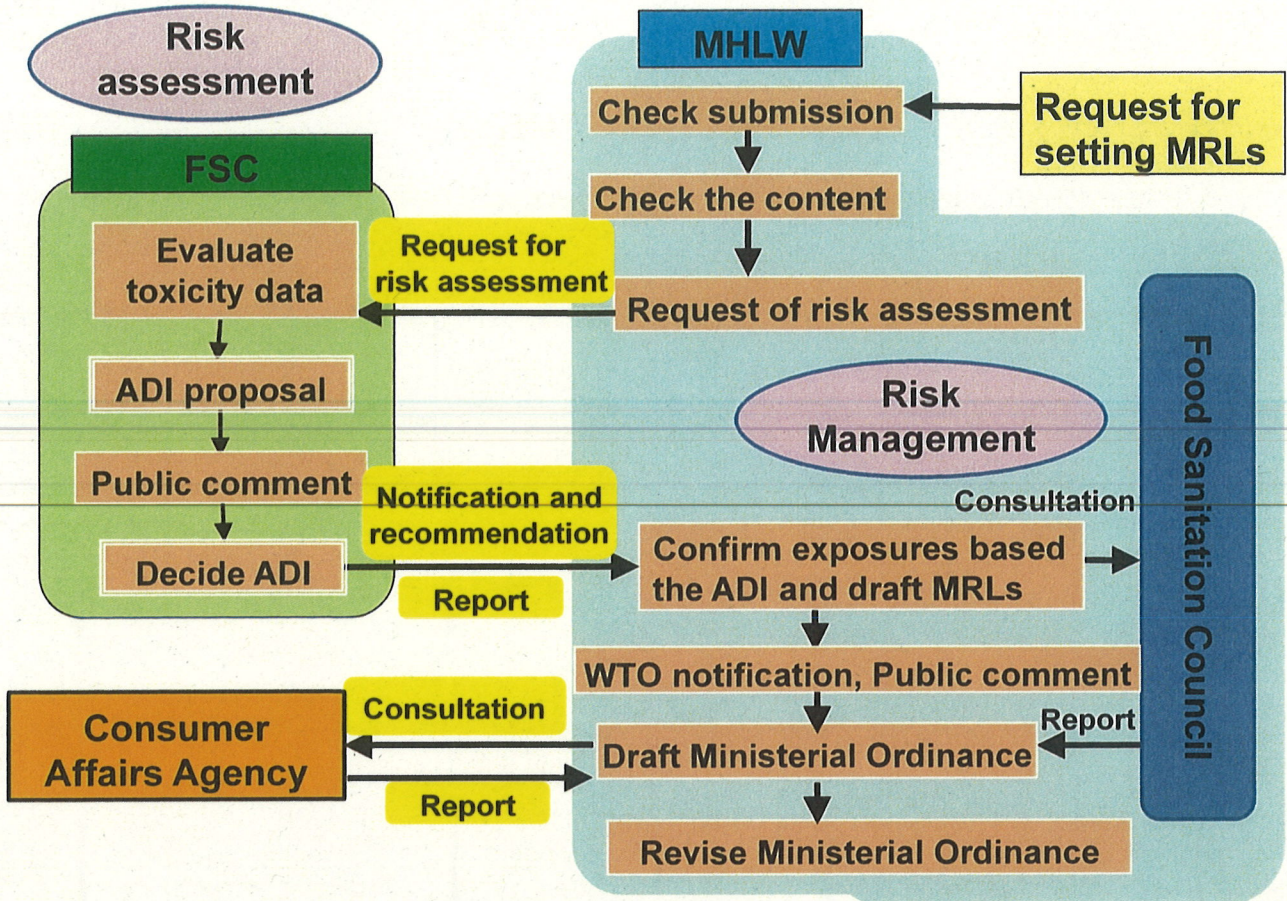
<http://www.mhlw.go.jp/english/topics/mrls/final/dl/mrls02.pdf>

