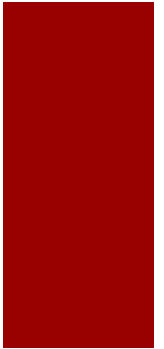


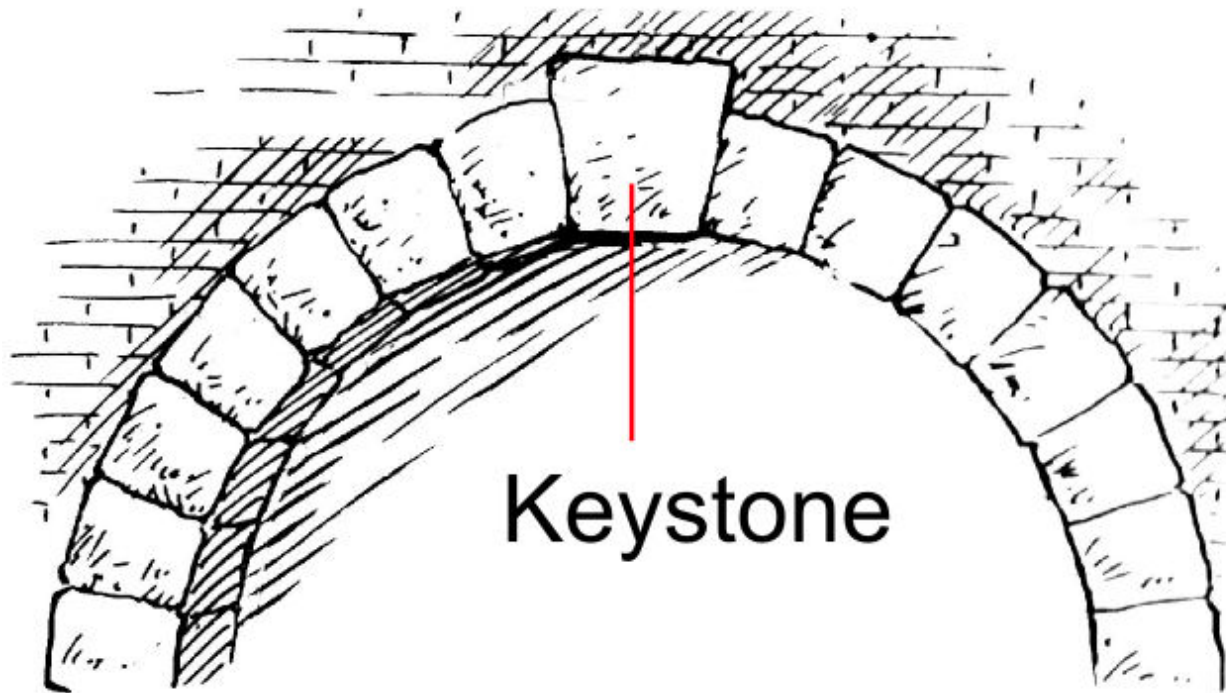
State of Regulatory Affairs in Ease of Doing Business



Protein Foods Nutrition Development Association of India (PFNDAI)

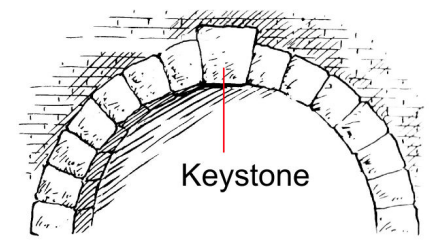
The Orchid Hotel , Mumbai
23rd March, 2017

Dr. Joseph I Lewis



- ✧ A keystone is a stone at the top of the arch, which keeps the other stones in place by its weight and position
- ✧ It is the core, principle or foundation of a policy, system on which all else depends

