TO TOLERANCE OF AGROCHEMICALS IN FOOD

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Abstract ---- The virtually safe level of the agrochemical residue in food is statistically discussed.

INTRODUCTION

Pesticides, fungicides, herbicides, animal drugs and feed additives are used to promote the productivity in agriculture. Although the chemicals have contributed greatly to the economy through stabilized high production of food and to our health through control of certain vector borne diseases, potential adverse effect on human health and on environment have been pointed out. In this review, the safety level of agrochemical residue in food is discussed briefly.

NONCARCINOGENIC CHEMICALS

A set of full toxicological data is required for legal approval or registration of pesticides and feed additives. ADI and tolerance in each product(food) are calculated by the routine method in which one hundredth of NOAEL(no
Fig. 1. low dose extrapolation for threshold recognizable response (TD84/TD16 = 10, TD16 = NOAEL)

observable effect level) is usually considered as safe level.

Fig. 1 shows a simulation of low dose extrapolation curves from a slow slope dose response relation (TD86/TD16 = 10 and TD16 is no effect level). TD16/100 will be the highest estimate of safe level for the response. If a normal distribution can apply to the dose response relation, possibility correspond to TD16/100 is about one to million. If the individual sensitivity to the response distribute dinominally, P will be about 3 to ten thousands.

Since a large number of chemicals with small amount is applied as animal drugs, a negligible residue level in food and withdrawal period after application are decided from the subchronic level toxicological data for each drug.

CARCINOGENIC CHEMICALS

The anticancer clause (Delany Clause) of US Food, Drug and Cosmetic Act provided the DES proviso which allows the use of a possible
carcinogen as an animal drug or feed additive if no residue in food will be found by the method approved by the Secretary. This brought a dispute on the sensitivity of method for a quarter of century. FDA published the final SOM(sensitivity of method) regulation on the end of 1987. In this rule, FDA described only the principles in the regulation and transferred the controversial items to guidelines which could revise any time.

1). Any animal drug is determined as to whether it is subjected to the SOM regulation by the threshold assessment guideline.

2). On the drug come under the regulation, a virtually safe level, by which the possibility of carcinogenesis is one to million, is estimate from the chronic feeding data(fig.2).

3). A guideline for detail statistical procedure is not published yet, but upper 95 % confidence limit at lowest positive dose is suggested as the starting point for low dose extrapolation(fig.3).

4). From the tests on target animal, adequate target tissue, marker residue and regulatory assay
method for residual detection must be established. 

5). Propose a withdrawal period.

The principal points of view underlying the SOM regulation seem to be 1) do not deny existence of nonthreshold response and 2) one to million is a socially acceptable possibility.

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