Reviewing Provisional MRLs

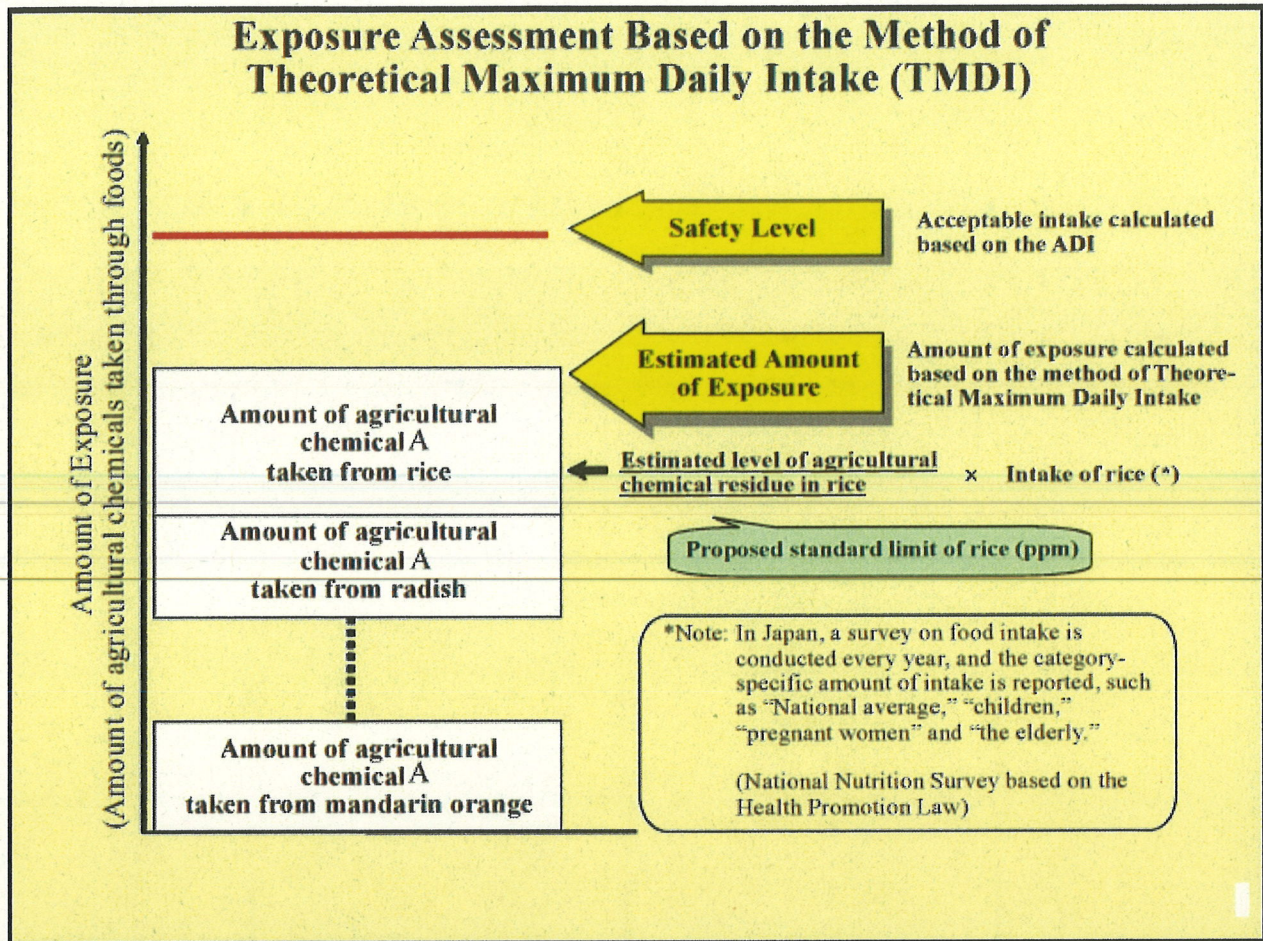


* MRLs for 38 chemicals were withdrawn. Basically, when definite adverse health effects of chemicals and their degree have been found, the MRLs for these chemicals are withdrawn.

Process of Setting MRLs



Exposure Assessment Based on the Method of Theoretical Maximum Daily Intake (TMDI)



Useful Information

- Search for the MRLs

<http://www.m5.ws001.squarestart.ne.jp/foundation/search.html>

- Import Tolerance

<http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html>