Meanings



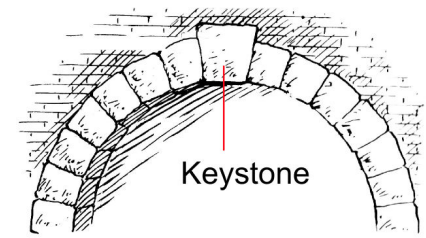
Ease

- ✧ Absence of difficulty or effort
- ✧ No trouble

Unease

- ✧ Mental dissatisfaction
- ✧ Anxiety, uncomfortable

Business Indications two kinds



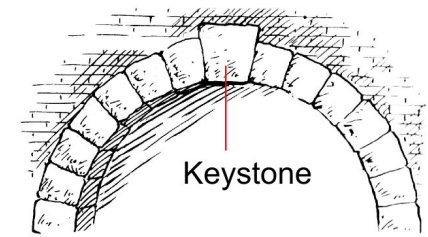
✧ Ease of doing business . . .

- ✧ operational difficulty
- ✧ maneuvering hurdles

✧ Unease in the business . . .

- ✧ unpredictability
- ✧ anxiety

Ease of doing business



Timelines

Nutraceuticals, Food Supplements etc.

30.03.2016 -
Order

✧ Enforcement - restricted to testing

24.11.2016 -
Direction 16(5)

✧ Granting licenses - 13.3,13.4,13.5,13.6 open

23.12.2016 -
Gazette

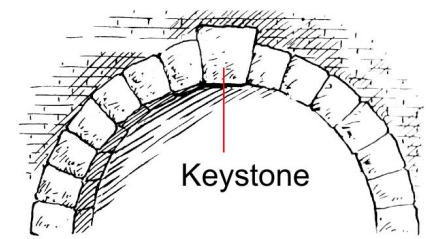
✧ Final Notification - enforced - Jan 2018

06th Jan 2017
Direction 16(5)

✧ Continuance of products in market prior to

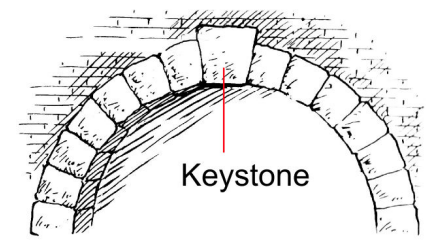
Act 2006, rules and regulations

Ease of doing business



Timelines	Proprietary Foods
<p>13.01.2016 - Operational</p> <p>19.04.2016 - Revised standards notified</p> <p>22.08.2016 - Final and operational</p> <p>10.10.2016 - Gazette</p>	<ul style="list-style-type: none">✧ Bifurcating types of Ingredients -<ul style="list-style-type: none">✧ Standardized or✧ Permitted for use in other standardized foods✧ Purposeless provisions ?<ul style="list-style-type: none">✧ Substantiated Health claims may be made✧ FBO fully responsible for safety

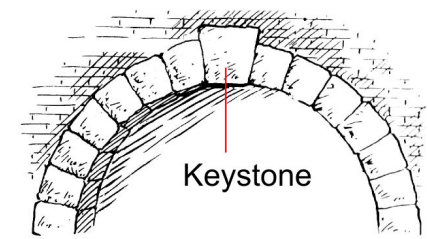
Ease of doing business



Food businesses - Initiatives by FSSAI

- ✧ **Hotels, restaurants** - trained supervisors
- ✧ **Partnership Activities**
 - ✧ Street food vendors - hygiene standards
 - ✧ Food Fortification
 - ✧ FSMP - Importation
- ✧ **Mid-day Meals:** HACCP measures
- ✧ **FSMS Initiative** - with Industry participation
- ✧ **Risk based Inspection System** : EU-CITD collaboration

