

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 3a

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-Fifth Session

MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 99TH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

(Comments of Kenya, Nigeria, Republic of Korea, Russian Federation, African Union, East African Community)

Kenya

Comment: Kenya takes note of all the matters from FAO/WHO and agrees with findings of JECFA and therefore supports recommendation for adoption by CAC.

Nigeria

1. Nigeria appreciates the work done by JECFA and supports JECFA's reaffirmation of the ADI of 0-0.3mg/kg bw for Natamycin and 0-2mg/kg bw for Nisin A

Rationale

JECFA has adequately evaluated the safety of Natamycin and concluded that there are no risk of Natamycin's induction of antimicrobial resistance and that the risk of Natamycin having a disrupting effect on the microbiome of the human gastrointestinal tract is low.

2. Nigeria appreciates the work done by JECFA and supports JECFA's reaffirmation of the ADI of 0-25mg/kg bw for Polyglycerol esters of fatty acids.

Rationale

The result of JECFA's long-term study carried out in rats showed that there were no effects at 2500mg/kg bw, which was the highest dose tested.

Republic of Korea

The Republic of Korea will provide dietary exposure estimates of polyglycerol esters of fatty acids(INS 475) if we have available data.

Russian Federation

Matters of interest arising from FAO/WHO and from the 99th meeting of the joint FAO/WHO expert committee on food additives (JECFA)

The Russian Federation takes note of the FAO JECFA Monographs 34 (2025), following 99th JECFA meeting. However we believe that the risk re-assessment for nisin (INS 234) and natamycin (INS 235) consider revising, as it does not reflect microbiological negative effects of these food additives on the intestinal microbiota and related AMR risks as well as other risks associated with their impact on pathogenic and opportunistic microorganisms that contaminate food products and/or are representatives of the human intestinal microbiocenosis.

Russia provided the necessary data, confirming antimicrobial activities of nisin (INS 234) and natamycin (INS 235) at the CCFA49 in 2017 and with the official letter to the WHO Department of Food Safety and Zoonoses, as well as JECFA and CCFA secretariats in 2019. The data provided, as well as the sources we use to reaffirm the AMR risks of these preservatives can also be found in the open Internet sources. This data particularly focused on the AMR formation mechanisms in opportunistic and pathogenic microorganisms when exposed to nisin (INS 234) and natamycin (INS 235), their possible negative effect on the intestinal microflora, as well as risk assessment of their microbiological adverse effects.

The 99th JECFA report states that “there are few in vivo studies that have investigated the possible antimicrobial activity of nisin in the lower gastrointestinal tract”. However we must highlight that, the antimicrobial resistance can also develop when microorganisms are exposed to subinhibitory concentrations of antimicrobials. Therefore, we can not agree with JECFA’s conclusion on the absence of AMR risks of nisin and natamycin.

At the same natamycin can cause oxidative stress in mold and yeast-like fungi, affects the transport mechanisms of membranes and DNA of protozoan fungi, thus affecting their growth and metabolic activity. These changes characterize the main mechanisms of AMR formation in microorganisms.

We therefore are open for further cooperation with JECFA on the issue and ready to submit all the necessary data again.

African Union

Position: The African Union has taken note of all matters arising from FAO/WHO and agrees with the findings of JECFA. Consequently, the African Union supports the recommendation for adoption by the Codex Alimentarius Commission (CAC).

East African Community

EAC Position

General comment: EAC takes note of all the matters from FAO/WHO and agrees with findings of JECFA and therefore supports recommendation for adoption by CAC.