

# *The Reform of the Pesticide Registration Procedure in Tunisia (2009 - 2012)*

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- November 2015 -

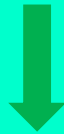
# Introduction

## Pesticides

- **Poisonous chemicals to combat pests,**
- **Most efficient control method against pests,**
- **But, usually toxic to human and animal health,**
- **And pollutant the environment and unbalancing its equilibrium**

# All countries

- Develop an arsenal of legislative texts to organize and control production and trading of pesticides,




- To reduce to the minimum, the negative effect of pesticides on health and environment



- Pesticides used over more than a century,

- Man became more and more aware of the high pesticide risk utilization

# Universal trend

- Over 4-5 past decades, research is working on alternative methods of pest control,
- To replace and/or reduce the chemical method (pesticides),  

- Methods: cultural, biolog., genetic,... → IPM
- France: Working to reduce by 50% the pesticides used in agriculture (2010-2018),
- EU: Directives changing to IPM

# Historical

## **Tunisia:** *Official Gazette of the Republic of Tunisia*

**Loi n° 92-72 du 3 août 1992, portant refonte de la législation relative à la protection des végétaux (1).**

Au nom du Peuple;

La Chambre des Députés ayant adopté;

Le Président de la République promulgue la loi dont la teneur suit :

### **TITRE I DISPOSITIONS GENERALES ET DEFINITIONS**

#### **CHAPITRE I**

##### **Dispositions générales**

Article premier. — La présente loi fixe les dispositions générales relatives à la protection des végétaux et à l'organisation du secteur des pesticides à usage agricole.

Journal Officiel de la République Tunisienne - 4 août 1992 N° 51

# Tunisia: *Official Gazette of the Republic of Tunisia*

**Loi n° 92-72 du 3 août 1992, portant refonte de la législation relative à la protection des végétaux (1).**

## **TITRE III DU CONTROLE DU COMMERCE, DE LA DISTRIBUTION ET DE L'UTILISATION DES PRODUITS PESTICIDES**

Art. 16. — Sous réserve des dispositions de la législation en vigueur, il est interdit de fabriquer, d'importer, de formuler, de conditionner, de tenir, de transporter, de vendre, de distribuer tout produit pesticide utilisé pour combattre les organismes nuisibles n'ayant pas fait l'objet d'une homologation ou autorisation provisoire de vente délivrée par le

## **6 Articles (Pesticides)**

Journal Officiel de la République Tunisienne - 4 août 1992 N° 51

# Tunisia: *Official Gazette of the Republic of Tunisia*

**Décret n° 92-2246 du 28 décembre 1992, fixant les modalités et les conditions d'obtention de l'homologation ou de l'autorisation provisoire de vente des pesticides à usage agricole ainsi que des autorisation de leurs fabrication, importation, formulation, conditionnement, vente et distribution.**

Le Président de la République,

Sur proposition du ministre de l'agriculture,

Vu la loi n° 92-72 du 3 août 1992, portant refonte de la législation relative à la protection des végétaux et notamment ses articles 16 et 17;

Vu le décret n° 61-300 du 28 août 1961, portant application de la loi n° 61-39 du 7 juillet 1961, instituant un contrôle du commerce et de l'utilisation des produits pesticides à usage agricole;

## **25 Articles (Pesticides)**

Journal Officiel de la République Tunisienne - 1-5 janvier 1993 N° 1

# Tunisia: *Official Gazette of the Republic of Tunisia*

## **Arrêté du ministre de l'agriculture du 18 août 1992, fixant la liste des laboratoires de référence spécialisés dans l'analyse des pesticides.**

Le ministre de l'agriculture;

Vu la loi n° 92-72 du 3 août 1992, portant refonte de la législation relative à la protection des végétaux et notamment son article 18.

Arrête :

Article unique. - La liste des laboratoires de référence spécialisés dans l'analyse des pesticides est fixée comme suit :

- Laboratoire de contrôle et d'analyse des pesticides relevant du ministère de l'agriculture.