Unease in the business



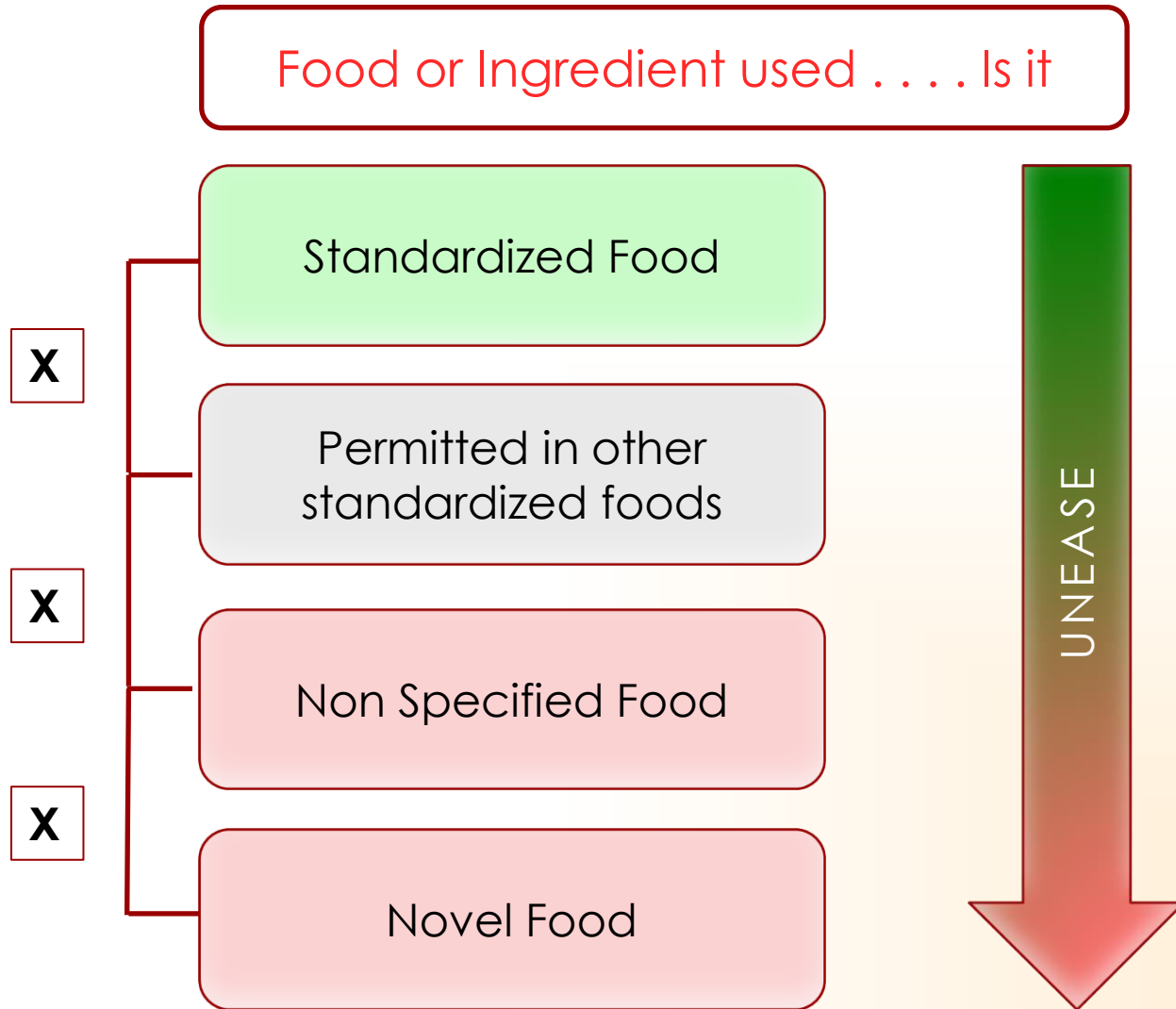
Issue	1. Interpretations
<ul style="list-style-type: none">✧ Chocolate box✧ Alcoholic beverage	<ul style="list-style-type: none">✧ Label <u>attached</u> to package<ul style="list-style-type: none">✧ Hence “ sticker”✧ Definition by law - “ stamped, written, printed on or “ attached” to container✧ Label - considered violation<ul style="list-style-type: none">✧ Two labels (front/back)✧ “every package of food shall carry <u>a label</u>”

