European Food Safety Authority

Scientific requirements for substantiation of claims on the immune function

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The immune system

An effectively functioning immune system is crucial for maintaining physiological integrity and thus for health

The immune system provides defence against tumours and infections caused by pathogenic microorganisms

Allergies

Allergic manifestations, such as asthma, urticaria, and eczema, are caused by undesired immune responses to environmental allergens

Immunological parameters, e.g.

- lymphoid subpopulations
- production of cytokines

- phagocytic activity
- lytic activity of natural killer cells
- Langerhans cells

- proliferative responses of lymphocytes
- lytic activity of cytotoxic T cells
- immunoglobulin levels
- delayed-type hypersensitivity responses

Stimulation of immune parameters is not necessarily beneficial

Claims related to the immune system

Non-defined, e.g.

- Immune system
- Immune health
- Natural defence
- Strengthening the immune system

Defined, e.g.

- Maintaining the normal skin immune function after UV-exposure
- Defence against pathogens by stimulating immunologic responses
- Reducing risk factors of e.g. allergic rhinitis

Outcome measures

- Claims related to immune defence against pathogens
  - Incidence/duration/severity/relative risk of upper respiratory tract infection, gastrointestinal tract, infection, urinary tract infection
  - Reduction of numbers of pathogens
  - The incidence of infection or reduction of numbers of pathogens may not necessarily represent an effect on the immune system, for claims involving the immune system, evidence of a relevant change in immunological parameters needs to be provided

Outcome measures, e.g.

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preferentially in same studies

Restoring immunological parameters – evidence alone might be sufficient

- Naturally outside normal range (e.g. elderly)
- Outside normal range associated with life styles/events (e.g diet, stress)
- Outside normal range due to an experimental challenge-model of life style/event (e.g. stress, sleep deprivation)
- Outside the normal range by other factors (e.g. UV)

A measure that might be enough

Stimulation of protective antibody response to vaccination

Protective antibody titres

Number of protected individuals

Impact goes beyond the purpose of vaccination

Claim: Defence against pathogens by stimulating immunologic responses

Allergy

- Claims related to response to allergens
  - Incidence of allergic manifestations
  - Self reported allergies are usually unreliable
  - Need to include physician diagnosed allergies
  - Immunologic nature needs to be corroborated with appropriate measures

Inflammation

- Chronic inflammation is associated with a number of diseases

Inflammatory markers, e.g.

- Cytokines (TNFα, IL-1α, IL-6, etc)
- Components of arachidonic acid pathway
- sCRP
- Components of complement cascade
- Neutrophils
- Lymphocytes
- etc

Inflammation

- Inflammation is a non-specific physiologic response to tissue damage that is mediated by the immune system.
- Adequate inflammatory responses are of primary importance for the defence against injury of any origin.
- Changes in markers of inflammation such as various interleukins and others *per se* do not indicate a beneficial physiological effect.

Inflammation

- Suggestions received:
  - in study populations with life events (e.g. injury, high saturated fat diet)
  - in study populations where the response is out of normal range
  - elderly population

- Consequence or cause?
- Reducing inflammatory markers without reduction of the cause of inflammation may not imply a beneficial effect

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THANK YOU