Journal Officiel de la République Tunisienne - 18 septembre 1992 N° 62



# Tunisia: *Official Gazette of the Republic of Tunisia*

**Arrêté du ministre de l'agriculture, de l'environnement et des ressources hydrauliques du 5 mai 2003, portant approbation du cahier des charges relatif à la fabrication des pesticides à usage agricole, leur importation, formulation, conditionnement, stockage, vente et distribution.**

Le ministre de l'agriculture, de l'environnement et des ressources hydrauliques,

Vu la loi n° 92-72 du 3 août 1992, portant refonte de la législation relative à la protection des végétaux telle que

**(Procurement statement of work instead of License)**

*Journal Officiel de la République Tunisienne* — 16 mai 2003 N° 39

# Old Situation

## **Tunisia:** *Official Gazette of the Republic of Tunisia*

**Decree n° 2008-3615 dated 21 November 2008, amending decree n° 93-1145 dated 17 May 1993, fixing the amount and the collection methods of the contribution related to the operations of the plant-care control of analysis, confirmation and provisional authorizations of pesticides sale.**

The President of the Republic,

On a proposal from the Minister of Agriculture and Water Resources,

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*Official Gazette of the Republic of Tunisia* — 28 November 2008 N° 96

# Tunisia: *Official Gazette of the Republic of Tunisia*

## 2- Tarifs des contributions relatives aux analyses et à l'homologation des pesticides

### 2-2 - Produits destinés aux traitements terrestres :

a - Homologation d'un pesticide :pour une dose, un parasite et une culture donnée :

- Analyse de laboratoire : 2 500D

- Essai sur le terrain : 2000D

e - Homologation d'un pesticide conformément au dossier y-joint : 600 D

*Official Gazette of the Republic of Tunisia* —28 November 2008 N° 96

# Registration fee comparison

- **Original pesticide (4,500 TD)**
  - \* **Lab analysis: 2,500 TD**
  - \* **Field experiment: 2,000 TD**
  - \* **Awaiting 1 to 2 years**
- **Generic pesticide (600 TD, Dossier/Internet)**
  - \* **Lab analysis**
  - \* **No field experiment**
  - \* **Awaiting some weeks to few months**

# Result of old polity

- **Generic pesticides invaded Tunisia**
- **Most generics came from developing countries:**
  - \* **Not conform to international standards**
  - \* **Containing toxic additives that cannot be analyzed in Tunisia (solvents, heavy metals, impurities,...): Only Active Ingredients are analyzed.**

