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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 15193.18-2015

Replacing GB 15193.18-2003

National food safety standard -- Health guidance values

食品安全国家标准 健康指导值

(English Translation)

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Foreword

This standard replaces GB 15193.18-2003 "acceptable daily intake (ADI development)." this standard compared with GB 15193.18-2003, the main changes are as follows.

--- Standard name was changed to "national food safety standard health-based guidance value";

--- Modify the scope of the standard;

--- Modify the terms and definitions;

--- Added "health-based guidance value";

--- Revised ADI developed overview;

--- Delete the words "the development of acceptable daily intake of some exceptions."

National Food Safety Standard Health-based guidance values

1 Scope

This standard specifies the method for the development of food and food-related chemical health guidance values.

This standard applies to have the threshold can cause toxic effect of the test substance.

2 Terms and definitions

NOTE: health-based guidance values related terms covered in this chapter bilingual and acronyms in Appendix A.

2.1 Health-based guidance values

Human a period of time (lifetime or 24h) ingested something (or some) substance without producing detectable adverse health effects of Safety limits, including the acceptable daily intake, tolerable intake, acute reference dose and the like.

2.2 Starting point

Or sensitive data from dose groups observed indicators of experimental animals - response relations for extrapolated dose values of health-based guidance values, If no observed adverse effect level and the reference dose and the like.

2.3 No observed adverse effect level

Through animal experiments, the existing technical means and detection index was not observed any harmful effects of the test substance-related maximum dose.

2.4 Minimum observed adverse effect level

Under specified conditions, the test substance causing a minimal effect dose animal tissue morphology, function, growth and development, and other harmful effects.

2.5 Benchmark dose

Based on the dose - response relationship of research results, obtained using statistical model was caused by a particular test, a lower health risk issue Students rate (typically 10% quantitative data, qualitative data was 5%) 95% confidence interval dose limits.

2.6 Uncertainty factor

Safety factor

For the development of health-based guidance values applied outside push from animals to humans (assuming that the most sensitive), or from some individuals extrapolated to the

general Composite coefficient group used.

3 Health-based guidance values

Note: This chapter covered health-based guidance values related terms and acronyms bilingual word Appendix A.

3.1 Acceptable daily intake

A human lifetime daily intake of chemicals normally used (such as food additives), no detectable adverse health effects of the amount. An amount per kilogram of body weight can be ingested, ie mg/kg body weight.

3.1.1 Category ADI

If the toxicity of several similar substances are used or used for food, the group should develop category ADI compound to limit its cumulative intake. Developing category ADI, sometimes based on the average NOAEL/BMD compound of the group, but the group of compounds commonly used in the lowest NOAEL/BMD, but also consider the relative quality of the individual compounds and test cycle studies.

3.1.2 No provision ADI

According to available information (chemistry, toxicology, etc.) demonstrate that a low toxicity test substance, and its usage and total human dietary intake of people Does not harm healthy body, you can not have to set specific ADI.

3.1.3 Provisional ADI

When a substance is limited safety information or the safety of a substance has been developed ADI questioned according to the latest information, such as to in order to further provide the required data security in the short term, there is sufficient information that the use of the substance is safe in the short term, but without Sufficient to determine the long-term food safety, may formulate tentative ADI and the use of larger uncertainty factor, the need to provision tentative ADI Validity Limit, and in the meantime requested after toxicology test results proved that the test substance is safe, the provisional value to ADI ADI value; as Toxicology test results prove to be safety problems, revoke provisional ADI value.

3.1.4 can not propose ADI in the following cases, the test substance does not propose ADI.

- a) can take advantage of the safety information is not sufficient;
- b) lack of information on substances used in foods;
- c) lack of material properties and purity quality specifications.

3.2 Tolerable intake

Humans over a period of time or lifetime exposure to certain chemicals, does not produce the amount of adverse health effects can be detected. Per kg the amount of weight that can be ingested, ie mg/kg body weight, including tolerable daily intake provisional maximum tolerable daily intake, Provisional Tolerable Weekly Intake and the amount of the provisional tolerable monthly intake.

3.2.1 Tolerable daily intake

Similar to ADI, for those who are not intentionally added substances, such as contaminants in food.

3.2.2 Type TI

If a similar toxicity of several substances used as or in food, in this group of compounds should be developed to limit its category TI cumulative intake Into. Developing Type TI, sometimes based on an average of the group of compounds NOAEL/BMD, but the group of compounds commonly used in the lowest NOA-EL/BMD, but also consider the relative quality of the individual compounds and test cycle studies.

3.2.3 Provisional maximum tolerable daily intake

Applies to no accumulation of contaminants in food, contaminants in food and drinking water due to the naturally occurring, and therefore represents the humanity allowed Exposure levels. For both essential nutrients and trace elements food ingredients, places a range to represent the lower limit of the representative body shall Required level, the upper limit is PMTDI. Because usually the lack of results of human exposure to low doses, therefore, generally known as the tolerable intake "Tentative", the new data may change the provisional tolerable intake.

3.2.4 Provisional Tolerable Weekly Intake

Applicable to the accumulated effect of food contaminants (such as heavy metals), which represents the inevitable human exposure to these contaminants, the weekly Permissible exposure.

3.2.5 Provisional tolerable monthly intake

Applicable to the accumulation effect in the human body and has a long half-life of food contaminants, which represents human exposure to these inevitable when contaminants monthly allowable exposure.