Regulation to control Autogenous Vaccine in Thailand
## Autogenous vaccine

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>EU</th>
<th>Canada</th>
<th>Thailand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation</td>
<td>9 CFR 113.113</td>
<td>not cover by Directive 2001/82</td>
<td>CFIA-CCVB</td>
<td>- Drug Act</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Under National specific regulation</td>
<td></td>
<td>- DLD policy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(harmonized recommendation on process)</td>
<td></td>
<td>- Vet Council</td>
</tr>
</tbody>
</table>
The Drug law in Thailand controls both human and veterinary medicinal products.

Require licensing for manufacturing, importing, selling and registration of all medical products.

However, the Drug law has some exemptions. For example:
Drug Act (exemption)

1. **Government** under the duty to control the diseases can produce/ import and sell MP (including autogenous vaccine for animal) without license

- Under this exemption, Drug Act could issue Ministerial regulation to establish criteria/ condition to control the production/ importation of those products operate by government.
2. The production of medicinal products for animals under veterinary responsibilities and prescription.

(They do not require the licensing to produce medicinal product for animal of which he takes care (look after, raise).

Note: Vet client patient relationship (VCPR) and prescription detail should establish under Vet council and DLD policy.
3. Veterinarians do not require the license to sell medicinal products to animal for which they take care.
Last year, The Minister of Ministry of Agriculture and Cooperatives sent the official letter to the Minister of Public Health as ever reach the consensus on the meeting to amend this exemption of Drug Act.

To establish **specific criteria and conditions** for veterinarians to produce vaccines for animals in their charge under the exemption of Drug Act.
Proposed to Amend Drug Act

- Vet Medicinal Product Regulation require Signing from
  - Minister of Ministry of Public Health
  - Minister of Ministry of Agriculture and Cooperative

(ever reach this agreement at Council of State)
Propose to amend Drug Act
Propose to amend Drug act supported by Vet council and Multi-stakeholder to cabinet Secretariat
# Autogenous Vaccine (Drug Act)

<table>
<thead>
<tr>
<th>Production</th>
<th>USA</th>
<th>EU</th>
<th>Canada</th>
<th>Thailand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licensing</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>GMP</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>By a qualified person</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>For a restricted list of pathogens and animal species</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

- **Production**
- Licensing
- GMP
- By a qualified person
- For a restricted list of pathogens and animal species
- DLD could develop policy with stakeholder
- Vet / pharmacist
## Autogenous vaccine

### (Criteria to Use condition not under Drug Act)

<table>
<thead>
<tr>
<th>Specific Criteria for Used condition</th>
<th>USA</th>
<th>EU</th>
<th>Canada</th>
<th>Thailand</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No licensed vac.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>• Lack of efficacy of licensed vac.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>or</td>
<td></td>
<td></td>
<td></td>
<td>DLD could develop policy with stakeholder or develop criteria to control the use of autogenous vaccine by Agriculture Standard Act</td>
</tr>
<tr>
<td>licensed vac. not contain exactly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Autogenous vaccine

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</tr>
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<tbody>
<tr>
<td>Registration</td>
<td>× Not required</td>
<td>× Not required</td>
<td>× Not required</td>
<td>× Not required</td>
</tr>
<tr>
<td>Approved antigen</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>DLD could develop policy with stakeholders</td>
</tr>
<tr>
<td>production</td>
<td>Vet order/prescription</td>
<td>Vet order/prescription</td>
<td>Vet order/prescription</td>
<td>Vet order/prescription</td>
</tr>
</tbody>
</table>
MoU (DLD and ANSES)

French Agency for Veterinary Medicinal Products

(OIE Collaborating Center for Veterinary Medicinal Products)

11 Sep 2015
EU / France regulation

EU perspective: recent developments

CMDμ
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

Recommendations for the use, manufacture and control of inactivated autogenous veterinary vaccines within the EEA

(To be validated by HMA)
In a 2011 study in the Netherlands, an average of 11.72% of sow farms used autogenous vaccines and 18.96% of the total sows were vaccinated with an autogenous vaccine. Autogenous vaccines were used for *Streptococcus suis*, *Staphylococcus hyicus*, *Pasteurella multocida*, *Bordetella bronchiseptica*, *Actinobacillus pleuropneumoniae*, *Clostridium perfringens*, *Clostridium difficile* and *E. coli* (van de Ven, 2013). Poultry autogenous vaccines are typically for *E. coli* and are quite widely used although no exact figures are available.

**EMEA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA)**
Autogenous vac. and Thai herb
autogenous vaccine and pig performance
Reference:

1. 9 CFR 113.113: Autogenous Biologics
2. VSM 88.69: Guideline for Autogenous Biologics
   Guideline for Autogenous Veterinary Biologics
4. The legal foundation of the production and use of herd specific vaccine in Europe
5. The pros and cons of using autogenous hog vaccines
6. The use of autogenous vaccine in Dutch pig industry and suggestions for new legislation of autogenous vaccines
7. Regulation of autogenous vaccines present by Dr. Noemi Garcia del Blanco
8. Autogenous Vaccines: Current use in the field in the U.S. cattle and hog industry
9. Autogenous vaccines present by Francoise PICHARD, June 13th 2016 and Mariette Saléry, 2017
THANK YOU FOR YOUR ATTENTION