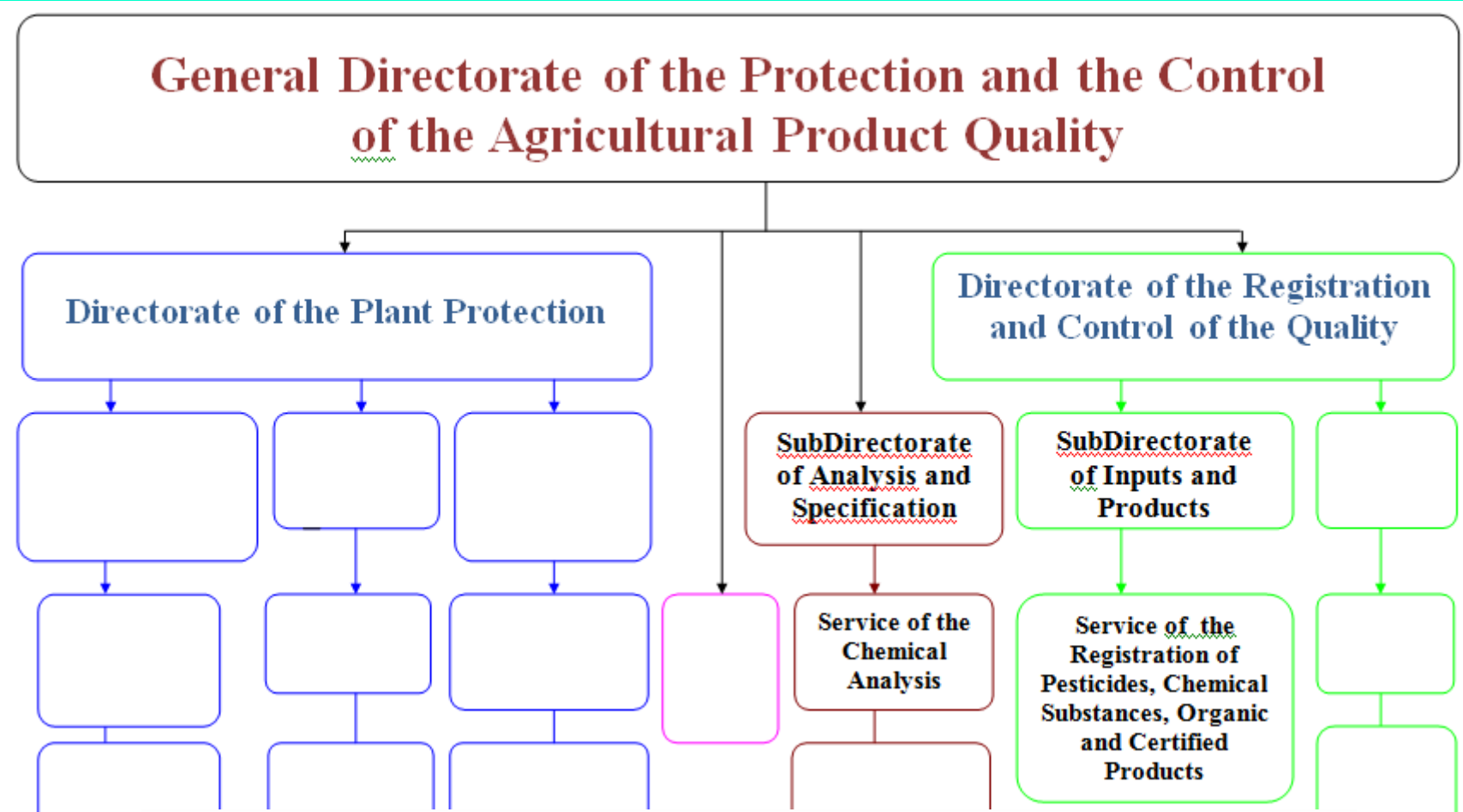
# Result of old polity

- Total pesticide number at 2008
  - \* Around 1200 Formulations  
*corresponding to*
  - \* Around 250 Active Ingredients
- Ratio  $1200/250 = 4.8$  (around 5)  
↓  
Among 5 pesticides, 4 are generics  
↓  
4/5 pesticides are generics (2008)

# Old registration pesticide management

Décret n° 2001-420 du 13 février 2001, portant organisation du ministère de l'agriculture. (Art. 29)

