What is being proposed?

The Commission amends the General Food Law and eight sectoral legislative acts dealing with the agri-food chain to increase transparency in the risk assessment process.

The General Food Law (GFL) is the cornerstone of the EU regulatory framework. It covers the entire agri-food sector, ‘from farm to fork’. It establishes:

→ The principle of risk analysis, with 3 components: risk assessment, risk management & risk communication.

→ The European Food Safety Authority (EFSA), an independent body entrusted with risk assessment.

What will change?

1. MORE TRANSPARENCY

Better access to scientific studies will be possible.

- Scientific Studies will be made public at an early stage;
- Duly justified confidential information, certain personal data as well as intellectual property rights will be respected;
- Interested parties will have easy access (e-format) to the studies on EFSA’s website.

2. MORE RELIABLE, INDEPENDENT STUDIES

EFSA will have more access to relevant scientific evidence in requests for authorisation:

- A register of all studies commissioned by the industry when applying for an authorisation;
- Consultation of stakeholders and the general public on submitted studies;
- For renewals, additional consultation on planned studies;
- Controls, including audits, will be carried out on the compliance of laboratories/studies with standards;
- Commission to ask EFSA, in exceptional circumstances, to carry out own studies for verification purposes.

3. BETTER GOVERNANCE

Members States will contribute more to EFSA’s governance and scientific Panels while respecting EFSA’s independence, excellent and multi-disciplinary expertise.

- EFSA’s management board composition will include representatives of all Member States;
- Strict independence criteria will be maintained;
- The appointment of experts to EFSA’s scientific panels will be made from a pool of nominations put forward by Member States;
- The scientific Panels’ work will be better organised.

4. EFFECTIVE RISK COMMUNICATION

Improve coordination between risk assessors and risk managers to ensure a better communication to stakeholders and the general public.
### A. Planning phase before submission of an authorisation application

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>EFSA receives applications for authorisations, including studies.</td>
</tr>
<tr>
<td>2</td>
<td>EFSA publishes the non-confidential version of the authorisation application.</td>
</tr>
<tr>
<td>3</td>
<td>EFSA starts the confidentiality assessment of the authorisation application. Once finalised, EFSA decides on confidentiality.</td>
</tr>
<tr>
<td>4</td>
<td>EFSA launches a consultation to identify whether other relevant information is available on the substance at stake.</td>
</tr>
<tr>
<td>5</td>
<td>EFSA carries out its scientific assessment.</td>
</tr>
<tr>
<td>6</td>
<td>EFSA's scientific opinion (including the outcome of the call for data).</td>
</tr>
</tbody>
</table>

### B. Submission of an authorisation application

- **POTENTIAL APPLICANT**
  - and laboratory
  - notifying EFSA of commissioned study
  - can ask for pre-submission meeting for ‘advice’ on the potential authorisation application

### C. Renewals

Only in case of “renewals” (GM food and feed, Feed additives, pesticides), an additional procedure applies.

- A pre-notification by a potential applicant of planned studies to EFSA is foreseen.
- EFSA will then systematically launch a consultation on the planned studies and issue advice on the content of dossier.