Unease in the business

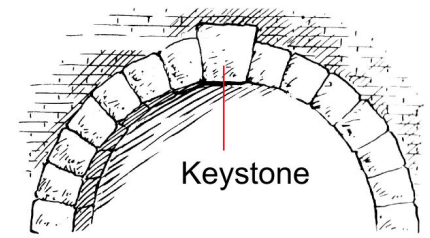


Issue	2. Clarity, Comprehension in Regulatory texts
✧ Nutraceutical Regulation	<p data-bbox="569 544 1688 596">Definitions: “meanings assigned in Section - 22.</p> <ul data-bbox="666 665 1653 829" style="list-style-type: none"><li data-bbox="666 665 1309 715">✧ Category distinctiveness<li data-bbox="666 779 1653 829">✧ E.g. Nutraceuticals & Food supplement <p data-bbox="569 901 1547 951">✧ Not for medicinal use - declaration</p> <ul data-bbox="666 1022 1495 1186" style="list-style-type: none"><li data-bbox="666 1022 1392 1072">✧ All categories (except FSMP)<li data-bbox="666 1136 1495 1186">✧ Coconut water (S-IV) - 100-200ml

Unease in the business



Summary:



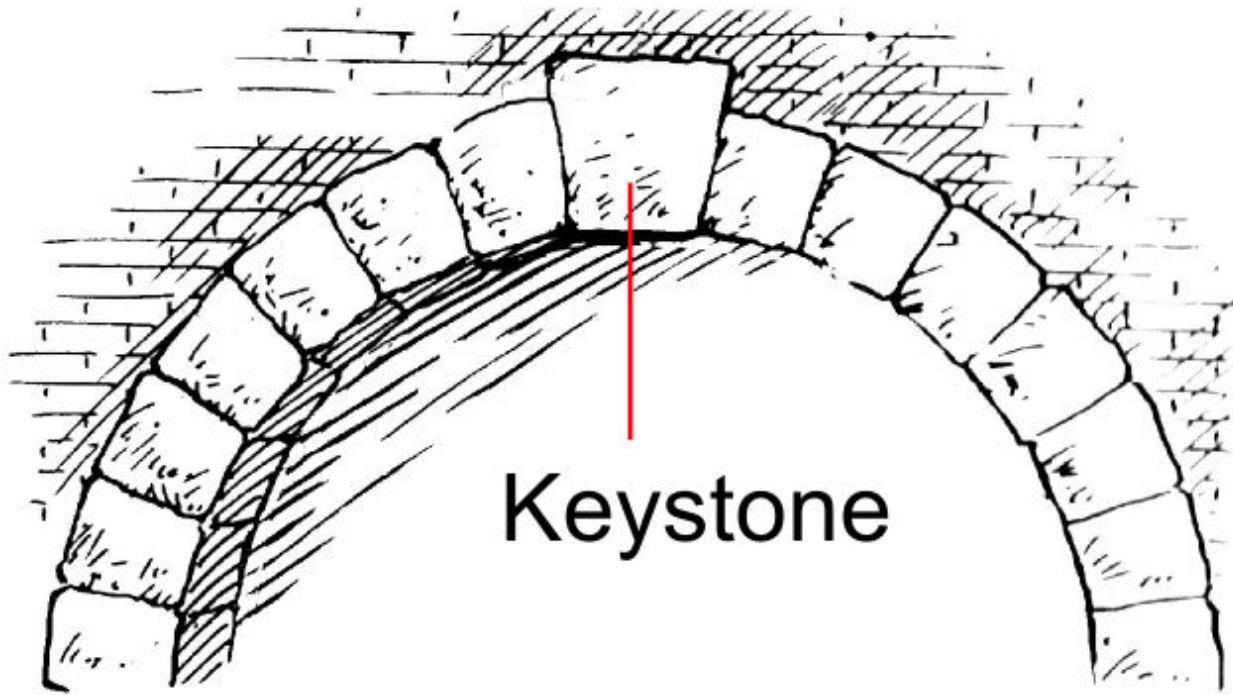
The State of Regulatory Affairs

- Relief

Reform

- Opinion

Scientific evidence



FSSA 2006: a modern science based law

Thank you