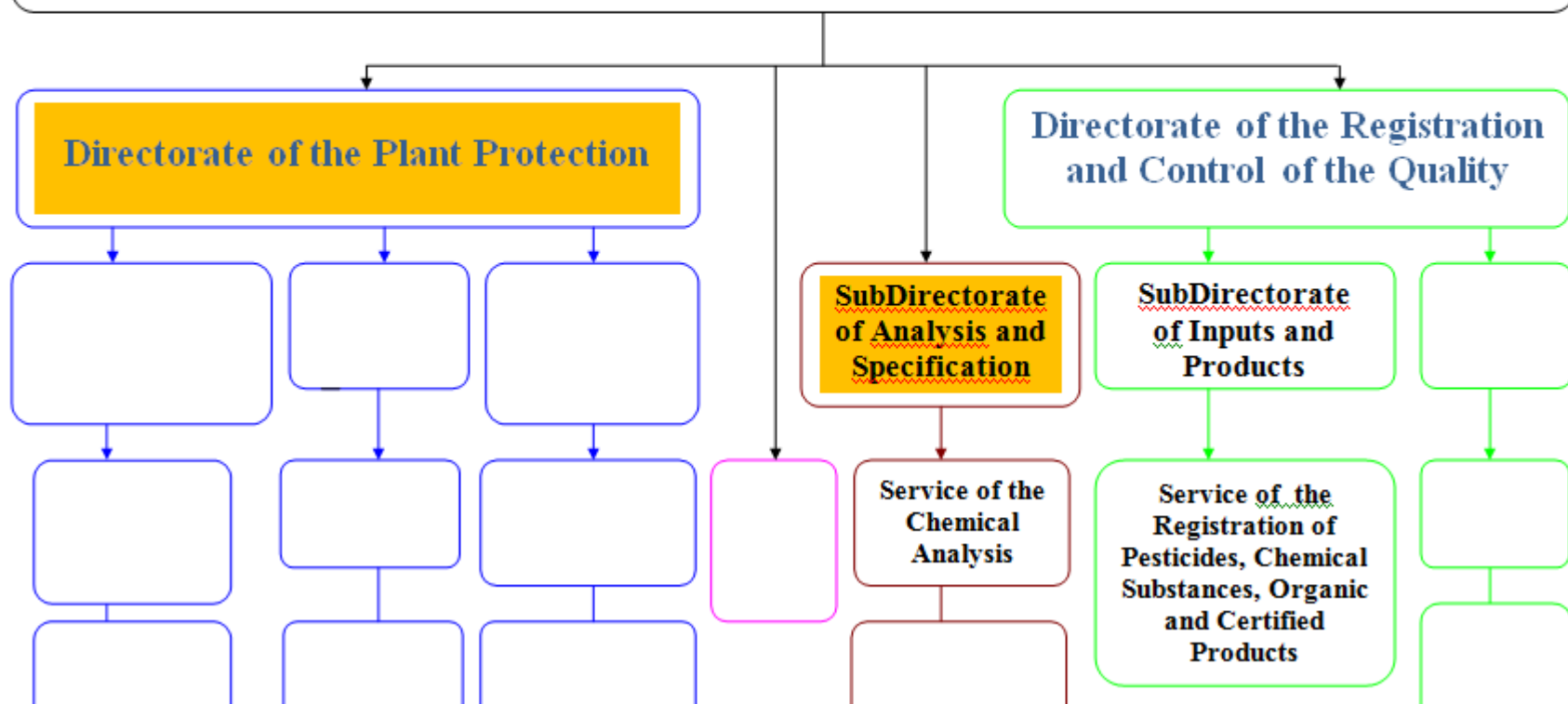
## Organizing Chart



*Journal Officiel de la République Tunisienne* — 20 février 2001 N° 15

# Old registration pesticide management

## General Directorate of the Protection and the Control of the Agricultural Product Quality



Journal Officiel de la République Tunisienne — 20 février 2001 N° 15

(Art. 29)

