

Reclassification of Sports Electrolyte Supplements

Natural and Non-Prescription Health Products Directorate/Food
and Nutrition Directorate
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Health
Canada

Santé
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Background

- Product Licence Applications for Sports Electrolyte Supplements (SES) have been received by NNHPD for several years
 - Approximately 20-30 have been approved and issued NPNs
- These products are distinct from Oral Rehydration Solutions (ORS), which are to be used for rehydration solely in the context of diarrhea and vomiting.
- While ORSs have a narrow context of use, the settings for rehydration intended for SESs (e.g. exercise, high heat environments) place them on the interface with foods.
 - The regulatory framework for *Supplemented Foods*, available since 2022, facilitates the positioning of these products in the Food regulatory framework.

Current situation

- Dual regulatory framework exposes industry to uneven requirements:
 - Companies applying for NPNs must wait for pre-market review and approval, while those marketing their products as foods can enter the market directly.
 - Labelling requirements differ between the two categories (more extensive risk labelling and dosage information required for NHPs).
 - Significant overlap existed between the classification of products under the two regulatory frameworks (i.e., format, composition, intended use).
- Potential for consumer confusion and misuse:
 - Two SESs may be almost identical in composition and intended use, but ultimately be presented differently to consumers.

Sport electrolyte supplements



Supplemented Food



NHP



Krono Nutrition Fizz -
Sports Electrolyte
Drink Tablets

OR



Reclassification

- In early 2025, NNHPD consulted on two product monographs, one for ORSs and a separate one for SESs, to establish a clear distinction between ORSs and SESs and resolve some confusion. The ORS monograph was published and is currently fully in use for Class I licensing of NHPs.
- Publication of the SES monograph was halted following discussions with FND regarding reclassification of SESs that are currently regulated as Supplemented foods or as NHPs. NNHPD and FND have determined that all **SESs should be reclassified as Supplemented foods** since:
 - Dosage forms associated with SESs, such as effervescent tablets (to be solubilized in liquid), powders for solution, liquids or concentrated liquids, would be acceptable as food and such products are already regulated as foods.
 - Specific claims listed on the draft SES monograph would likely be acceptable for foods as long as industry has supportive evidence on file to provide upon request.
 - Re-classifying these products under the Supplemented Foods framework would reduce unnecessary regulatory burden, free review resources at a time of fiscal restraint and prevent potential consumer confusion.

Next steps

- Licence holders for SESs approved as NHPs will be notified of the reclassification with details on the transition period.
- Licence holders for products containing both ORS and SES-type claims will be notified of the need to submit notifications to remove the SES-type claims (or to discontinue the licence if the intent is to position the products as SESs rather than ORSs).
- A joint communication notice explaining the re-classification will be posted online beginning of 2026.
- The transition period will align with the one established to comply with the FDR requirements for Supplemented food labelling which follows Health Canada-Canadian Food Inspection Agency (HC-CFIA) labelling coordination policy, meaning industry will have until January 1, 2028 to comply. If more time is needed, licence holders will be advised to submit their transition plan to NNHPD.

QUESTIONS?