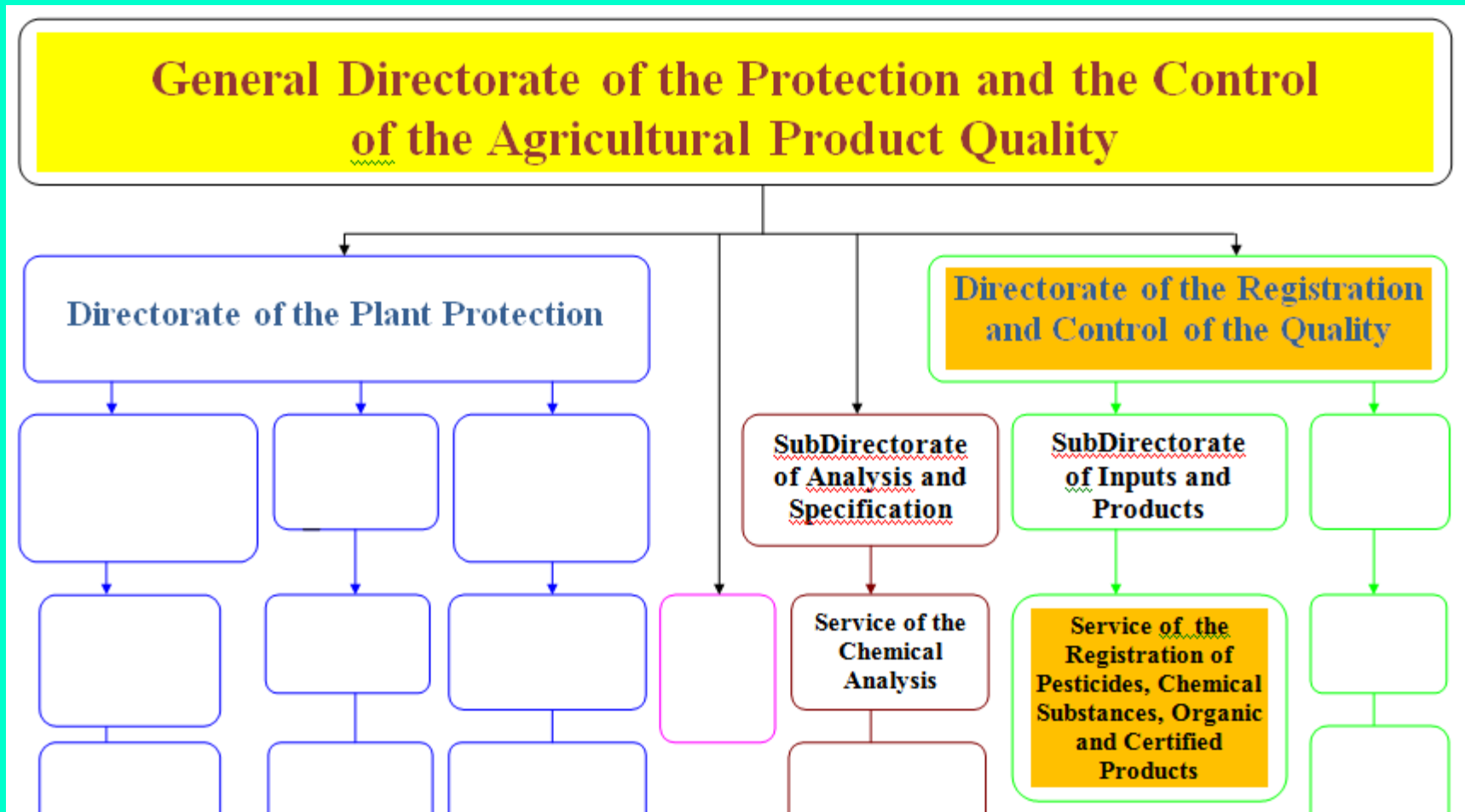


# Old registration pesticide management

- **Strange organizing of the National Committee of Pesticides:**
  - \* **President : General Director**
  - \* **President Deputy : Director of Plant Protection**
  - \* **Rapporteur : Head of the Analysis Service**
  - \* **Plus other members from other Ministries**
- **Directorate of Registration and Control : totally absent**
- **Analysis Service: Judge and Jury**

# New Situation: Reform

## Registration pesticide management



# Modification of the Registration pesticide management

- **Re-organizing the National Committee of Pesticides:**

\* **President : General Director**

\* **President Deputy: Director of Registration and Control**

\* **Rapporteur : Head of the Registration Service**

\* **Plus other members of other Ministries**

- **SubDirectorate of Analysis: Out of the Committee (Receiving and analyzing coded samples).**

# Tunisia: Official Gazette of the Republic of Tunisia

Decree n° 2010-2973 dated 15 November 2010, amending and completing decree n° 92- 2246 dated 28 December 1992, fixing the methods and conditions of obtaining the approval, the provisional authorizations of sale of the pesticides of agricultural use, as well as the conditions of their manufacture, importation, formulation, conditioning, storage, sale, distribution and the conditions of use of the pesticides of extremely dangerous agricultural use.

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*Official Gazette of the Republic of Tunisia* — 23 November 2010 N° 94

# Tunisia: Official Gazette of the Republic of Tunisia

Article one - Is repealed article 5 of the decree n° 92-2246 dated 28 December 1992 referred to above and replaced by the following provisions:

Article 5 (new): To obtain the approval or the provisional authorization of sale of the pesticides of agricultural use, any applicant shall address to the Minister of Agriculture, Water Resources and Fishing a file including:

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*Official Gazette of the Republic of Tunisia* — 23 November 2010 N° 94

# Tunisia: Official Gazette of the Republic of Tunisia

2 - For the imported pesticides, the original of the certificate of approval of the pesticide delivered by the official authorities of the country of origin or an authenticated copy certified valid by the embassy of Tunisia of the country of origin and mentioning that the pesticide to be approved is used and in the course of use in the country of origin at the date of the application.

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*Official Gazette of the Republic of Tunisia* — 23 November 2010 N° 94



# Tunisia: Official Gazette of the Republic of Tunisia

7 - For the pesticides of origin, a study of reference relating to the toxicity of the pesticides with respect to the man and the environment and emanating from the manufacturer of origin. For the generic pesticides, an original file which relates to the study of the different types of toxicity of the active substance and the product formulated with respect to the man and the environment, the residues of these substances, their outcome in the agricultural products, the ground and water and their effects on the environmental systems, this original file shall contain recent information according to the international standards applied in this field and delivered by specialized and internationally accredited laboratories.

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*Official Gazette of the Republic of Tunisia* — 23 November 2010 N° 94

# Tunisia: Official Gazette of the Republic of Tunisia

10 - For the imported pesticides, a sample of the pesticide to be marketed prepared in the packing of origin used in the country of origin which is sealed, different batches and available in sufficient quantity to carry out the laboratory analyses and the field experiments.

11 - A detailed bulletin of analysis mentioning the composition of the pesticide, including the active substance, the additives, the solvents, the impurities and others, delivered by specialized internationally accredited laboratories on the matter and accompanied by a safety card for all the mentioned components.

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*Official Gazette of the Republic of Tunisia* — 23 November 2010 N° 94



# Tunisia: Official Gazette of the Republic of Tunisia

Art. 2 - The concerned persons shall benefit from a six-month period to present the files and the documents required for the pesticides which obtained the approval before the entry into force of the decree herein.

The imported quantities of the pesticides whose related approval is withdrawn shall be liquidated within a deadline not exceeding one year as of the date of the notification of the withdrawal of the approval.

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*Official Gazette of the Republic of Tunisia* — 23 November 2010 N° 94

# Summarizing : *Decree 2973 dated 15 November 2010*

- **Re-registration of all already registered pesticides on the basis of updated dossiers,**
- **All dossiers must be strong and convincing, specially for generic pesticides,**
- **There is a deadline to complete the re-registration, otherwise each concerned pesticide will be removed from the official list,**
- **There is a deadline to liquidate the stock of non re-registered pesticides.**

# Tunisia: Official Gazette of the Republic of Tunisia

**Arrêté du ministre de l'agriculture et de l'environnement et du ministre des finances du 3 juin 2011, fixant le montant et les modalités de perception de la contribution relative aux opérations de contrôle phytosanitaire d'analyse, d'homologation et des autorisations provisoires de vente de pesticides.**

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*Journal Officiel de la République Tunisienne* — 10 juin 2011 N° 42

# Tunisia : Official Gazette of the Republic of Tunisia

## 2-Tarifs des contributions relatives aux analyses et à l'inscription des pesticides:

### 2-2 - Produits destinés aux traitements terrestres :

a - Homologation d'un pesticide pour une dose, un parasite et une culture donnée

- Analyse de laboratoire    2 500D

- Essai sur le terrain        2000D

*Journal Officiel de la République Tunisienne* — 10 juin 2011    N° 42

# Tunisia: Official Gazette of the Republic of Tunisia

Art. 3 - Les pesticides biologiques et les pesticides dont l'utilisation est tolérée dans la production biologique bénéficient d'une réduction au taux de 50% des redevances dues aux analyses, aux inscriptions et aux expériences sur terrain.

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*Journal Officiel de la République Tunisienne* — 10 juin 2011 N° 42

# Summarizing : *Order dated June, 3<sup>rd</sup> 2011*

- **No more difference between Original and Generic pesticides for registration :**
  - \* **Strong dossier needed**
  - \* **Same registration fees (4,500 TD)**
  - \* **Laboratory analysis**
  - \* **Field experiment for both**
  - \* **Same awaiting (1 to 2 years)**
  
- **Encouraging Organic Agriculture: 50% reduction on the registration fees of biological pesticides.**

# Result of this reform

- Total pesticide number at 2012
  - \* Reduction to near 500 Pesticides (1200 at 2008)  
*corresponding to*
  - \* Reduction to around 200 Active Ingredients (250 at 2008)
- **Ratio  $500/250 = 2$** 
  - \* **Among 2 pesticides, only 1 is generic**
  - \* **1/2 pesticides are (acceptable) generics (2012)**
  - \* **Old situation: 4/5 pesticides were generics (2008)**

# Similar trend

## - European Union

- \* Revising of the registration of Active Ingredients (AI)

- \* Working from 1993 to 2009



- \* **Reducing AI number : From 1000 to 250**



**3/4 AI were removed**



# Other decisions of reform :

## The National Committee of Pesticides



**prohibits the registration of all**



- **Prior Informed Consent traded pesticides (PIC Rotterdam Convention), and**
- **Persistent Organic Pollutants traded pesticides (POPs Stockholm Convention)**

# Other steps of reform

## The Laboratory of Pesticide Analysis [at 2012]

- Received new equipment (around 360 000 DT) enhancing analysis of pesticide residues from 12 molecules to more than 200 molecules (Collaboration with AFD, France)
- Was very close to the Accreditation ISO 17025 of pesticide analysis (Collaboration with EU).

# Other proposed reform

General reform was proposed since 2010:

**Lab analysis and field experimentation**



**become**

**Autonomous structure (EPNA, flexible management)**



**For**

**Quicker Registration & Easier Accreditation**

# قطاع الصحة النباتية في تونس: الواقع و الآفاق و مقترح إصلاح جوهرى

د. بوزيد نصراوى

أستاذ جامعى فى علم أمراض النباتات  
مدير عام سابق لحماية و مراقبة جودة المنتجات الفلاحية بوزارة الفلاحة

مع قرص مضغوط يحتوى على:

- ملحق 1: النصوص القانونية التونسية المتعلقة بالصحة النباتية
- ملحق 2: نصوص المعاهدات الدولية التي تنتمي إليها مصالح الصحة النباتية التونسية

*Proposition of a general reform of the Health Plant General Directorate (2013)*